NUCLEAR ENERGY INSTITUTE

Dr. Ronald L. Simard
SENIOR DIRECTOR, NEW PLANT DEPLOYMENT
NUCLEAR GENERATION DIVISION

September 16, 2003

Annette L. Vietti-Cook
Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

ATTENTION: Rulemakings and Adjudications Staff

SUBJECT: *Federal Register* Notice 68 FR 40026, July 3, 2003, Notice of Proposed Rule for Early Site Permits, Standard Design Certifications, and Combined Licenses for Nuclear Power Plants.

Dear Ms. Vietti-Cook:

The Nuclear Energy Institute[1] (NEI) is submitting the enclosed comments on behalf of the nuclear energy industry in response to the subject *Federal Register* notice.

The proposed rulemaking would make sweeping changes to the existing regulations, both as to substantive matters and a complete restructuring of Part 52. The nature and number of proposed changes has complicated our analysis of the changes and made it difficult to complete in the required time for comments. To try to make our concerns clear, we will be providing our comments on the notice of proposed rulemaking (NOPR) in two separate letters. Enclosure 1 to this letter provides the industry's comments on the most significant issues; these issues and recommendations are important to achieving the goal of Part 52 to provide a predictable, stable and efficient licensing process for future plants. Our responses to the seven questions posed in Section IV of the NOPR are provided in Enclosure 2. By September 30, we

[1] NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including regulatory aspects of generic operational and technical issues. NEI members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

will provide a complete set of detailed comments on the proposed rule, including a complete red-line markup.

In reviewing the proposed rule, the nuclear industry has identified seven issues that we especially wish to bring to the Commission's attention. These are summarized below and discussed fully in Enclosure 1.

Applicability of Part 50 and Other NRC Requirements to Part 52 Processes – The proposed rule would dramatically depart from a fundamental principle that has underlain Part 52 since its original inception in 1989 – that Part 52 is a new way to license a nuclear power plant, but substantive requirements would continue to be established by the NRC's other regulations. Extensive cross-references to Part 50 and other parts of Chapter I are proposed to address the applicability of these requirements under Part 52. This proposal would impose a host of Part 50 and other NRC requirements on Part 52 applicants, holders and licensees. Enclosure 1, Issue 1, provides several examples of the inappropriate and confusing requirements that would result under this approach and cause us to conclude that the proposal is seriously flawed. We recommend an alternative approach consistent with Commission guidance provided in the 1989 Statements of Consideration on the original Part 52 rulemaking. Specifically, we recommend the following general provision in place of proposed Section 52.5:

> Section 52.5 – Applicability of NRC requirements – Unless otherwise specifically provided for in this part, a licensee, holder of, or applicant for an approval, certification, permit, site report, or license issued under this part shall comply with all requirements in 10 CFR Chapter I as they apply and are technically relevant to the particular licensing action.

Adopting this or an equivalent provision would efficiently address the issue of applicability of Part 50 and other regulations, as well as the NRC staff concern that developing general provisions tailored for the various Part 52 processes would be too burdensome.

<u>If the NRC does not adopt the above approach, we strongly recommend that the portions of this rulemaking that address the applicability of Part 50 and other regulations be deleted so that the balance of this important rulemaking may go forward.</u> As the balance of this rulemaking goes forward, we urge the NRC staff to engage stakeholders in a full consideration of the impacts of the sweeping approach proposed in the NOPR to address the applicability of Part 50 and other NRC requirements, and to consider alternatives to it. The outcome of those stakeholder interactions could be implemented via direct final

rulemaking after the current lessons learned rulemaking on Part 52 is completed.

NRC Verification of Inspections, Tests, Analyses and Acceptance Criteria (ITAAC) – This topic is crucial to the successful application of Part 52 for a combined license (COL) applicant. Per §52.103(g), the Commission, based on NRC staff ITAAC conclusions under §52.99, must ultimately find that the ITAAC have been successfully completed prior to fuel loading and beginning of operation. This finding cannot be made until just prior to scheduled fuel load. It thus becomes imperative that the conduct of the NRC staff verification under §52.99 be done in a timely and conclusive manner as construction proceeds and the combined license holder determines that the individual ITAAC have been completed. Absent new information, the staff's verification must be final. The proposed language falls short of achieving this certainty and is not consistent with the language approved by the Commission for each of the design certification rules in Part 52 Appendices A, B and C. The industry considers this to be a critical issue for this rulemaking, as discussed further in Enclosure 1, Issue 2.

