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OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

Docket No. 52-002

Mr. John Hoyle, Secretary
Office of the Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

DOCKET NUMBER
PROPOSED RULE PR 52
(60FR17924)

Supplement to Comment # 10

ATTN: Docketing and Services Branch

SUBJECT: Proposed Rule: Standard Design Certification for
the System 80+™ Advanced Pressurized Water
Reactor (60 Fed. Reg. 17925, April 7, 1995);
Docket No. 52-002

Dear Mr. Hoyle:

On August 4, Combustion Engineering, Inc. (ABB-CE) filed comments on NRC's proposed design certification rule, referenced above, for the System 80+™ Standard Plant Design. Our comments included the text of a revised proposed rule reflecting the changes in NRC's proposed rule that are deemed necessary and desirable by ABB-CE and the nuclear industry.

Enclosed please find ABB-CE's proposed Statement of Considerations to accompany ABB-CE's proposed rule, presented in the form of a complete rulemaking package. The NRC's Notice of Proposed Rulemaking (NOPR) authorizes ABB-CE, as the design certification applicant, to file proposed findings and conclusions for each controverted hearing matter within 30 days of the close of the record in the form of a proposed final rule and accompanying Statement of Considerations. 60 Fed. Reg. at 17942. Although none of the commenters requested a hearing, ABB-CE believes the intent of the NOPR would be served by supplying the Commission with the enclosed proposed Statement of Considerations addressing controverted matters raised by the comments on the NOPR.

We believe the attached material provides a succinct and useful synthesis of the comments on the System 80+ NOPR, and is an additional useful tool to aid NRC in its evaluation of the NOPR.

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PDR PR
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Nuclear License
Committed 1990



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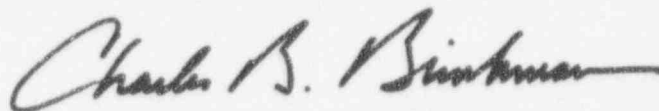
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If you have any questions on this submittal or if you wish to discuss it, please contact me at (301) 881-7040, or ABB-CE's counsel, Joe Egan, at (202) 663-9200.

Respectfully submitted,

COMBUSTION ENGINEERING, INC.

A handwritten signature in black ink that reads "Charles B. Brinkman". The signature is written in a cursive style with a long horizontal flourish at the end.

Charles B. Brinkman, Director
Nuclear Licensing

cc: Chairman Shirley Jackson
Commissioner Kenneth Rogers
James Taylor
Karen Cyr
James Milhoan
William Russell
Martin Malsch
Dennis Crutchfield
Theodore Quay
Jerry Wilson
Stewart Magruder
Sterling Franks (DOE)
Norman Fletcher (DOE)
Ronald Simard (NEI)

NUCLEAR REGULATORY COMMISSION

10 CFR PART 52

Standard Design Certification for the
System 80+™ Standard Plant Design

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC or Commission) is amending its regulations to approve by rulemaking the standard design certification for the System 80+™ Standard Plant Design (System 80+) design. The applicant for certification of the System 80+ design is Combustion Engineering, Inc. (ABB-CE). The NRC is adding 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 appendix.

EFFECTIVE DATE: (30 days after publication of the final rule in the Federal Register).

ADDRESSES: Copies of comments received in response to the notice of proposed rulemaking are 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 System 80+ Design Control Document (DCD) is also available for examination and copying at the PDR. Copies of the DCD may be purchased from National Technical Information Service, Springfield, VA 22161.

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.

SUPPLEMENTARY INFORMATION:

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I. Background

For more than thirty years, the licensing and regulation of nuclear power plants has proceeded under the two-step licensing process of 10 CFR Part 50. Under this two-step process, issues decided during the construction permit proceeding are subject to re-review and re-litigation at the operating license stage. The inability to achieve final resolution of these issues has caused instability in the licensing process and substantial escalation in the cost of constructing and operating nuclear power plants.

In the 1980's, the NRC recognized that a new approach to the licensing and regulation of power plants was warranted and began developing procedures for certification of standardized designs. 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 specifies the process for obtaining design certifications. The major purposes of Part 52 are to achieve early resolution of licensing issues, to enhance the safety and reliability of nuclear power plants, and to provide a more stable and predictable licensing process. Subsequent to the promulgation of Part 52, Congress underscored and reinforced the purposes of Part 52 in the Energy Policy Act of 1993 (EPACT).

Application for Certification of System 80+

On March 30, 1989, Combustion Engineering, Inc. applied for certification of the System 80+ design in accordance with the procedures specified in 10 CFR Part 50, Appendix O, and the Policy Statement on Nuclear Power Plant Standardization, dated September 15, 1987. The application was docketed on May 1, 1991 (Docket No. 50-470).

On August 21, 1989, Combustion Engineering requested that its Part 50 application be considered as an application for final design approval and subsequent design certification pursuant to 10 CFR 52.45. A new docket number (52-002) was assigned on May 1, 1991. By letter dated May 26, 1992, Combustion Engineering notified NRC that it is a wholly-owned subsidiary of Asea Brown Boveri, Inc., and the appropriate abbreviation for the company is

ABB-CE. ABB-CE's application, including the System 80+ Standard Safety Analysis Report (SSAR) up to and including amendment W and the Certified Design Material is available for inspection and copying at the NRC's Public Document Room.

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, 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 by NRC on July 26, 1994, and noticed in the Federal Register on August 2, 1994 (59 FR 39371). A revised version of the FDA was issued on November 23, 1994 and noticed in the Federal Register on December 1, 1994 (59 FR 61647).

After the FDA was issued, ABB-CE developed the Design Control Document (DCD) for the System 80+ based upon staff guidance and direction. The DCD contains information from the various documents comprising the design certification application for the System 80+ Standard Plant Design. Its purpose is to

provide, in a single document, design-related information to be incorporated by reference in the design certification rule. The DCD contains the DCD Introduction, the Certified Design Material (i.e., Tier 1), and the Approved Design Material (i.e., Tier 2). A copy of the DCD is available for examination and copying at the NRC's PDR, and may be purchased from National Technical Information Service, Springfield, VA 22161.

The Rulemaking Process and Development of the Proposed Rule

Subpart B of 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), 5 U.S.C. 553, 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 in a design certification rulemaking. While Part 52 describes a general framework for conducting a design certification rulemaking, Section 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, 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, Secretary, to William C. Parler (OGC)). 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 NRC's PDR.

OGC's final analyses and recommendations for design certification rulemaking procedures were set forth in SECY-92-381 (November 10, 1992). This 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 set forth the Commission's determinations with respect to the procedural issues raised by the General Counsel's paper.

Since the issuance of 10 CFR Part 52, the NRC has been working on Subpart B implementation, including addressing issues such as the acceptability of using a two-tiered design certification rule and the level of design detail required for design certification. On August 18, 1992, the NRC staff originally proposed a model 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 model rule in SECY-92-287 to incorporate Commission guidance and published a draft model of a proposed design certification rule in the Federal Register on November 3, 1993 (58 FR 58664), 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 NRC's PDR.

In SECY 95-023, NRC Staff submitted a proposed notice of proposed rulemaking for System 80+ to the Commission. The Commission directed Staff to publish this notice of proposed rulemaking in the Federal Register for public comment.

On April 7, 1995, the Commission published a notice of proposed rulemaking (60 FR 17924) proposing to approve by rulemaking a standard design certification for the System 80+ Standard Plant Design. In addition to providing public notice of the opportunity to submit written and electronic comments and discussing the opportunity for any person to request an informal hearing on one or more specific matters with respect to the proposed design certification rule, the notice of proposed rulemaking provided a detailed description of the hearing process, the process for resolution of issues for the final rule, procedures for access to proprietary information, and *ex parte*

and separation of functions restrictions. The notice of proposed rulemaking also requested comments on a number of issues of specific interest to the Commission.

Following the publication of the proposed rule, the NRC conducted public meetings to answer questions regarding the proposed rule. The first of these meetings was held on May 11, 1995, and featured a panel composed of representatives from the NRC Offices of Nuclear Regulatory Research, Nuclear Reactor Regulation, and General Counsel. The meeting was attended by representatives from ABB-CE, the other design certification applicants, the industry, and a public interest group. A transcript of this meeting is available for inspection and copying in the NRC Public Document Room in Washington, DC.

Another public meeting was held on June 27, 1995 in response to a request from the Nuclear Energy Institute (NEI). This meeting was attended by representatives from ABB-CE and the other design certification applicants as well as NEI. The purpose of this second meeting was to answer NEI's questions regarding NRC's intent with respect to specific sections of the proposed rule, thereby assisting the parties in preparing their written comments. A meeting summary, dated July 13, 1995, is available from the NRC Public Document Room in Washington, DC.

As discussed in more detail in Section IV below, written comments on the proposed rule were submitted by a number of

persons. ABB-CE submitted a proposed final rule and statement of considerations. None of the comments requested a hearing. Therefore, the Commission is issuing this rule based upon the information in the rulemaking docket, the comments received, and ABB-CE's proposed final rule and statement of considerations.

II. Safety Findings

System 80+ is an advanced light water nuclear power plant which utilizes proven pressurized water reactor (PWR) technology. Numerous design features and improvements have been incorporated to produce a robust design with a higher level of safety than those plants currently in operation. For example, the probability of an event causing core damage is lower for System 80+ than its prior design by at least two orders of magnitude, easily meeting the Commission's safety goal, as stated in the Staff Requirements Memorandum (SRM) dated June 26, 1990, on SECY-90-016. In addition, System 80+ contains numerous severe accident prevention and mitigation features that substantially increase the capability of System 80+ to withstand severe accidents. Finally, System 80+ contains features that address the NRC's severe accident and other technical positions in SECY-90-016 and SECY-93-087, as modified by the Commission.

Based upon the analyses in the System 80+ SSAR, the System 80+ DCD, the FSER for System 80+, and the other material on the System 80+ docket, the Commission finds that the System 80+ Standard Plant Design satisfies the Commission's policy on safety goals in 51 FR 28044 (August 4, 1986) and 51 FR 30028 (August 21, 1986), and concludes that System 80+ provides adequate protection of the public health and safety. Additionally, the Commission finds, as required by 10 CFR 52.54, that System 80+ meets the applicable standards and requirements of the Atomic Energy Act and the Commission's regulations. Therefore, the Commission is issuing this design certification rule for the System 80+ in accordance with the requirements of 10 CFR 52.54.

III. Summary Description of the Rule

When the NRC added Part 52 to its regulations, it provided for issuance of early site permits, certification of standard designs, and the issuance of combined construction permits and operating licenses (COLs). In these proceedings, the bulk of issues are resolved prior to construction and are not open to review or re-litigation in subsequent proceedings. Specifically, in promulgating Part 52, the Commission sought to achieve the following goals:

- Early resolution of licensing issues;

- Standardization;
- Enhanced safety; and
- A more stable and predictable licensing process.

See, e.g., 52 FR 32060, 32060-1 (August 23, 1988); 54 FR 15372, 15372-6 (April 18, 1989).

A major purpose of rulemaking for standardized reactor designs is to realize the safety benefits of nuclear power plant standardization while, at the same time, achieving early resolution of licensing issues associated with those designs, thereby furthering both a more predictable and stable licensing process and more timely and effective public participation. A design certification rule can be referenced in a subsequent application for a Part 52 combined license (COL) or for a Part 50 construction permit or operating license. Except as provided in 10 CFR 2.758, all matters resolved in connection with the issuance of a design certification rule (i.e., all matters within the scope of the design approved by this rulemaking) will be treated by the Commission as resolved in any subsequent proceeding. See 10 CFR 52.63(a)(4). Section 6 of the design certification rule provides a more complete description of the matters that have finality under Section 52.63(a)(4).

In promulgating Part 52, the Commission recognized that there were safety benefits in maintaining standardization, and therefore determined to restrict the conditions under which

generic or plant-specific changes could be made to a standardized design approved by the Commission. The Commission determined to restrict NRC-imposed changes to those that meet the backfit standards in 10 CFR 52.63(a). Pursuant to this section, the Commission may not modify, rescind, or impose new requirements on the certification unless it determines in a rulemaking that a modification is necessary to bring the certification or the referencing plants into compliance with the applicable NRC regulations, or to assure adequate protection of the public health and safety or the common defense and security.

As respects any plant-specific changes which may be required by the NRC for the certified design, in addition to satisfying the aforesaid standards, special circumstances, as defined in 10 CFR 50.12(a), must be present and consideration must be given to whether those special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the plant-specific order. Pursuant to 10 CFR 52.63(b), similar constraints also apply to proposed facility-specific design changes to the certified design by an applicant for or holder of a license that references a standard design certification.

The Commission recognized, however, that an applicant or licensee of a plant that references a standard design may be obliged to deviate from the standard design to accommodate the

particularities of procurement, as-built construction needs, or technological improvements. For this reason, Part 52 provides for appropriate change flexibility through use of a process similar to that of 10 CFR 50.59.

To accommodate both the objective of design standardization and the need to permit limited change flexibility, designs approved in a design certification rule have been divided into two parts or tiers: Tier 1, which describes the most salient safety aspects of the design features (referred to as the "certified design"); and Tier 2 (referred to as the "approved design"), which describes the more detailed design information approved by the rule and from which Tier 1 is derived. A fuller description of the bases for determining the design information to be contained in each tier is set forth in Section 14.3 of the SSAR, and Tier 2, and the corresponding section of the NRC's FSER. More stringent criteria have been established in Section 8 of the design certification rule for making changes in the certified design in Tier 1 than for the more detailed design information in Tier 2.

A two-tiered structure has been inherent in Part 52 from the outset. In promulgating Part 52, the Commission recognized that, while all of the information in a design certification application would be subject to Commission review and approval, only those safety significant aspects of the design features

would comprise the certified design portion of the rule. In particular, the Commission stated:

The Commission does expect, however, that there will be less detail in a certification than in an application for certification, and that a rule certifying a design is likely to encompass roughly the same design features that § 50.59 prohibits changing without prior NRC approval. (54 FR 15372, 15377 (1989)).

This Commission expectation is codified in 10 CFR 52.63(b). This section provides that facility-specific design changes by an applicant or a licensee will be subject to differing criteria, depending upon whether the proposed change pertains to the certified design (Tier 1) or the remainder of the approved design (Tier 2). Under Section 52.63(b)(1), facility-specific changes to the certified design can be made only by means of an exemption. The Commission may grant an exemption request only if it determines that the exemption will comply with 10 CFR 50.12(a) and that the special circumstances, which Section 50.12(a)(2) requires to be present, outweigh any decrease in standardization caused by the exemption. The granting of an applicant's exemption request is subject to litigation in the same manner as other issues in the COL or operating license hearing. In contrast, Section 52.63(b)(2) provides that, subject to Section 50.59, a licensee who references a standard design certification may make changes to the design, without prior Commission approval, unless the proposed change involves a change to the

certified design (i.e., Tier 1). As the Commission noted in the Statement of Considerations for Part 52, "§ 50.59 will continue to apply to the uncertified portion" of the approved design. (54 FR 15377 (1989)). This change process is sometimes referred to as the "50.59-like" change process since it is based upon the provisions of 10 CFR 50.59.

In order to consolidate design-related information that is referenced by this rule into a free-standing master document, the Commission has developed the concept of a Design Control Document (DCD). The DCD contains the Tier 1 and Tier 2 design-related information. The DCD is incorporated by reference in Section 4 of the design certification rule.

Tier 1 for System 80+ includes the following information:

- (1) Definitions and General Provisions;
- (2) Design Descriptions;
- (3) Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC);
- (4) significant Interface Requirements for interfaces between systems within the scope of the System 80+ Standard Plant Design and other systems that are wholly or partially outside the scope of the System 80+ Standard Plant Design; and
- (5) significant Site Parameters for the System 80+ Standard Plant Design.

Tier 2 includes, to the extent technically applicable for the System 80+ Standard Plant Design, the following information:

- (1) the applicable information required for a final safety

analysis report under 10 CFR 50.34(b); (2) information related to the Three Mile Island requirements under 10 CFR 50.34(f); (3) technical resolutions of the Unresolved Safety Issues and medium and high priority Generic Safety Issues; and (4) important features identified from the probabilistic risk assessment (PRA) for System 80+ and a description of design features for preventing and mitigating severe accidents. Tier 2 is essentially equivalent to the Standard Safety Analysis Report (SSAR), minus the details from the PRA, plus Emergency Operations Guidelines (EOGs).

The Design Descriptions, Interface Requirements, and Site Parameters in Tier 1 are derived entirely from the provisions of Tier 2, and generally consist of the most salient safety aspects of the design features and functions. Although the provisions in Tier 1 are derived from Tier 2, these provisions may be more general than the provisions in Tier 2. Compliance with the more detailed Tier 2 material provides a sufficient method, but not the only acceptable method, for complying with the design provisions in Tier 1.

The change processes applicable to each tier are specified in Section 8 of the design certification rule. With the exception of one additional provision, the criteria specified for performing 50.59-like safety evaluations for Tier 2 changes are the same as those currently used in Part 50 practice. The

additional provision expands the scope of 50.59 safety evaluations (which traditionally have only applied to design basis accidents) to require evaluations of changes to the important severe accident and PRA features discussed in Section 19.15 of Tier 2.

As part of its approval of the design certification applications, the NRC staff created a concept called "Tier 2*". The Tier 2* concept was an outgrowth of the staff's review of the design certification applications, during which the NRC staff concluded that there were certain design methodologies in Tier 2 that were not sufficiently important to warrant inclusion in Tier 1 and yet should not be changed without prior NRC approval. The staff designated these design methodologies as Tier 2*. Section 2 of the design certification rule states that these Tier 2* provisions may not be changed without prior NRC approval (even if the change does not involve an unreviewed safety question). This Section also states that the Tier 2* restrictions expire at first full power, when the design will have been completed and the Tier 2* restrictions will have served their purpose.

IV. Analysis of Public Comments

General Comments

In response to the April 7, 1995 proposed rule, the Commission received written comments from twenty-one organizations. Specifically, comments were provided by the industry trade organization Nuclear Energy Institute (NEI), by three design certification applicants including ABB-CE, two architect-engineer firms, thirteen nuclear utilities, and the U.S. Department of Energy (DOE). Additionally, one public interest group, Ohio Citizens for Responsible Energy, Inc. (OCRE), submitted comments responding to NRC's specific questions (see Section V below). ABB-CE submitted a proposed final rule and statement of considerations. None of the written comments received included a request for a hearing on the proposed rule. Therefore, the Commission is basing its decision to issue a design certification rule for System 80+ upon the rulemaking docket, including the written comments and ABB-CE's proposed resolution of the comments. Copies of these documents may be examined and copied at the NRC Public Document Room, 2120 "L" Street N.W. (Lower Level), Washington DC.

In considering the comments received, the Commission viewed the comments in light of EPACT and its Part 52 goals of creating

a more stable and predictable licensing process, providing for early resolution of licensing issues, and enhancing safety through standardization of plant designs. All commenters expressed support for the goals of the design certification process. None of the commenters sought a change in the System 80+ Standard Plant Design.

NEI submitted extensive comments on behalf of the nuclear industry. These comments were strongly endorsed by ABB-CE, General Electric, Westinghouse, Stone & Webster Engineering Corporation, Duke Engineering and Services, Inc., and the nuclear utilities. The industry's comments primarily focused on the process-related provisions in the proposed rule. In general, the industry stated that a number of the proposed process-related provisions, which do not relate to the safety of System 80+, were inconsistent with or did not promote basic goals of Part 52. In particular, the nuclear utilities, which are potential users of the design certification, strongly emphasized that these process-related provisions would threaten the viability of design certification for use by future license applicants for nuclear power plants. DOE's comments forcefully made similar points.

As discussed in Section II above, the Commission has found that System 80+ complies with the applicable requirements and provides adequate protection of the public health and safety. In fact, the probability of an event causing core damage is at least

two orders of magnitude lower than ABB-CE's prior design. This represents a significant enhancement in safety relative to the current generation of nuclear power plants. Since the process-related provisions in question are not necessary to ensure the safety of System 80+ or to satisfy other statutory or regulatory requirements, the Commission has given careful consideration to the propriety of those provisions in light of the other important objectives of Part 52.

In this regard, the Commission has previously stated in its SRM on SECY-95-023 that "it is important that the potential COL applicants perceive the process to be workable from this point forward." Given the enhanced safety of the System 80+ Standard Plant Design, the Commission believes it is sound policy to assure that the process-related provisions do not constitute unnecessary obstacles to the use of this improved design in the licensing of new nuclear plants. If the industry does not view the design certification rule as supporting a workable licensing process, the rule will not be used and the enormous promise which design standardization holds will not be realized.

A. Finality

One of the principal purposes of Part 52 is to create a more stable and predictable licensing environment by resolving safety issues during design certification such that these issues have

finality in later licensing proceedings (i.e., issues resolved during each stage are not subject to re-review by the NRC or re-litigation in licensing proceedings). Defining the scope of issues accorded finality too narrowly would defeat the Commission's goal of creating a more stable licensing process -- and undermine design standardization as well -- by allowing unnecessary re-review or re-litigation of resolved issues at later stages of the licensing process.

Section 6 of the proposed design certification rule would have limited the scope of safety matters entitled to finality to the issues associated with the information in the DCD and FSER. Additionally, the NOPR and Section 8(b)(5) of the proposed rule stated that changes to the DCD, which are permitted by the rule, would not be considered matters resolved under Section 52.63(a)(4).

The industry and DOE objected to the limited scope of issues accorded finality and to the lack of finality for changes made in accordance with the provisions of the design certification rule, and also requested that finality be given to the design certification in all subsequent proceedings. Each of these comments and the Commission's response is provided below.

Comment: The industry and DOE stated that finality should be provided to a substantially broader scope of matters than those

specified in the proposed rule to ensure the viability of the design certification for use in licensing proceedings. In particular, the industry and DOE contended that the scope of issues accorded finality should be expanded to include the safety adequacy of the approved design, information contained in the Standard Safety Analysis Report (SSAR), secondary reference requirements and all other issues which, though not raised in the DCD, FSER, Technical Support Document (TSD) or Environmental Assessment (EA), were raised and resolved by the NRC staff during its review of ABB-CE's application for design certification. In this regard, both the industry and DOE have stated that the design certification rule should explicitly recite NRC's finding regarding the safety and acceptability of the System 80+ Standard Plant Design. In addition to citing the need for finality to ensure the viability of the design certification rule, the industry and DOE justified an expansion of the scope of finality by pointing to the broad language in Section 52.63(a)(4), and by underscoring the extensive scope of the design review performed by the NRC and the wide public opportunity to participate in the rulemaking process.

Response: In implementing Part 52, the Commission intended to create a more stable and predictable regulatory environment by resolving issues early in the licensing process such that they

would have finality in later licensing proceedings. In this regard, 10 CFR 52.63(a)(4) states that "the Commission shall treat as resolved those matters resolved in connection with the issuance or renewal of a design certification" (emphasis added). Thus, in promulgating Part 52, the Commission intended to accord finality to the broad range of issues necessarily resolved by design certification, and to prevent review and litigation of issues within the scope of the approved design in subsequent proceedings.

The design review and certification process has been long and comprehensive, involving the resolution of substantial numbers of issues in numerous extensive applicant submittals and corresponding NRC reviews. ABB-CE submitted an application which included a multi-volume standard SSAR. Based upon the SSAR, amendments to the SSAR, and ABB-CE's responses to numerous requests for additional information, the NRC staff and the Advisory Committee on Reactor Safeguards (ACRS) conducted extensive detailed reviews. Using the results of these reviews, the NRC staff prepared a Draft and a Final Safety Evaluation Report (FSER) for System 80+, which approved the SSAR. Finally, at the end of this process, the NRC required ABB-CE to prepare a Design Control Document (DCD) to describe the standard design and to control changes to it.

The FSER and DCD do not explicitly address all of the issues discussed in the SSAR, in the many meetings held between ABB-CE and the NRC staff/ACRS, or in the voluminous correspondence between ABB-CE and the NRC -- all of which is on the docket of this rulemaking and was subject to public comments and questions. Limiting the scope of issues accorded finality solely to those contained in the FSER or DCD would be contrary to what has actually transpired in the proceeding, to the underlying support for this rulemaking, and to a basic Commission purpose in promulgating Part 52. The Commission does not believe that matters reviewed by the NRC in connection with the design certification application should be subject to re-review or re-litigation in subsequent proceedings.

In light of the foregoing, the Commission has determined that finality should not be limited to those matters articulated in the FSER or DCD. The rule, accordingly, has been modified to recite NRC's finding regarding the safety and acceptability of System 80+ and to accord finality to all matters within the scope of the approved design, *i.e.*, only site-specific matters will be open for consideration in a license proceeding. Therefore, all matters on the rulemaking docket (including the SSAR and proprietary and safeguards information in the SSAR) or raised in the design certification rulemaking proceeding will be considered resolved in any subsequent proceeding. Similarly, material

contained in documents which are referenced in the DCD (so-called "secondary references") will be accorded finality where the material in those documentary references is treated as a design certification requirement.

Finality will also be extended to the conclusion that the System Standard Plant Design is sufficient as respects protection of the public health and safety, and that additional design features and functions are not necessary for that purpose. This conclusion derives from 10 CFR 52.63(a), which precludes imposition of new requirements by rulemaking or plant specific order absent a determination of the need to assure compliance with the applicable NRC regulations in 10 CFR Parts 20, 50, 73, and 100, or to assure adequate protection of the public health and safety. In particular, given the restrictions in Sections 52.63(a)(1) and (3), NRC cannot order a plant to add a new structure, system, component, or design feature within the scope of the approved design unless the criteria in these sections are satisfied. If NRC cannot require the addition of a structure, system, component, or design feature under Section 52.63(a)(1) and (3), it follows that the lack of need for such structure, system, component, or design feature is a matter resolved under Section 52.63(a)(4) -- in other words, the scope of design subject to finality under Section 52.63(a)(4) is at least as

broad as the scope of design subject to the change restrictions in Sections 52.63(a)(1) and (3).

Comment: The industry and DOE stated that plant specific changes made by an applicant or licensee in accordance with the change process described in Section 8 of the rule should have finality. In particular, the industry stated that the proposal to deprive 50.59-type changes of finality would provide less finality to such changes under Part 52 than is currently provided to such changes under Part 50, and would be contrary to the goal of a more stable and predictable licensing process. OCRE agreed that changes made after issuance of the COL should not be subject to challenge except under Section 2.206; however, OCRE also stated that changes made by a COL applicant should be subject to litigation in the COL hearing.

Response: All commenters and the NRC staff agree that 50.59-type changes made after issuance of a license should only be subject to challenge under Section 2.206. Thus, the only issue is whether 50.59-type changes should be subject to hearing at the initial licensing stage, and whether changes in general should have finality and thus protection under 10 CFR 52.63(a) against NRC-imposed changes.

In the proposed rule, changes to Tier 1 or Tier 2*, and all changes to Tier 2 that involve an unreviewed safety question or a change in the technical specifications, were not accorded finality in order to "minimize the consequences of the loss of standardization caused by these changes." However, as pointed out by several commenters, the "consequences of the loss of standardization" caused by such changes are not reduced by depriving such changes of finality. Rather, the Commission finds merit in the proposition that the proposed restrictions on finality might discourage the industry from making changes that increase the safety or effectiveness of the design, and thus could be counter-productive to safety. Further, because such changes trigger requirements for prior NRC approval and afford the opportunity for a public hearing as part of the NRC approval process, there is no safety benefit to be gained, and a great deal of uncertainty and cost to be incurred, in subjecting NRC approved, and possibly litigated, changes to potential re-review and re-litigation in subsequent proceedings. Giving due consideration to the Part 52 goal of a more stable and predictable licensing process, the Commission believes that finality should be accorded to such changes. Therefore, the Commission has modified the rule to accord finality to changes that have been approved by the NRC and were subject to an opportunity for a public hearing.

The Commission also believes that changes made by applicants and licensees in accordance with the 50.59-like process should be accorded finality. Such changes do not require prior NRC approval and are not subject to an opportunity for a public hearing, and they are authorized by Part 52 and the design certification rule. Furthermore, because such changes, by definition, do not involve an unreviewed safety question, those changes do not invalidate the NRC's safety determination for the affected portion of the standard design and do not warrant a hearing. Finally, affording hearings for such changes would be contrary to the Section 50.59 change process and the goal of a more stable and predictable licensing process under Part 52, and would afford such changes less finality under Part 52 than is afforded to 50.59 changes under Part 50. Therefore, the Commission has modified the rule to accord finality to changes made under the 50.59-like process.

Comment: The industry stated that the design certification rule should provide for the finality of the design certification in all subsequent proceedings. OCRE made similar comments in response to an NRC question in the NOPR.

Response: As discussed above, the Commission's intent in implementing Part 52 was to create a more stable and predictable

regulatory environment by resolving issues early in the licensing process such that they would have finality in later licensing proceedings. Therefore, the Commission has clarified in the final rule that finality is accorded in all subsequent proceedings involving licenses referencing the design certification, including license amendment proceedings, construction permit proceedings, and enforcement proceedings, as well as COL proceedings, Section 52.103 proceedings, design certification renewal proceedings, and operating license proceedings.

B. Applicable Regulations

In SECY-90-016 and SECY-93-087, the NRC staff identified a number of positions on severe accidents and other technical issues that are not embodied in the current NRC regulations in Part 50. The NRC staff proposed that the Commission adopt modified versions of these positions and technical issues as "applicable regulations" for System 80+, i.e., to give them the effect of the Commission's regulations for the purpose of issuance and renewal of design certification, controlling changes to the DCD, and imposing backfits on the DCD. In the NOPR, the Commission specifically sought comments on whether the "applicable regulations" set forth in Section 5(c) of the proposed rule are justified (See Section V below).

The industry and DOE raised a number of objections to the "applicable regulations." Each of these objections is discussed below, together with the Commission's response.

Comment: The industry stated there is no requirement to establish "applicable regulations." The industry noted that, indeed, 10 CFR 52.48 defines the applicable standards for the design certification as the technically relevant standards in Parts 20, 50, 73 and 100, and contains no allowance for the identification of additional "applicable regulations". OCRE stated that the "applicable regulations" were justified to respond to issues arising from operating experience and to reduce the risk of severe accidents.

Response: There is no requirement in Part 52 which compels the Commission to adopt these severe accident and other technical positions as "applicable regulations." Additionally, 52.48 does not provide any authorization for the NRC to identify additional "applicable regulations," except through an amendment to one of the aforementioned Parts of the Commission's regulations prior to issuance of the design certification.

Notwithstanding that Part 50 does not require the features that are the subject of the "applicable regulations," ABB-CE voluntarily agreed to include features in the System 80+ that

conform with these new technical positions. Promulgation of this design certification rule makes those voluntary features part of the rule's requirements. Further, as discussed in the System 80+ FSER, the NRC staff found that the standard design conforms with the staff's positions as modified and accepted by the Commission. Thus, even if the "applicable regulations" are not incorporated into the System 80+ design certification rule, the Commission believes that System 80+ achieves and exceeds the "higher standard of severe accident safety performance than their prior designs" desired in the Commission's Policy Statement on Severe Reactor Accidents (See 50 Fed. Reg. 32138 (August 8, 1985)).

Comment: The industry and DOE pointed to the Commission's SRM dated September 14, 1993, related to SECY-93-226 and the ANPR on severe accident issues, wherein the Commission directed the NRC staff to defer any generic rulemaking until after approval of the designs for the System 80+ and ABWR. The industry and DOE stated that the subject "applicable regulations" should not be implemented because they are, in fact, generic requirements. The "applicable regulations" for the System 80+ and ABWR are substantively identical (except for one position related to steam generator tube ruptures which is not relevant to the ABWR).

Response: In response to the ANPR on severe accidents, the Commission directed the NRC staff to defer generic rulemaking on severe accidents. However, it was the Commission's expectation that the evolutionary plants, including System 80+, would include measures to enhance safety, including enhanced protection against severe accidents. System 80+ fulfills this expectation.

The proposed "applicable regulations" are not geared to the specifics of the System 80+ Standard Plant Design. They are indeed generic, as evidenced by the fact that the proposed "applicable regulations" for System 80+ and the ABWR are substantively identical (except for one "applicable regulation" that does not relate to the ABWR, but which would be generically applicable to any advanced PWR design). The Commission believes that it is inappropriate at this time to be issuing generic regulations on severe accident and other technical issues that go beyond the existing requirements in the Commission's regulations.

Furthermore, given the generic nature of the "applicable regulations," they are not consistent with the Commission's intent in promulgating Part 52. Specifically, in the statement of considerations for Part 52, the Commission noted that new standard designs may incorporate new features not addressed by the Commission's regulations and that new criteria may need to be developed for such features. In this regard, the Commission said that it would consider the need for rulemaking to resolve generic

questions applicable to multiple designs. However, the Commission went on to state:

The objective of such rulemaking would be to incorporate any new standards in Part 50 or Part 100, as appropriate, rather than to develop such standards in the context of the Commission's review and approval of individual applications for design certification.

54 FR 15372, 15376 (April 18, 1989). Thus, the Commission indicated that it would not enact new generic regulatory standards, such as the "applicable regulations," as part of individual design certification rulemaking proceedings.

Comment: The industry stated that the proposed "applicable regulations" are unnecessary because the DCD contains provisions that conform with each of the "applicable regulations." In particular, ABB-CE demonstrated that each of the "applicable regulations" is addressed in whole or in part in Tier 1. In contrast, OCRE stated that the "applicable regulations" were justified to respond to issues arising from operating experience and to reduce the risk of severe accidents.

The industry and DOE also stated that the proposed "applicable regulations" would create substantial instability and uncertainty because they are "broadly stated," using vague and general terms -- terms such as "to the extent practical,"

"advanced" techniques, "most facilitate the ability of the operator," "reduce the potential for," "best estimate," "reduce the amount," "approximately," and "minimize." The industry and DOE were particularly concerned that these terms could be used in the future to impose backfits on applicants and licensees that could not otherwise be justified on the basis of adequate protection of public health and safety, thus threatening the viability of the design certification rule, and reducing licensing certainty. The industry and DOE also noted that the "applicable regulations" do not have any technical bases normally provided with substantive rulemaking.

The industry additionally objected to the "applicable regulations" for a number of other reasons. The industry stated that some of the "applicable regulations" contained programmatic requirements for licensees that are independent of the design being certified, that some "applicable regulations" are inconsistent with prior Commission directions, and that still other "applicable regulations" could be construed as being inconsistent with the NRC-approved standard design.

Response: As discussed above, ABB-CE voluntarily agreed to include the features in the System 80+ DCD necessary to address the NRC positions in question. In particular, as demonstrated in ABB-CE's comments, each of the "applicable regulations" is

addressed in whole or part in Tier 1, which is subject to the most stringent change controls. Since the DCD is incorporated by reference in the design certification rule, the DCD is an applicable regulation for purposes of issuance and renewal of design certification, controlling changes to the standard design, and imposing backfits. Therefore, there is no need to establish free-standing "applicable regulations" in order to accomplish the objectives sought by the NRC staff.

For the same reason, the "applicable regulations" are not necessary to accomplish the goals sought by OCRE. The DCD already contains provisions that conform with each of the technical positions that are the subject of the "applicable regulations." As a result, the DCD does respond to operating experience and reduce the risk of severe accidents, thereby achieving OCRE's goal without the need for "applicable regulations."

Further, as the commenters pointed out, the NOPR did not provide any technical bases for the "applicable regulations," and the proposed "applicable regulations" do contain some vague and general terms that could be susceptible to new interpretations as the state-of-the-art evolves. These new interpretations could be used to impose backfits even though the standard design is acceptable and backfits are unnecessary for adequate protection of the public health and safety. This is

especially true with respect to the broadly stated positions on severe accident issues, where new information is continuously being developed as a result of research programs.

The imposition of such backfits would be contrary to a basic purpose of Part 52, i.e., to provide a more stable and predictable licensing process through early resolution of licensing issues. Further, if backfits are required for adequate protection of the public health and safety, NRC has the authority under Section 52.63(a) to impose such changes.

The proposed "applicable regulations" on shutdown risk, the reliability assurance program, and inservice testing would impose programmatic requirements on applicants and licensees that are independent of the standard design being certified. The Commission believes that it would be inappropriate to use the design certification rule to impose programmatic requirements on applicants and licensees. If the NRC staff believes that additional regulations are needed for such matters, it should request the Commission to amend Part 50. Additionally, the proposed "applicable regulations" on ISLOCA, inservice testing, fire protection, and offsite power sources could be construed as being inconsistent with the NRC-approved design for System 80+ as described in the DCD. As a result, adoption of the proposed "applicable regulations" would create substantial instability.

Based on the reasons discussed above, the Commission believes that implementation of the proposed "applicable regulations" is unnecessary, would be inconsistent with the goals of Part 52, and would undercut the stability of the standard design. Therefore, the Commission has not included the proposed "applicable regulations" in the final rule.

C. NRC's Finding on ITAAC

The proposed design certification rule incorporated the DCD, which contains inspections, tests, analyses and acceptance criteria (ITAAC). The purpose of the ITAAC is to provide reasonable assurance that a plant has been constructed and will be operated in conformity with the license, the Atomic Energy Act and the Commission's rules and regulations. However, the proposed rule did not specify the manner in which the NRC staff is to verify that ITAAC are met.

The industry and DOE requested that the Commission define in the design certification rule the matters to be considered by the NRC in making its finding that the ITAAC acceptance criteria have been met. This comment and the Commission's response are discussed below.

Comment: The industry stated that the NRC staff has indicated that, in making its finding that the ITAAC acceptance criteria have been met, the staff will be considering various quality assurance issues related to the hardware that is the subject of the ITAAC (e.g., adequacy of the installation procedures for the hardware, adequacy of training of the personnel installing the hardware, and adequacy of the documentation for installation and inspection of the hardware). The industry stated that this approach undermines a basic objective of Part 52 and of the nuclear licensing provisions of the Energy Policy Act of 1992, and that it would essentially constitute a return to the two-step licensing process under Part 50. The industry recommended that the Commission specify in the rule that compliance with ITAAC shall be determined by verifying that the required inspections, tests, and analyses have been successfully completed and that, based solely thereon, the corresponding acceptance criteria have been satisfied. DOE had a similar comment.

Response: The purpose and intent of ITAAC have been clearly established by the Energy Policy Act of 1992, Part 52 and various Commission papers. ITAAC are intended to constitute an up-front and objective specification of the acceptance criteria for the constructed plant and the means for determining that the criteria have been met. ITAAC enhance certainty for the licensee building

the plant by spelling out before construction begins what conditions the completed plant must satisfy in order to operate. At the same time, ITAAC provide NRC personnel with objective safety standards (i.e., acceptance criteria) with which to measure the constructed plant in deciding whether the plant is safe to operate. Because of the importance the Commission attaches to ITAAC implementation and their relationship to the design requirements established by this rule, the Commission agrees that the design certification rule should define the nature of the NRC's ITAAC verification process.

ITAAC for System 80+ properly focus on the end products and results of construction, i.e., whether the as-built plant condition is acceptable. This focus of ITAAC reflects the recognition that it is the acceptability of the end products and results of construction -- not of underlying matters encompassed by the Quality Assurance Program (QAP) -- that is essential to the NRC's safety finding on the adequacy of plant construction. Proper implementation of underlying programs and processes is encompassed by the QAP and assured by NRC inspection and enforcement thereof. It follows directly that the focus of ITAAC on end products and results of construction -- and reliance on the QAP for addressing underlying programs and processes -- must extend to ITAAC implementation, including their ultimate verification by the NRC. Indeed, because of the special legal

significance of ITAAC under Part 52 (authorization to commence initial operation is solely dependent on ITAAC compliance, and properly supported contentions of ITAAC noncompliance are the sole basis for the post-construction hearing opportunity), the NRC's verification of ITAAC compliance should focus on the end products or results specified in the ITAAC acceptance criteria and not on underlying quality assurance matters.

Therefore, to ensure that the goals of Part 52 will be achieved, the Commission has modified the proposed rule to specify that compliance with ITAAC shall be determined by verifying that the required inspections, tests, and analyses have been successfully completed and that, based solely thereon, the corresponding acceptance criteria have been satisfied. The Commission would observe that the NRC retains plenary authority to take appropriate enforcement action to remedy QAP implementation deficiencies including, if necessary, action to modify, suspend, or revoke a combined license.

D. Application of the Change Process to Severe Accident Evaluations and the PRA

Under 10 CFR 50.59, a licensee may make changes in its safety analysis report (SAR) without prior NRC approval unless the change involves a change in the technical specifications or an unreviewed safety question (e.g., an increase in probability

or consequences of an accident evaluated in the SAR).

Traditionally for Part 50 plants, Section 50.59 evaluations have only applied to evaluations of design basis accidents. However, the proposed design certification rule would expand the scope of Section 50.59 evaluations to include not only changes related to design basis accidents but also changes related to the severe accident evaluations and probabilistic risk assessment (PRA), as contained in Chapter 19 of Tier 2 of the DCD. Furthermore, except for Section 19.11, the proposed rule could be construed as directing that a change in the severe accident evaluations and PRA in Chapter 19 would constitute an unreviewed safety question if the change would increase by any amount the probability or consequences of a severe accident evaluated in Chapter 19.

The industry and DOE objected to the scope of information in Chapter 19 that is subject to the 50.59-type process, and also objected to the criteria for determining whether a change in such information constitutes an unreviewed safety question. OCRE also recommended that certain changes be made in the criteria for unreviewed safety questions. Each of these comments is discussed below, together with the Commission's response.

Comment: As a threshold issue, industry and DOE objected to the scope of the 50.59-type evaluations required by the proposed rule for severe accidents and the PRA. The industry and DOE stated

that the proposed expansion of the scope of Section 50.59 evaluations would cover all of the severe accidents in Chapter 19, many of which are of extremely low probability and are not significant to safety.

The industry and DOE also stated that the important features identified by the severe accident evaluations and the PRA are contained in Section 19.15 of Tier 2 for System 80+. Since the Commission has previously stated that it desired to preserve the severe accident and PRA insights, and since application of the Section 50.59 change process to all of Chapter 19 would be burdensome and unnecessary to preserve these insights, the industry and DOE stated that the Commission should limit application of the severe accident change process to changes in the important features identified in Section 19.15.

Response: A key aspect of the System 80+ Standard Plant Design is that it achieves a significantly higher level of severe accident protection than the current generation of nuclear plants. The Commission believes that it would be beneficial to preserve the severe accident insights and features identified during the development of System 80+ that contribute significantly to the mitigation or prevention of severe accidents. To that end, the Commission issued an SKM on SECY-90-377 directing that such severe accident and PRA insights be

preserved. The important severe accident and PRA insights are identified in Section 19.15 of Tier 2, and the Commission agrees that the change process for severe accident and PRA information should be applied to that Section only.

Expanding the scope of the change process to require a safety evaluation for every change in Chapter 19 would be extremely burdensome for both licensees and the NRC staff. Chapter 19 is very extensive; it includes two volumes of material. Given the nature of PRA and severe accident analyses, essentially every area of the plant is discussed in Chapter 19. Thus, it may be expected that numerous plant changes will, in some manner, directly or indirectly affect Chapter 19 and therefore require safety evaluations. Furthermore, much of the information in Chapter 19 discusses extremely low probability events, and other information in Chapter 19 addresses structures, systems, and components that have no intended safety function. A requirement to perform safety evaluations for changes in such information would divert licensee resources from more safety significant issues while providing little or no commensurate improvement in safety. Therefore, the Commission has modified the language in the rule and the DCD Introduction to limit application of the change process to those severe accident and PRA insights contained in Section 19.15 only.

Comment: The industry and DOE also objected to defining an unreviewed safety question as any increase in the probability or consequences of a severe accident. The industry and DOE stated that, when performing § 50.59-type evaluations on changes related to severe accident issues, only a substantial increase in the probability or consequences of a severe accident should be considered an unreviewed safety question.

Response: Chapter 19 evaluates accidents that have extremely low probabilities of occurrence and extremely high consequences, each of which has a relatively high uncertainty band. As a result, changes which cause only minor increases in the probability or consequences of these accidents should not be considered unreviewed safety questions. The impact on safety of such changes would be trivial, and none of the findings or conclusions in Chapter 19 or the NRC's FSER would be affected by such changes. Therefore, a minor increase in the probability or consequences of a severe accident should not be defined as an unreviewed safety question.

Furthermore, because changes involving unreviewed safety questions require formal application to the NRC and NRC review and approval, defining an unreviewed safety question as any increase in the probability or consequences of a severe accident

would be unduly burdensome to both the NRC and the industry and would divert their resources from more important safety issues.

Based on the foregoing reasons, the Commission has modified the change process in the final rule to clarify that only a substantial increase in the probability or consequences of severe accidents will be considered an unreviewed safety question when performing § 50.59 evaluations of changes related to severe accident issues.

Comment: OCRE agreed with the concept in Section 8(b)(5)(iii) of the proposed rule, but recommended two changes in the criteria in that section. First, OCRE stated that the reference in this section to a severe accident becoming "credible" should be deleted because the term "credible" is subjective and undefined. Second, OCRE stated that another criterion should be added to this section; namely, that an unreviewed safety question should exist if "a possibility for a severe accident of a different type than any reviewed previously may be created."

Response: The Commission believes that there is value to retaining the term "credible" in the definition of unreviewed safety question. The System 80+ PCB evaluates severe accidents that are of extremely low probability. In some cases, the

probability of a severe accident evaluated in the DCD could increase by several orders of magnitude, and yet the accident still would not be credible. There is no reason for the Commission to define such changes as unreviewed safety questions and to require their prior NRC approval. The Commission recognizes that the term "credible" is not currently defined. However, the industry has stated that it will be developing guidance for implementing the change process with respect to severe accident evaluations. It is expected that this guidance will, among other things, define or provide examples of what is deemed credible. This guidance will be reviewed and, if appropriate, endorsed by the NRC staff. Therefore, it is not necessary to define this term in the rule itself.

Similarly, it is not reasonable to classify as an unreviewed safety question any change that creates a new severe accident scenario. Given the nature of severe accidents, it will in general always be possible to postulate an accident scenario of exceedingly small probability that has not been previously reviewed. If the criterion recommended by OCRE were adopted, essentially all changes could be construed as involving an unreviewed safety question. The Commission believes that such a result would be both unworkable and unnecessary for safety purposes. Given the extensive nature of the severe accident evaluations in the DCD, it is not realistic to expect that a

change will create a credible severe accident of a different type than previously reviewed in the DCD. Therefore, the Commission does not believe that the inclusion of another criterion in Section 8(b)(5)(iii) is warranted.

E. Applicability of ITAAC to Part 50 applicants and licensees

Part 52 permits a design certification to be referenced in a construction permit or operating license issued under Part 50. The proposed design certification rule stated that an applicant for a construction permit or operating license who intends to reference the design certification under Part 50 would be required to meet the ITAAC for the certified design. The NRC invited comments concerning the status of the design certification in the context of Part 50 licensing.

Comment: The industry commented that, because ITAAC are uniquely applicable to COLs under Part 52, ITAAC should not be applicable to Part 50 applicants and licensees. Part 50 provides an alternative means for accomplishing the purpose of ITAAC. DOE had a similar comment.

OCRE stated that a construction permit (CP) applicant who references a design certification should be required to reference the ITAAC because the ITAAC are in Tier 1. OCRE also stated that the operating license (OL) hearing with respect to design-related

issues should be limited to issues related to compliance with the ITAAC. OCRE recognized that, under its recommendation, a CP/OL would approximate a COL, and that it would be extremely unlikely that an applicant would ever opt for the CP/OL process rather than the COL process.

Response: The concept of ITAAC was created by the NRC in promulgating Part 52 in order to facilitate the change from a two-step Part 50 licensing process to the one-step Part 52 licensing process wherein all safety issues -- except conformance of the constructed plant with the ITAAC -- are resolved before the license is issued and construction begins. Specifically, the Commission determined that it was possible for the NRC to resolve all licensing issues identified in Section 185 of the Atomic Energy Act during review of the application for a COL, except for the provision in Section 185 which requires the NRC to find that the plant has been constructed and will operate in accordance with applicable regulatory requirements. The Commission established the concept of ITAAC to correspond with this provision in Section 185 of the Act. See 54 FR 15372, 15380 (1989).

Under Part 50, the purpose of ITAAC is accomplished through other traditional and well-understood means. In particular, the NRC must explicitly find prior to issuance of an operating

license that the plant has been constructed and will operate in conformance with applicable regulatory requirements. See 10 CFR 50.57(a)(1) and (2). For Part 50 plants that will reference the design certification rule, the NRC can make this finding in the same manner as it has always made its finding under Section 50.57, except that design-related issues resolved during design certification will have finality as provided in Section 52.63. Interested members of the public will have an opportunity to litigate Section 50.57(a) findings in hearings on issuance of the operating license.

There is another reason why ITAAC need not be applied to Part 50 plants. The ITAAC are derived from the Tier 1 design descriptions, which themselves constitute a portion of the applicable DCD requirements. The ITAAC contain no design provisions or acceptance criteria that are not contained in other portions of the DCD. Thus, the ITAAC are not necessary to control the design, and are not necessary to the NRC's safety finding regarding the adequacy of the design.

If ITAAC were applied to Part 50 applicants and licensees, the Part 50 process would be indistinguishable from the Part 52 COL process with respect to the standardized portion of the plant and there would not be any reason to reference a design certification under Part 50. This was not the Commission's intended purpose in preserving an applicant's ability to

reference a design certification in either a Part 50 or Part 52 license application. Since the Commission intended design certification to be usable under either Part 50 or Part 52, the Commission has determined that ITAAC should not be applied to Part 50 licensing proceedings, to ensure that referencing of a design certification in Part 50 licenses will be a viable option.

OCRE implies that the Commission is required to impose ITAAC on Part 50 applicants that reference a DCD, because the ITAAC are part of Tier 1 of the DCD. However, because Part 50 provides an alternative method for achieving the purpose of ITAAC, the Commission has the discretion with respect to Part 50 applicants to separate the ITAAC from the rest of Tier 1, and not to apply the ITAAC to Part 50 applicants. For the policy reasons discussed above, the Commission believes it is appropriate to do so.

After consideration of the submitted comments, the Commission has modified the rule to provide that ITAAC are not applicable to Part 50 plants.

**F. Incorporation of substantive provisions in the DCD
Introduction into the design certification rule**

The DCD contains an Introduction which prescribes how various provisions in the DCD are to be applied or utilized by license applicants and licensees. The proposed rule stated that

the DCD Introduction would not be part of the information in the DCD that is incorporated by reference in the design certification rule. Further, the proposed rule stated that if there were a conflict between the DCD Introduction and the statement of considerations (SOC) for the design certification rule, then the SOC would be controlling.

The industry and DOE stated that the substantive provisions in the DCD Introduction should be incorporated in the design certification rule. This comment and the Commission's response are discussed below.

Comment: The industry and DOE contend that the DCD Introduction should be incorporated in the design certification rule. The industry and DOE pointed out that the DCD Introduction contains a number of substantive provisions that are not in the design certification rule or expressly stated in Part 52, and that the SOC either neglects these provisions entirely or paraphrases these provisions imprecisely or incorrectly. The industry noted that, in any case, the SOC is not legally binding and is not an adequate substitute for incorporating the DCD Introduction into the rule itself. Furthermore, it was an objective of both NRC Staff and industry that the DCD be a self-contained document which, therefore, required the incorporation of an adequate introduction that explains the purposes and uses of the DCD.

In support of its position, the industry stated that ABB-CE spent several months in 1993 and 1994 in close consultation with the NRC staff developing the principles and text comprising the System 80+ DCD Introduction. The DCD Introduction was intended to reflect those principles and agreements between the staff and ABB-CE that were thought to be essential elements of the design certification process, but were not discussed in Part 52. Accordingly, the final text of the DCD Introduction was carefully reviewed, revised, and finalized in meetings during the spring and summer of 1994 with senior representatives of the NRC staff and NRC's Office of General Counsel (OGC). Public meetings were held by the staff and OGC in October and November 1994 to finalize the DCD Introduction on a section-by-section basis. The DCD Introduction was drafted and finalized in the expectation that it would have the status of the rule itself.

Response: The DCD Introduction contains a number of substantive provisions that are not addressed in either Part 52 or the proposed rule. For example, the DCD Introduction includes provisions governing compliance with ITAAC, the status of items designated in the DCD as COL Information Items, the applicability of ITAAC during operation, expiration of Tier 2* restrictions, and the status of references to the Standard Safety Analysis Report.

Some of the substantive provisions in the DCD Introduction were imprecisely or incorrectly paraphrased in the SOC. Other provisions were completely omitted from the SOC. Such inconsistencies would inevitably lead to uncertainty and confusion. However, even if such inconsistencies in the SOC were eliminated, the SOC would not be a substitute for making the provisions binding requirements by incorporating the DCD Introduction directly into the rule.

Further, the Commission sees no benefit in requiring applicants and licensees to refer to the rule's statement of considerations when the important provisions are readily available in the DCD Introduction. Such a requirement would only lead to confusion over the applicable requirements and would be inconsistent with the objective of making the DCD a free-standing document. Additionally, such a requirement is unnecessary, since the NRC has approved each of the substantive provisions in the DCD Introduction.

For all the reasons discussed above, the Commission believes that the System 80+ DCD Introduction should be accorded the status of a rulemaking requirement by incorporating by reference in the design certification rule the DCD Introduction, as amended in the final rule.

G. The change process criteria

The proposed rule stated that an applicant or licensee who references the design certification must obtain prior NRC approval for departures from Tier 2 information "if the change involves issues that the NRC staff has not previously approved" or "if changes were made to the DCD that violated [NRC's] resolutions without NRC approval."

The industry objected to these statements. The industry's objection and the Commission's response are discussed below.

Comment: The industry commented that these provisions are contrary to and inconsistent with 10 CFR 52.63 and 50.59, and over 30 years of practice under Section 50.59.

Response: Section 50.59, which is incorporated by reference in 10 CFR 52.63(b)(2), requires prior NRC approval for proposed changes, tests, or experiments that involve a change to the technical specifications incorporated in the license or an unreviewed safety question. Both 10 CFR 50.59 and Section 8(b)(5) of the proposed rule define "unreviewed safety question" in terms of the impact of the change upon safety, *i.e.*, whether the change involves: (1) an increase in probability or consequences of an accident; (2) a new or different kind of accident; or (3) a decrease in the margin of safety. As the commenters point out, neither of these sections defines an

unreviewed safety question in relation to issues previously approved or resolved by the NRC.

Further, application of the proposed requirements would fundamentally alter over thirty years of practice under Section 50.59. Neither the original Section 50.59 rule issued in April 1961 nor any subsequent revision has required prior NRC approval of changes "involving issues that the NRC staff has not previously approved," nor has such a requirement been imposed in practice.

In addition, the language in the proposed rule would, in essence, prohibit almost all changes without prior NRC approval. By definition, a change involves a departure from a provision that has previously been reviewed and approved by the NRC. As a result, almost all changes either involve matters not previously approved by the NRC or involve a resolution that is different from the resolution discussed in the FSER. Therefore, given the language in the proposed rule, applicants and licensees would be prohibited from making almost any change without first seeking prior NRC approval. This result is contrary to Section 50.59 and the intent of the Commission in adopting the Section 50.59-like process for Tier 2 changes. Therefore, the Commission is not adopting the quoted language from the NOPR.

H. Change process implementation

The industry objected to various provisions in the NOPR regarding the change process, including the requirement for exemptions for changes to technical specifications and Tier 2* provisions, the frequency for submitting reports of 50.59-type changes during construction, and the role of Section 52.63(b)(2). Each of these comments is discussed below, together with the Commission's response.

Comment: The industry stated that exemptions should not be required for changes to technical specifications or to Tier 2* that do not involve an unreviewed safety question.

Response: While it was not the intent, the Commission agrees that Sections 8(b)(4) and 8(b)(5)(i) of the proposed rule could be read together to require an exemption for changes to the technical specifications or Tier 2* that do not involve an unreviewed safety question. Therefore, the rule has been changed to clarify that changes to technical specifications under Part 52 will be treated in the same manner as technical specification changes for Part 50 plants, *i.e.*, such changes will be subject to an application for a license amendment and will not require an exemption.

The rule has also been changed to clarify that Tier 2* changes do not require an exemption unless they involve an

unreviewed safety question. It would be inconsistent to require exemptions for Tier 2* changes that do not involve an unreviewed safety question when exemptions are not required for other Tier 2 changes that similarly do not involve an unreviewed safety question.

Comment: The industry stated that, under Part 50, licensees are required to submit summaries of Section 50.59 changes once every one to two years. However, the NOPR stated that more frequent (quarterly) reporting of design changes during the period of construction is necessary to enable the NRC staff to tailor its inspection program for determining that the ITAAC have been satisfied. The industry stated that quarterly reporting of Section 50.59 changes, as proposed in Section 9(b) of the proposed rule, is overly burdensome and unnecessary, and that the frequency of reporting should be reduced to no more than once every six months.

Response: The proposed rule would have required a four to eight-fold increase in reporting frequency. This would have imposed additional burdens on licensees without resulting in any increase in safety. Because construction itself cannot impact public health and safety, and because the NRC has a variety of other mechanisms for staying informed of changes that may relate to the

ITAAC (including resident inspectors), the Commission believes that quarterly reporting of Section 50.59 changes is unnecessary, and that reporting once every six months will be sufficient. Therefore, the rule has been modified to require semi-annual reporting.

Comment: The NOPR stated that there does not appear to be a need for 10 CFR 52.63(b)(2) in a two-tiered structure. The industry stated that Section 52.63(b)(2) is directly applicable to and is the basis for the change process for Tier 2.

Response: When Part 52 was written, Section 52.63(b)(1) was intended to be the change process for the certified design, and Section 52.63(b)(2) was intended to be the change process for information that was not certified but was approved. As the two-tier structure was developed, Section 52.63(b)(1) controls changes to Tier 1 (i.e., the certified design) while Section 52.63(b)(2) controls changes to Tier 2 (i.e., the approved design). Accordingly, Section 52.63(b)(2) still serves a valuable purpose. It provides an important underpinning for the two-tier structure as applied in the design certification rules. Therefore, the Commission intends to retain Section 52.63(b)(2).

I. Post certification changes by the design certification applicant

Section 52.62 and the proposed System 80+ design certification rule allow the NRC, applicants and licensees to make changes in the System 80+ design under carefully controlled conditions. However, Part 52 and the proposed rule do not contain a provision that would allow the design certification applicant to make changes to the standard design after issuance of the design certification.

The industry and DOE recommended that the design certification rule include a provision to allow design certification applicants to make limited changes after certification and before the first license application referencing the design certification. This comment and the Commission's response are discussed below.

Comment: The industry and DOE recommended that the design certification rule contain a provision that would allow the design certification applicant to make 50.59-like changes in Tier 2 prior to the first referencing license application. In support, the industry reasoned that allowing the design certification applicant to make changes to Tier 2 prior to the first license application referencing the design certification

would promote standardization, economy and administrative efficiency.

Response: A basic purpose of Part 52 is to provide for and maintain standardization. Allowing the design certification applicant to make post-certification Tier 2 changes under the 50.59-like process will promote standardization because such changes will be generic, and therefore applicable to all license applicants and licensees that reference the design certification. Additionally, such a process will be economical of resources, since only one 50.59 change for all plants (rather than a 50.59 change for each plant) will have to be processed. Finally, this process will also ease the administrative burden on the NRC because the NRC will only have to review a qualifying change once, rather than repetitively for each license application. Therefore, the Commission has modified the final rule to provide for such changes.

The final rule includes requirements that will tightly control changes by the design certification applicant. The types of changes permitted under this process will be limited to conform with the general principles embodied in Part 52. Specifically, changes are limited to Tier 2 changes that have been evaluated under the 50.59-like process and determined not to involve either an unreviewed safety question or a change in Tier

1. Thus, changes are limited to those matters which, by definition, do not adversely affect safety.

Additionally, the design certification applicant will be responsible for taking inventory of proposed generic 50.59-type changes in Tier 2, for performing the requisite safety evaluations, for submitting summaries of the evaluations to NRC, for effecting the changes that qualify and for amending and maintaining the DCD. Because NRC will be notified of the change and be provided with a summary of the safety evaluation for the change, the NRC will have an opportunity to review the change. If, based upon its review, the NRC were to conclude that the change involves an unreviewed safety question or a change in Tier 1, the NRC could invalidate the change as being inconsistent with the design certification rule. Additionally, because changes and summaries of their associated safety evaluations would be submitted to the NRC and, in turn, placed in the NRC's Public Document Room, both the public and prospective license applicants will have full access to relevant information related to the change.

J. Secondary References

The proposed rule stated that "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 codes, standards, and other guidance documents that are referenced in the DCD" (so-called secondary references).

Comment: The industry commented that not all secondary references in the DCD are intended to create requirements, and that the context of the reference indicates whether the reference is intended to be a requirement. Therefore, the final rule should clarify the status of these "secondary references."

Response: The DCD cites secondary references for a number of purposes. Some of the secondary references are cited to impose requirements. However, in context, it is clear that other secondary references in the DCD are not intended to be requirements. For example, some references contain information regarding historical events discussed in the DCD (e.g., references to the Browns Ferry fire and TMI-2 accident). Other secondary references merely contain source information (but not requirements) related to matters discussed in the DCD (e.g., Information Notices). In other cases, references are made to documents or information for the purpose of explaining why the information is not applicable to the standard design. Thus, it is clear that not all secondary references contain, or are intended to contain, requirements applicable to the standard design.

Although it was not the intent, the language in the NOPR could be construed as implying that all secondary references contain requirements. Therefore, the Commission is hereby clarifying that not all secondary references are requirements, and that the context of the secondary reference within the DCD indicates whether a specific secondary reference contains a requirement.

K. Deletion of Section 19.7 tables

Comment: ABB-CE states that all tables within Section 19.7 of the System 80+ DCD, entitled "External Events Analysis," should be deleted, since they were not intended by NRC Staff or ABB-CE for use in the DCD due to their contents. The tables contain detailed probabilistic numerical results from the System 80+ PRA.

Response: The Staff has confirmed to the Commission that the inclusion of the tables was an oversight and, accordingly, the Commission directs that the DCD accompanying the final rule shall not contain any of the tables that were present in the Section 19.7 of the DCD incorporated by the NOPR.

L. Tier 2* Restrictions

As part of its approval of the design certification applications for System 80+ and the ABWR, the NRC staff concluded

that there were a limited number of provisions in Tier 2 that were not sufficiently important to warrant inclusion in Tier 1, yet which should not be changed without prior NRC approval. The NRC staff designated these provisions in Tier 2 as "Tier 2*." These provisions pertain to design methodologies in areas where detailed designs cannot presently be developed due to the lack of as-built data or rapidly changing technology. Because these Tier 2* provisions pertain to design methodologies, the NRC staff designated that the Tier 2* provisions would, in general, expire at first full power, when development of the design details will have been completed.

The industry commented that all Tier 2* restrictions for System 80+ should expire at first full power. This comment and the Commission's response are discussed below.

Comment: Because all of the Tier 2* provisions relate to design methodologies, ABB-CE and the industry stated that they will have been fully implemented by the time the plant reaches full power operation. Therefore, ABB-CE and the industry recommended that all Tier 2* provisions for System 80+ should expire at first full power.

Response: The Tier 2* restrictions which expire at first full power pertain to design methodologies rather than the detailed

design. Since the Tier 2* provisions that currently do not expire at first full power (e.g., piping design acceptance criteria and human factors engineering) also pertain to design methodologies, there is no reason to distinguish them from the balance of the Tier 2* restrictions. Moreover, the Commission would observe that NRC's existing inspection and enforcement authority is adequate to maintain the safety of the design. The Commission concurs with industry's assessment. Therefore, to provide for consistent treatment of the Tier 2* provisions, the Commission has changed the design certification rule to state that all of the Tier 2* restrictions expire at first full power.

M. Proposed Technical Specifications in Tier 2

Sections 8 and 9 of the proposed rule use the term "technical specifications," which the NRC staff has indicated refers to the proposed technical specifications contained in Chapter 16 of Tier 2 of the System 80+ DCD. Under the proposed rule, changes to these Tier 2 technical specifications would require prior NRC approval and an exemption.

The industry objected to creating a separate set of technical specifications in the DCD with a separate change process. The industry's objection and the Commission's response are discussed below.

Comment: The industry commented that the NOPR's proposal would create two sets of technical specifications; one in the license for plant-specific technical specifications and one in the DCD for generic technical specifications. Two sets of technical specifications would be confusing for operators and inspectors when trying to determine the applicable requirements. Further, maintenance of two sets of technical specifications would be burdensome. The industry believes that plants should have a single set of technical specifications attached to the license, and this set should be subject to the same change process as is currently applied to technical specification changes for plants licensed under Part 50.

Response: Creating two sets of technical specifications, each subject to its own change process, is impractical and would be burdensome. Dual technical specifications would require operators, NRC inspectors, and other affected personnel to refer to and compare two sets of technical specifications to identify the applicable requirements and determine the appropriate course of action. Such a provision creates the opportunity for confusion in the control room. In contrast, a single set of technical specifications would be significantly easier to implement and administer than two partial sets of technical specifications.

Additionally, the proposed technical specifications in Chapter 16 are unusable in their present form; they contain numerous estimates, e.g., for setpoints that must be finalized from as-built information and as-procured information. It will not be possible to complete these technical specifications until construction of the affected structures, systems, or components are complete. Given the status of the proposed technical specifications in Chapter 16, the only reasonable course of action is to require an applicant for a COL or operating license (OL) to submit as part of its application a final set of setpoints and proposed technical specifications for approval by the NRC and attachment to the license. This comprehensive set of technical specifications should be subject to one change process, i.e., the one currently used by Part 50 licensees.

The technical specifications submitted with license applications referencing a design certification rule will include the proposed technical specifications in Chapter 16 of Tier 2, including any changes made in accordance with the change process for Tier 2 material, plus supplementary site-specific technical specifications developed by the license applicant. The resulting integrated set of proposed technical specifications will be subject to NRC review and opportunity for hearing as part of the license proceeding. Because Chapter 16 of Tier 2 has finality under 10 CFR 52.63(a)(4), the matters subject to NRC review and

hearing will be limited to the site-specific portions of the technical specifications and any changes made by the license applicant in the proposed technical specifications in Chapter 16 of Tier 2. This set of technical specifications, including any modifications resulting from the license proceeding, will be incorporated into the license as the governing technical specifications for the plant. Licensees will be able to make changes to the plant technical specifications in the license by requesting a license amendment pursuant to 10 CFR 50.90, the same process as for current licensees.

For the foregoing reasons, the Commission has modified Sections 8 and 9 of the rule to substitute the term "technical specifications in an operating license or combined license" in place of the term "technical specifications," and has modified Section 2 to state that the proposed technical specifications in the DCD are not effective for a licensee after issuance of its COL or operating license.

N. PRA Information To Be Submitted by a COL Applicant

The NOPR stated that, predicated on NEI's acceptance, there would be future generic rulemaking to require a COL applicant to have a plant-specific PRA that updates and supersedes the design-specific PRA.

Comment: The industry noted that this provision in the NOPR was not consistent with NEI's previous statements or SECY-94-182, which would allow COL applicants to demonstrate that their plants are bounded by the design certification PRA in lieu of developing a plant-specific PRA.

Response: The Commission agrees that the NOPR was imprecisely worded and that future generic rulemaking should provide COL applicants the option of either preparing a plant-specific PRA, or demonstrating that the design certification PRA is bounding, or some combination of both.

O. Need for the DCD

Comment: DOE stated that the DCD is not necessary, and recommended that the design certification rule be simplified by eliminating the DCD. In its place, DOE stated that the Commission should reference the Certified Design Material (CDM) (which became Tier 1) and the Standard Safety Analysis Report (SSAR) (which became the basis for Tier 2, minus the details of the PRA). In this regard, DOE would apply essentially the same change process to the CDM and the SSAR as the change process recommended by the industry for Tier 1 and Tier 2, respectively.

Response: The industry raised the same points as DOE when the NRC staff first suggested the concept of a DCD in 1992. However, in compliance with directions from the staff, and at considerable expense, ABB-CE developed a DCD. As the industry points out, the System 80+ DCD appropriately reflects various Commission policy decisions.

Given the current situation in which an acceptable DCD has been developed for System 80+, the Commission believes it is appropriate to reference the DCD in the design certification rule. Furthermore, since DOE is recommending that the Commission adopt a process involving the CDM and the SSAR which is substantively equivalent to the process involving the DCD, there appears to be little or no benefit to administrative efficiency by eliminating the DCD and substituting for it the CDM and the SSAR. If the Commission were to adopt DOE's proposal, changes would have to be made to the SSAR to reflect some of the policy decisions governing development of Tier 2 of the DCD, an undertaking which proved to be an extensive and costly effort. Therefore, the Commission has decided to retain the DCD and use it as the basis for the design certification rule.

P. Other clarifications requested by the industry

Comment: The industry commented that there are two other provisions in the proposed rules that are ambiguous or incomplete

and should be clarified. First, Section 8(c) allows an applicant or licensee to request an exemption from the design certification rule, but does not identify any provision for making generic changes in the rule. The industry stated that Section 8(c) should be augmented to specify a process for making changes in the design certification rule other than Tier 1 or Tier 2 (i.e., through rulemaking under Subpart H of 10 CFR Part 2). Second, the industry said that the language in Section 8(c) regarding exemptions from the design certification rule is confusing and should be reworded to more clearly identify the criteria to be applied to exemptions from the language of the rule.

Response: In addition to the change process for Tier 1 and Tier 2, the change process contained in the rule should provide criteria for making changes to provisions in the rule itself. The rule should also clearly identify the criteria to be applied to exemptions from the language of the rule. Therefore, the Commission has added Section 8(c)(1) to clarify that Subpart H of 10 CFR Part 2 governs generic (rulemaking) changes to the design certification rule and to the DCD Introduction. In addition, Section 8(c)(2) was added to clarify that applicants and licensees may request an exemption from the provisions in this rule or the DCD Introduction pursuant to 10 CFR 50.12.

V. Responses to NRC's Request for Comments

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

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

Comments: The proposed change is administrative in nature, and thus does not change any substantive requirements. On that basis, the commenters had no objection to the proposed change in Part 52.

Commission Response: As noted by the commenters, the proposed change is administrative in nature. The Commission believes the change clarifies what information is to be submitted as part of the application. Because there were no objections, the Commission plans to add a new section 52.79(e) as proposed. This addition will be included as part of a subsequent rulemaking action to revise Part 52 to reflect the lessons learned from the first two design certification rulemakings.

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

Comments: None of the commenters identified additional terms to be defined in Section 2 of the design certification rule.

Commission Response: The Commission agrees with the commenters that it is unnecessary to define additional words or phrases in Section 2 of the rule.

3. **Commission Request:** What change process should apply to design-related information developed by a COL applicant or holder that references this design certification rule?

Comments: The industry explained that changes to the Final Safety Analysis Report (FSAR) submitted by license applicants will be controlled by 10 CFR 50.54 and 50.59, which are incorporated by reference in 10 CFR 52.63. Under the terms of the design certification rule, applicants and licensees must also consider the impact of changes on Tier 1 and Tier 2. If a proposed change affects Tier 1 or Tier 2, the change process in the design certification rule would apply. Performance of tests and experiments not described in the FSAR or DCD is covered by Section 50.59, which is applicable to licensees. Therefore,

there is no need for the design certification rules to address such tests and experiments.

The industry stated that other detailed design information (e.g., design specifications and drawings) developed by a license applicant will be treated similarly to detailed design information developed by Part 50 applicants and licensees. For example, changes in safety-related design specifications and drawings will be subject to the controls in Criterion III of Appendix B to Part 50; however, such changes will not be subject to 10 CFR 50.59 and will not otherwise require prior NRC review and approval.

OCRE stated that the change process for the license applicant or holder should be that set forth in Section 8(b)(5)(i) of the design certification rule. Additionally, OCRE stated that design-related information developed by the license applicant or holder must not have issue preclusion and must be subject to litigation in the COL hearing.

NRC Response: The Commission has concluded that the existing provisions in Part 50 and Part 52 provide sufficient controls over design-related information developed by an applicant or licensee, and that additional controls need not be included in the design certification rule.

In this regard, it should be emphasized that changes in design-related information developed by the license applicant or holder will have to be reviewed against the information in Tier 2, and that any changes in Tier 2 will be subject to Section 8(b)(5)(i), as suggested by OCRE. Additionally, any design-related information developed by the license applicant and included in the license application will be subject to litigation in the licensing hearing. However, to the extent that there is a change in information developed by the license applicant or holder that does not affect the DCD, the licensee will be able to make changes in that information pursuant to Section 50.59 and Appendix B, as applicable.

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

Comments: As discussed in detail in Section IV.B above, the industry and DOE raised a number of objections to these added "applicable regulations." OCRE stated that the "applicable regulations" were justified to respond to issues arising from operating experience and to reduce the risk of severe accidents.

Commission Response: In response to ABB-CE's, the industry's, and DOE's comments discussed in Section IV.B above, the

Commission has determined that the "applicable regulations" are unnecessary and would decrease the stability and predictability of the licensing process. Accordingly, the proposed "applicable regulations" have not been included in the final rule.

The Commission acknowledges that the DCD already contains provisions that conform with each of the technical positions that are the subject of the "applicable regulations." As a result, the "applicable regulations" are not necessary to accomplish the goal sought by OCRE; namely, to respond to operating experience and reduce the risk of severe accidents.

5. NRC Request: 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?

Comments: As discussed in detail in Section IV.A above, the industry and DOE stated that changes made in accordance with the design certification rule should have finality and should only be subject to challenge pursuant to 10 CFR 2.206. In response to Question 6, OCRE agreed that changes made after issuance of the COL should only be subject to challenge under Section 2.206; however, OCRE also stated that changes made by a COL applicant should be subject to litigation in the COL hearing on the grounds that the criteria in Section 8(b)(5) of the design certification rule were not satisfied or on the grounds that the change did not satisfy the Commission's regulations.

Commission Response: All commenters and the NRC staff agree that changes made after issuance of a license should only be subject to challenge under Section 2.206. As discussed in Section IV.A above, the Commission has concluded that changes made in accordance with 10 CFR 52.63(b) and the change processes specified in the design certification rule should be accorded finality in the license proceeding as well. Providing an opportunity for hearings on changes that do not involve an unreviewed safety question would be inconsistent with 10 CFR

50.59, the goals of Part 52, and long-standing NRC practice. Therefore, the referenced provision in Section 8(b)(5)(i) of the proposed rule has not been included in the final design certification rule. Rather, the rule has been modified to state that changes made in accordance with the design certification rule have finality.

6. NRC Request: 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?

Comments: The industry stated that a mechanism already exists for informing the public of changes made pursuant to Section 8(b)(5)(i) of the design certification rule. Specifically, pursuant to 10 CFR 50.59(b) and Section 9(b) of the design certification rule, an applicant or licensee must submit periodic reports to the NRC which summarize changes made under Section 8(b)(5)(i)), and these reports will be available for public review in the NRC's Public Document Room. OCRE made similar comments, and also stated that the descriptions of the changes should be provided to parties in the COL proceeding.

Commission Response: The Commission agrees with the commenters that the existing method of informing the public of changes made pursuant to 50.59(b) is adequate for the purposes of the rule. Furthermore, pursuant to the so-called "McGuire Rule," Duke Power Co. (William B. McGuire Nuclear Station, Units 1 and 2), ALAB-143, 6 AEC 623, 625 (1973), parties already have an obligation to inform the licensing board and other parties of new information that is material to the matters being adjudicated. Accordingly, no change has been made to the rule.

7. **NRC Request:** 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?

Comments: The industry stated that changes to Tier 2* information should be treated in a manner similar to the changes which require prior NRC approval under 10 CFR 50.54(a), (p) and (q). Specifically, prior NRC approval should be in the form of a letter to the applicant or licensee which explains the basis for NRC's approval. The change should be subject to an opportunity for public hearing only as provided in 10 CFR 52.63(b)(2); *i.e.*, an opportunity for public hearing would be provided only for those Tier 2* changes that also involve either a change in Tier

1, a change in the technical specifications in the license, or an unreviewed safety question.

OCRE commented that Tier 2* changes should be subject to approval as part of a license amendment proceeding. In this regard, OCRE pointed to cases which state that a grant of authority for a licensee to do something that it could not otherwise have done under existing licensing authority is a license amendment.

Commission Response: The Commission believes that changes to Tier 2* information should be treated in a manner similar to the changes which require NRC approval under 10 CFR 50.54(a), (p), and (q) as described in the comment. There is no legal or practical reason to require license amendments or afford hearings on Tier 2* changes that do not involve an unreviewed safety question. The rule has been clarified accordingly.

The cases cited by OCRE are inapposite to Tier 2* changes. These cases involved permission for venting of a containment in a situation in which a previous NRC order had explicitly prohibited venting, and authorization to engage in major component dismantling without an NRC approved decommissioning plan. Unlike these cases, a licensee is explicitly authorized by 10 CFR 50.59 and 10 CFR 52.63(b)(2) to make changes (including changes in Tier 2 and Tier 2*) without a license amendment if those changes do

not involve a change in the technical specifications, a change to the certified design (i.e., Tier 1), or an unreviewed safety question. Given this authorization, it is clear that a change to Tier 2* requires a license amendment (or a hearing on an initial license) only if the change involves an unreviewed safety question, a change in technical specifications, or a change in Tier 1.

OCRE's recommendation would render the distinction between Tier 2* and Tier 1 essentially meaningless. A licensee may seek a change in Tier 1 only by means of an exemption from the design certification rule and a license amendment. If a licensee were required to obtain a license amendment for Tier 2* changes, Section 8(b)(5)(iv) of the design certification rule would also require an exemption for the change. Thus, under OCRE's proposal, an exemption and license amendment would be needed for changes to either Tier 1 or Tier 2*. This would negate the entire purpose for creating Tier 2*.

8. NRC Request: 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?

Comments: As discussed in detail in Section IV.D above, the industry and DOE stated that a change in the severe accident evaluations should constitute an unreviewed safety question only if there is a change to an important feature identified in Section 19.15 of Tier 2 and there is a substantial increase in the probability or consequences of a severe accident previously reviewed. OCRE recommended that the reference to a severe accident becoming "credible" should be deleted and that another criterion should be added regarding the possibility for a severe accident of a different type than any reviewed previously.

Commission Response: For the reasons discussed in Section IV.D above, the Commission has concluded that the definition of unreviewed safety question as applied to severe accidents should be modified to refer to a "substantial increase" in the probability or consequences of a severe accident. The Commission also has concluded that safety evaluations should be performed only for those changes to the important severe accident features identified in Section 19.15 of Tier 2 for System 80+.

For the reasons discussed in Section IV.D above, the Commission believes that the term "credible" should be retained because the System 80+ DCD evaluates severe accidents that are of extremely low probability, and even substantial increases in such probability should not be deemed an unreviewed safety question

unless the severe accident in question were to become credible. Similarly, it is not reasonable to classify as an unreviewed safety question a change that creates a new severe accident scenario, because it is always possible to postulate a severe accident scenario of exceedingly small probability that has not been previously reviewed.

The Commission directs that the DCD Introduction be amended to correspond with the rule language.

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

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

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

(4) What would distinguish the "old" 10 CFR Part 50 2-step process from the 10 CFR Part 52 combined license process if a

construction permit applicant is permitted to reference a design certification rule and the final design and ITAAC are given full issue preclusion in the operating license proceeding? To the extent this circumstance approximates a combined license, without being one, is it inconsistent with Section 189(b) of the Atomic Energy Act (added by the Energy Policy Act of 1992) providing specifically for combined licenses?

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?

(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).

Comments: The industry and OCRE stated that applicants for construction permits (CP) and operating licenses (OL) under Part 50 should be allowed to reference the design certification rule. Any other result would be inconsistent with Part 52, which

clearly states that applicants for CPs and OLs may reference a design certification (see, e.g., 10 CFR 52.55(b), 52.55(c), 52.63(a)(4), 52.63(b)(1), 52.63(c)). Further, the industry and OCRE stated that a design certification should have issue preclusion effect in subsequent proceedings, including OL and enforcement proceedings; however, OCRE stated that an OL should not be allowed to reference a design certification if the corresponding CP did not reference the certification.

The industry also stated that the rule should not require a construction permit applicant who references the design certification rule to utilize the ITAAC. Such a requirement would, in essence, convert a CP into a COL and eliminate any reason for a CP applicant to reference a design certification rule. OCRE stated that a CP applicant who references a design certification should be required to reference the ITAAC because the ITAAC are in Tier 1, but that the OL hearing with respect to design-related issues would be limited to issues related to compliance with the ITAAC. OCRE recognized that, under its recommendation, a CP/OL would approximate a COL, and that it would be extremely unlikely that an applicant would ever opt for the CP/OL process rather than the COL process.

Commission Response: The Commission believes that it is desirable to resolve these issues now and not defer them until

after design certification. As the industry pointed out, both the proposed rule and the DCD Introduction contain explicit and implicit provisions related to use of the design certification by license applicants and licensees under Part 50. Therefore, the Commission agrees with the commenters that applicants for construction permits (CP) and operating licenses (OL) under Part 50 should be allowed to reference the design certification rule.

The Commission agrees with the commenters that the design certification should have issue preclusion effect in all subsequent Part 50 proceedings, including CP, OL, license amendment, and enforcement proceedings. Any other treatment would lead to the inconsistent treatment of two identical plants, one being licensed under Part 50 and the other under Part 52, where adequacy of the design could be challenged in the Part 50 proceeding but not in the Part 52 proceeding. The Commission also agrees with OCRE that an OL should be allowed to reference a design certification only if the corresponding CP referenced the certification.

Finally, the Commission has concluded that the ITAAC should not be applicable to a construction permit applicant who references the design certification, as discussed in Section IV.E above. As the commenters recognized, a requirement for a CP to reference the ITAAC would essentially make the CP/OL process indistinguishable from the COL process. To preserve the value of

design certification for use in Part 50 licensing proceedings, ITAAC should not constitute requirements for such proceedings. Contrary to OCRE's statement, the Commission has the discretion to allow Part 50 license applicants to reference Tier 1 without requiring them also to reference the ITAAC.

VI. Section By Section Analysis

After careful consideration of all the comments received, the Commission has made both editorial and substantive changes to the text of the proposed rule. Throughout the following discussion of the substantive modifications, the reader should refer to the text of the final regulations to aid in understanding the specific points of this discussion.

Section 1, Scope.

Section 1 is unchanged from the proposed rule.

Section 2, Definitions.

The following modifications have been made to the definitions provided in Section 2 of the rule:

The definition of *Design Control Document* was modified to include the DCD Introduction, as well as Tier 1 and Tier 2 information incorporated by reference into the design

certification rule. As discussed in Section IV.F above, the change was made because the DCD Introduction contains numerous substantive provisions that were not addressed in the text of the proposed rule, and therefore would have no binding effect unless the DCD Introduction is incorporated by reference in the design certification rule.

The definition of *Tier 1* was modified to clarify that compliance with the more detailed *Tier 2* material provides a sufficient, but not the only acceptable, method for complying with the more general provisions in *Tier 1*. Additionally, the definition was changed to state that the methods and provisions specified in *Tier 2* shall be followed unless a change is made in accordance with the change processes specified in the rule. Finally, the revised definition states that the design descriptions in *Tier 1* pertain only to the design of System 80+ structures, systems and components, not to their operation, maintenance or administration, and that, in the event of inconsistencies between *Tier 1* and *Tier 2*, *Tier 1* governs. All of these new provisions are also part of the DCD Introduction, and are being included in the design certification rule to clarify that these provisions are regulatory requirements.

The definition of *Tier 2* was modified to reflect the changes in the definition of *Tier 1* discussed above, and was expanded to explain the purpose of COL Information Items, conceptual design

information, and references to the SSAR. These provisions are also in the DCD Introduction and are being included in the rule to ensure their binding effect. Additionally, the definition of Tier 2 was modified to explain the status of the proposed technical specifications in Tier 2, as discussed in Section IV.M above.

Finally, the definition of Tier 2* was modified to clarify that a license or license amendment is not necessary for Tier 2* changes, and that all of the Tier 2* restrictions expire at first full power, consistent with the discussion in Section IV.L above.

Section 4, Contents of the design certification.

Section 4(a) was modified, consistent with the discussion in Section IV.F above, to incorporate the entire System 80+ Design Control Document (including the DCD Introduction) by reference, not just Tier 1 and Tier 2. In addition, the rule was changed to indicate that copies of the System 80+ DCD can be purchased from the National Technical Information Service.

Section 4(b) was revised to state that the ITAAC in Tier 1 are not required for an application for a construction permit or operating license. As discussed in Section IV.E above, ITAAC are not needed to ensure that a facility licensed under Part 50 is built in accordance with the certified design and the Commission's regulations.

Section 5, Exemptions and applicable regulations.

As discussed in Section IV.B above, Section 5(c) of the proposed rule has been deleted to remove the "applicable regulations" proposed in the NOPR. The Commission has determined that the proposed "applicable regulations" are unnecessary because all of the related technical positions are implemented by provisions in Tier 1 and Tier 2. Retaining the broadly-stated "applicable regulations" could give rise to uncertainty in their future interpretation and to destabilizing backfits, which would be contrary to a basic purpose of Part 52.

Section 6, Issue resolution for the design certification.

As discussed in Section IV.A above, Section 6 was modified to broaden the issues entitled to finality under the rule.

A new Section 6(a) was added to clarify that the sufficiency of the System 80+ Standard Plant Design is considered a matter resolved in connection with issuance of this design certification rule.

Former Section 6(a) was relabeled as Section 6(b). Additionally, this Section was modified to provide finality not only to matters associated with the DCD and FSER, but also with the SSAR, the docket for certification of System 80+, and the System 80+ rulemaking record. Finally, this Section and was modified to clarify that the NRC may not require applicants or

licensees to provide additional structures, systems, components, or design features, or additional design criteria, testing, analysis or justification therefor, beyond those already discussed in the FSER or DCD.

Former Section 6(b) was relabeled as Section 6(c).

A new Section 6(d) was added, consistent with the discussion in Section IV.A, to clarify that changes made in accordance with the change process set forth in Section 8 of the final design certification rule are resolved within the meaning of 10 CFR 52.63(a)(4).

A new Section 6(e) was added to clarify that the design certification has finality in all subsequent proceedings.

Section 7, Duration of the design certification.

No changes.

Section 8, Change process.

No substantive changes were made to Section 8(a) or Sections 8(b)(1) through (4).

Section 8(b)(5) in the proposed rule was modified in several areas. First, the last sentence of Section 8(5)(i), which stated "[t]hese 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)." was

deleted. As discussed in Section IV.A above, the Commission believes that these changes should have finality.

Section 8(b)(5)(iii) was modified to limit the application of the 50.59-like change process to Section 19.15 of Tier 2 rather than all of Chapter 19 as originally proposed. Further, the standard for determining the existence of an unreviewed safety question was changed such that departures from information associated with severe accident issues shall be deemed to involve an unreviewed safety question only if there is a substantial increase in the probability or consequences of a severe accident, consistent with the discussion in Section IV.D above.

Section 8(b)(5)(iv) was modified, consistent with the discussion in Section IV.H, to clarify that exemptions are not required for changes to the technical specifications and Tier 2*, unless such changes involve an unreviewed safety question.

Section 8(c)(1) was added to clarify that Subpart H of 10 CFR Part 2 governs generic (rulemaking) changes to the design certification rule (other than Tier 1 or Tier 2) or to the DCD Introduction. Section 8(c)(2) was added to clarify that applicants and licensees may request an exemption under Section 50.12 from the provisions in this rule or the DCD Introduction.

Section 8(d) was added to provide a change process for generic changes to the DCD by the design certification applicant, as discussed in Section IV.I above.

Section 9, Records and reports.

Section 9 was modified to require semi-annual reporting of Section 50.59 changes, as discussed in Section IV.H.

Section 10, Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC).

A new Section 10 was added to require applicants or holders of combined licenses to demonstrate compliance with the ITAAC prior to fuel load or to take corrective action or request and obtain an exemption or NRC approval for change in the ITAAC in the event an activity is in noncompliance with an ITAAC. Section 10 also clarifies that while the Commission must find, prior to operation, that the acceptance criteria in the ITAAC have been met, ITAAC do not subsequently constitute regulatory requirements for modifications, for the COL holder, or for renewals of the COL. Both of these provisions are discussed in the DCD Introduction.

Section 11, ITAAC Verification

A new Section 11 was added to clarify the nature of NRC's ITAAC verification. As discussed in Section IV.C above, the rule specifies that the NRC shall determine compliance with ITAAC by verifying that the required inspections, tests, and analyses have been successfully completed and that, based solely thereon, the

corresponding acceptance criteria have been satisfied.

Compliance with other requirements, such as quality assurance issues, will be confirmed through the Part 50 inspection and enforcement process.

**VII. Finding of No Significant
Environmental Impact: Availability**

The Commission has determined under the National Environmental Policy Act (NEPA) and the Commission's regulations in 10 CFR Part 51, Subpart A, that this design certification rule is not a major Federal action significantly affecting the quality of the human environment, and therefore an environmental impact statement (EIS) is not required. Rather, an environmental assessment was performed and made available to the public. No comments were received by the NRC on the environment assessment.

The basis for the no significant environmental impact determination, as documented in the environmental assessment, is that this amendment to 10 CFR Part 52 does not authorize the siting, construction, or operation of a facility using the System 80+ design; it only codifies the System 80+ design in a rule. The NRC will evaluate the environmental impacts and issue an EIS as appropriate in accordance with NEPA as part of an application 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 were submitted in ABB-CE's "Technical Support Document" for 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 System 80+ 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+ Standard Plant Design.

The environmental assessment, upon which the Commission's finding of no significant impact is based, and the Technical Support Document for 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.

VIII. Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget approval number _____.

IX. Regulatory Analysis

The NRC has not prepared a regulatory analysis for this rule. The NRC prepares regulatory analyses for rulemakings that establish generic regulatory requirements. Because the Commission has deleted the proposed "applicable regulations," this design certification is not a generic rulemaking. Rather, this design certification is a Commission approval of a specific nuclear power plant design by rulemaking. Furthermore, this design certification rulemaking was initiated by an applicant for a design certification, rather than the NRC. For these reasons, the Commission concludes that preparation of a regulatory analysis is neither required nor appropriate.

X. Regulatory Flexibility Act Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rulemaking will

not have a significant economic impact upon a substantial number of small entities. The rule provides a 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.

XI. Backfit Analysis

The Commission has determined that the backfit rule, 10 CFR 50.109, does not apply to this rule because these amendments do not impose requirements on existing 10 CFR Part 50 licensees or the Final Design Approval for System 80+. Therefore, a backfit analysis was not prepared for this rule.

XII. 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.

Text of Final Regulations

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 is adopting the following amendment to 10 CFR Part 52.

Part 52 - EARLY SITE PERMITS; STANDARD DESIGN CERTIFICATIONS AND COMBINED LICENSES FOR NUCLEAR POWER PLANTS

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, and Appendix B.

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

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

1. Scope.

This Appendix constitutes the standard design certification for the System 80+^{1/} Standard Plant design, in accordance with 10 CFR Part 52, Subpart B. The applicant for certification of the

^{1/} "System 80+" is a trademark of Combustion Engineering, Inc.

System 80+ Standard Plant 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 DCD Introduction, 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, but may be more general than the provisions in Tier 2. Compliance with the more detailed Tier 2 material provides a sufficient method, but not the only acceptable method, for complying with the more general design provisions in Tier 1. However, the methods and provisions specified in Tier 2 shall be followed unless a change is made in accordance with the change processes specified in the design certification rule for the System 80+ Standard Plant Design.

The Design Descriptions in Tier 1 pertain only to the design of the structures, systems and components of a System 80+ Standard Plant Design and not to their operation, maintenance and administration. In the event of an inconsistency between Tier 1 and Tier 2, Tier 1 shall govern. Design activities for structures, systems, and components outside the scope of the System 80+ Standard Plant Design may be performed using site-specific design parameters.

(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;

- (2) The information required for a final safety analysis report under 10 CFR 50.34(b);
- (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. Compliance with Tier 2 is a sufficient, but not necessarily the only, method for complying with the ITAAC. The provisions and methods specified in Tier 2 shall be followed unless a change is made in accordance with the change process specified in the design certification rule for the System 80+ Standard Plant Design;
- (4) COL Information Items, which identify certain matters that need to be addressed by an applicant or licensee referencing the design certification rule for the System 80+ Standard Plant Design. The purpose of these COL Information Items is to identify the type of information that must be addressed in plant-specific Safety Analysis Reports (SARs) that reference the design certification rule for the System 80+ Standard Plant Design. These COL Information Items do not establish requirements; rather, they identify an acceptable set of information, but not the only acceptable set of information, for inclusion in a

plant-specific SAR. An applicant may deviate from or omit these COL Information Items provided that the deviation or omission is identified and justified in the plant-specific SAR. After issuance of a construction permit or license, the COL Information Items have no further effect for that licensee; instead, the corresponding provisions in the plant-specific SAR become applicable;

- (5) Conceptual designs for those portions of the plant that are outside the scope of the System 80+ Standard Plant Design, which are described and designated as out-of-scope in various locations within Tier 2. As provided by 10 CFR 52.47(a)(1)(ix), these conceptual designs are not a part of the design certification rule for the System 80+ Standard Plant Design, and do not impose requirements applicable to a license, nor to an application for a license, that references the design certification rule for the System 80+ Standard Plant Design;
- (6) References to the System 80+ Standard Safety Analysis Report, which shall not be construed as incorporating its sections, or the information therein, within Tier 2; and

(7) Proposed technical specifications for the portion of the plant within the scope of the standard design. These proposed technical specifications are applicable to an applicant for a combined license or an operating license referencing this design certification rule, and shall be incorporated in the technical specifications in the license, except as changed pursuant to the provisions in Section 8 of this design certification rule that apply to changes in Tier 2 information. Changes in the proposed technical specifications by a license applicant are subject to NRC review and approval and a hearing as part of the license proceeding. After issuance of a combined license or operating license, the proposed technical specifications in Tier 2 have no further effect to that licensee, and the technical specifications in the license are effective.

Tier 2 does not include proprietary information from the Standard Safety Analysis Report for the System 80+ Standard Plant. The proprietary references or their equivalent must be included or referenced as part of the license application that references the design certification rule for the System 80+ Standard Plant.

(d) Tier 2* means the portion of the Tier 2 information which cannot be changed without prior NRC approval by letter or other written document. This information is identified in the DCD. The restrictions on changes to Tier 2* information expire at first full power for a plant that references this design certification rule. Thereafter, changes to the Tier 2* information shall be controlled in the same manner as changes to other Tier 2 information.

(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) The System 80+ Design Control Document, ABB-CE, Revision 2, [dated,] is 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 purchased from the National Technical Information Service, Springfield, VA 22161. 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 shall reference both Tier 1 and Tier 2 of the System 80+ DCD. However, the ITAAC in Tier 1 are not applicable to an applicant for a construction permit or operating license.

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

5. Exemptions and applicable regulations.

(a) The System 80+ Standard Plant 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 (f)(2)(iv) of 10 CFR 50.34 - Separate Plant Safety Parameter Display Console;

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

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

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

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

(b) Except as indicated in paragraph (a) of this section, the regulations that apply to the System 80+ Standard Plant 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.

6. Issue resolution for the design certification.

(a) The Commission has found that the structures, systems, components, and design features of the System 80+ Standard Plant design as described in the DCD and FSER satisfy the relevant Commission regulations and provide adequate protection of the health and safety of the public. Inherent in this finding is the

determination that additional or alternative structures, systems, components, design features, design criteria, testing, analyses, or justifications are not necessary for the System 80+ Standard Plant design. The lack of need thereof is, accordingly, also considered a matter resolved in connection with issuance of this design certification rule.

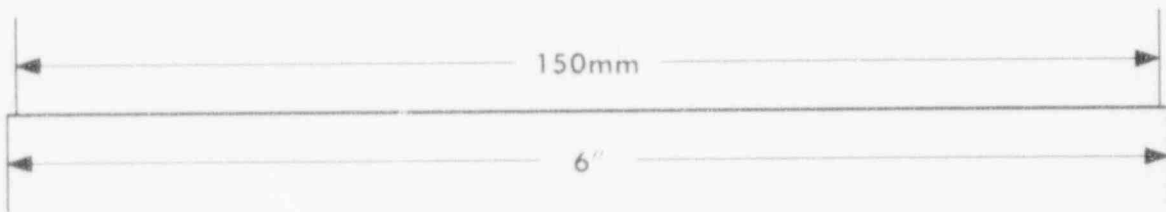
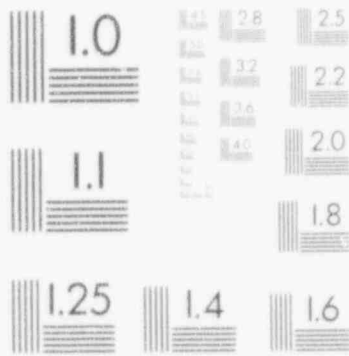
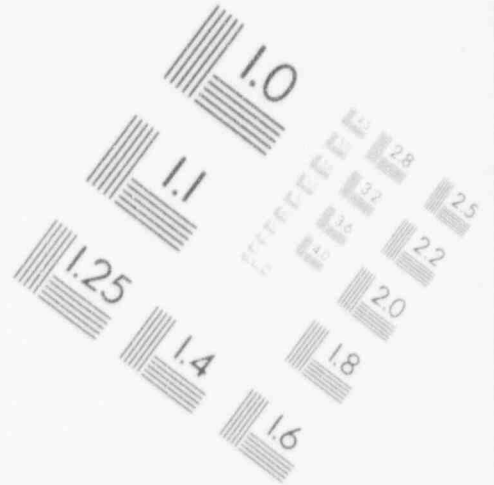
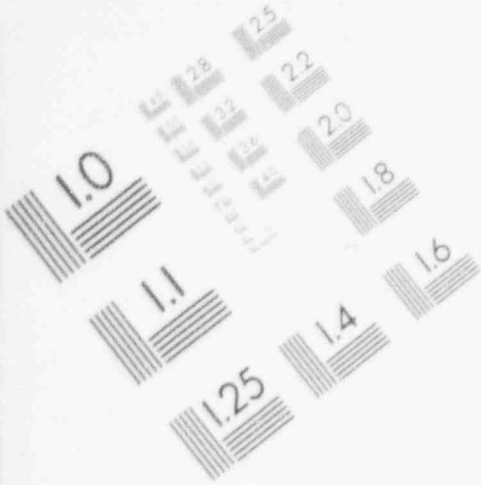
(b) All nuclear safety issues associated with the information in the FSER, DCD, application for design certification of the System 80+ Standard Plant, including the System 80+ Standard Safety Analysis Report, docket of the application for design certification of the System 80+ Standard Plant, and the rulemaking record for design certification of the System 80+ Standard Plant, are resolved within the meaning of 10 CFR 52.63(a)(4). Within the scope of the standard design as discussed in the FSER and DCD, the NRC may not require an applicant or licensee to:

- (1) provide structures, systems, components, or design features not discussed in the FSER or DCD; or
- (2) provide additional design criteria, testing, analysis, or justification for structures, systems, components, or design features discussed in the FSER or DCD;

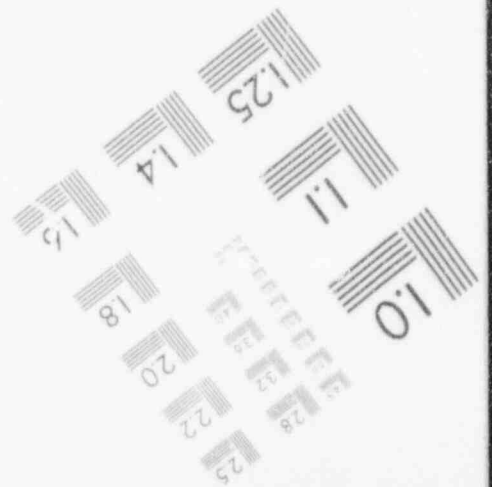
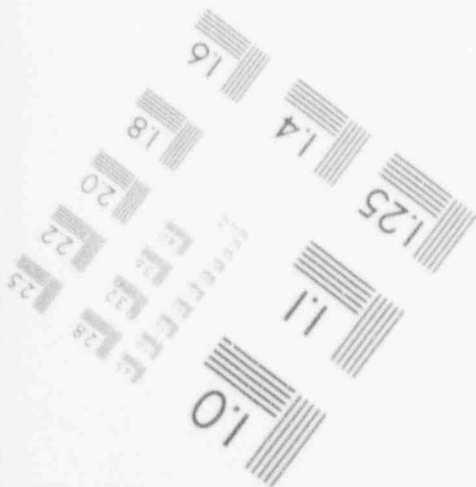
except in accordance with the change processes and other provisions in this design certification rule.

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

(d) Any change made in accordance with the change process set forth in Section 8 of this design certification rule is resolved within the meaning of 10 CFR 52.63(a)(4).

(e) The matters listed above shall be considered resolved in all subsequent proceedings, including proceedings for issuance of a combined license, construction permit, or operating license; permit or license amendment proceedings; design certification and license renewal proceedings; proceedings under 10 CFR 52.103; and enforcement proceedings.

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 of the final rule 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 (rulemaking) 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, combined license, or permit or license amendment 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 in an operating license or combined

license, 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, but excluding the information in Chapter 19 of Tier 2 other than the information in Section 19.15.

(ii) A proposed departure from Tier 2 information, other than severe accident issues identified in Section 19.15, shall 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 in an operating license or combined license is reduced.

(iii) A proposed departure from information associated with severe accident issues identified in Section 19.15 of Tier 2 shall 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, technical specification changes, and Tier 2* changes that do not involve an unreviewed safety question do not require an exemption from this design certification rule.

(c) Other requirements of this design certification rule.

(1) Generic (rulemaking) changes to the provisions in this Appendix or to the DCD Introduction are governed by the requirements of Subpart H of 10 CFR Part 2.

(2) An applicant or licensee may request an exemption from the provisions in this Appendix or the DCD Introduction in accordance with 10 CFR 50.12(a).

(d) Generic Changes to the DCD by the Design Certification Applicant

(1) Changes to Tier 1 - Any change to Tier 1 proposed by the design certification applicant shall be the subject of a

request for proposed rulemaking in accordance with the provisions of subsection (a) of this Section.

(2) Changes to Tier 2 - Prior to the first license application that references the DCD, the design certification applicant may make a change to Tier 2, unless the proposed change involves a change in Tier 1 or an unreviewed safety question. Any change by the design certification applicant to Tier 2* information designated in the DCD shall be subject to prior NRC Staff approval.

(i) The design certification applicant shall submit reports of any change in Tier 2 to the NRC. The reports shall describe the change and provide a summary of a safety evaluation which provides the basis for the determination that the change does not involve an unreviewed safety question.

(ii) For changes made hereunder, the design certification applicant shall submit to the NRC an update to the DCD on a replacement-page basis, which shall indicate the area changed, e.g., a bold line vertically drawn in the margin adjacent to the portion changed, and a page change identification (date of change or change number, or both).

(iii) A change made hereunder shall be considered resolved under 10 CFR 52.63(a)(4) unless the NRC determines, within six months of submission of the change, that the change involves an unreviewed safety question as defined in Section 8(b)(5) above.

(iv) A license applicant shall reference and utilize the updated DCD, unless the license applicant makes a change in accordance with the other provisions of this Section.

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 the DCD, including 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 in the operating license or combined license.

(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 departure. 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 Tier 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 semiannually. 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 plant-specific DCD, and the records of changes to and departures from the plant-specific DCD,

must be maintained until the date of termination of the construction permit or license.

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

(a) An applicant for or holder of a combined license (COL) that references the design certification rule for the System 80+ Standard Plant Design shall perform and demonstrate conformance with the ITAAC prior to fuel load. With respect to activities subject to an ITAAC, an applicant for a COL may proceed at its own risk with design and procurement activities, and a holder of a COL may proceed at its own risk with design, procurement, construction, and preoperational activities, even though the NRC Staff may not yet have agreed that any particular ITAAC has been satisfied. In the event that an activity is subject to and in noncompliance with an ITAAC, the applicant for or holder of a COL shall either take corrective actions to successfully complete that ITAAC or request and obtain NRC approval of a change in or exemption from the ITAAC in accordance with the design certification rule for the System 80+ Standard Plant Design.

(b) In accordance with 10 CFR 52.103(g), the Commission must find that the acceptance criteria in the ITAAC are met prior to operation. After the Commission has made the finding required

by Section 52.103(g), the ITAAC do not constitute regulatory requirements for subsequent plant modifications. However, subsequent modifications must comply with Tier 1 Design Descriptions, unless changes are made in the Tier 1 Design Descriptions in accordance with the change processes in the design certification rule for the System 80+ Standard Plant Design. Furthermore, after the NRC has issued its finding in accordance with 10 CFR 52.103(g), the ITAAC do not, by virtue of their inclusion in the Design Control Document, constitute requirements for the COL holder or for renewals of the COL.

11. ITAAC Implementation and Verification.

In order to provide a basis for the NRC to make the findings required by §§ 52.99 and 52.103(g), the licensee shall notify the NRC that the required inspections, tests, and analyses specified in the ITAAC have been successfully completed and that the corresponding acceptance criteria have been met. The NRC shall verify that the inspections, tests, and analyses referenced by the licensee have been successfully completed and, based solely

thereon, find that the prescribed acceptance criteria have been met. The NRC shall publish notice of successful completion of inspections, tests, and analyses in the Federal Register as required by § 52.99.

Dated at Rockville, Maryland, this ____ day of _____, _____.

For the Nuclear Regulatory Commission.

John C. Hoyle,
Secretary of the Commission