Vendor Design Change Process – The industry continues to support the incorporation of a change process into Part 52 to allow the original design certification applicant to seek amendments to the design certification (DC) rule to accommodate design improvements that arise under completion of a first-of-a-kind engineering effort or from other improvements in technology. These design changes would be subject to a notice-and-comment rulemaking and would obviate the need for subsequent applicants referencing the design to seek exemptions to the DC rule. Amplification and proposed rule language is provided in Enclosure 1, Issue 3.

Requirements for Prototype Plants – The NOPR would add a requirement that the same testing that would be required for a DC applicant must be performed by a COL applicant that seeks a license for a non-evolutionary plant. The industry does not believe that it is appropriate to apply these requirements to a COL applicant and that the potential requirement for a full-scale prototype testing is particularly inappropriate. Our reasoning is laid out in Enclosure 1, Issue 4.

Formatting of the Proposed Part 52 – In a highly unusual move, the NOPR would completely restructure the existing rule in order to incorporate appendices into the main body of the regulation. The industry does not oppose integration of the appendices into the regulation, but is concerned that existing subsections have been renumbered with little apparent benefit to the regulatory process. Such an action needlessly compromises all of the existing

documentation that references existing sections of Part 52. Furthermore, it creates an unestimated, but certainly not insignificant, burden on the industry to identify and correct references that have been rendered inaccurate because of this rulemaking. In Enclosure 1, Issue 5, we recommend a more user-friendly method of integrating Part 52 sub-processes into the regulation.

Lessons Learned from Pilot Early Site Permit Applications – The ongoing pilot ESP applications have provided significant insight into the scenario whereby an ESP application does not specify the particular plant for which site approval is sought. Under this scenario, bounding design parameters – the plant parameters envelope approach – are used as a surrogate for actual design information to support the reviews and findings necessary for ESP. Based on experience with the pilot ESP applications, we recommend that Section 52.17(a) (1) should be clarified in two respects, as discussed in Enclosure 1, Issue 6. First, it should be clarified to appropriately reflect the optional use of bounding design parameters in lieu of actual design information. And second, modification is necessary to clarify the nature of radiological consequence analyses that are required of ESP applicants. In this regard, we do not agree with the NRC staff interpretation that the existing language requires complete radiological consequence analyses be developed and reviewed for ESP, including both site-related and design-dependent factors. Rather, the rule language we recommend places the focus for ESP on establishing the site-related factors of radiological consequence analyses, namely the site atmospheric dispersion characteristics.

Updating ESP Emergency Planning Information at Licensing Stage – The industry concurs with the NOPR intent to assure that information that was provided in the ESP application that impacted the Commission's finding on the emergency plans described in the ESP must be updated and corrected at the time of the license application referencing the ESP is filed. However, the NOPR would impose on the new information a too-low threshold for being subject to NRC review and litigation that does not maintain the licensing stability which the ESP is intended to provide. The industry proposes use of the same standard for NRC review and litigation that is imposed upon operating reactors when they make or apply for changes to their emergency plans. Additional information is provided in Enclosure 1, Issue 7.

Apart from these seven issues, several of the rulemaking proposals provide valuable enhancements to Part 52 processes, and we support them. These include:

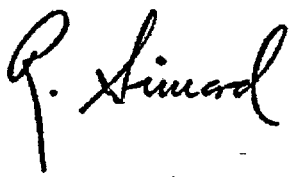
- New ability for the NRC to make generic changes to a design certification that reduce regulatory burden while maintaining safety

- Conforming of the design certification rules to reflect the 1999 changes to 10 CFR 50.59
- Clarification that ESP applicants need not address alternative energy sources
- Clarification that Part 140 financial protection requirements must be fully implemented by the time of the 52.231(g) finding, but not before.
- Provisions allowing completion of certain ITAAC in connection with the COL proceeding

This rulemaking is vitally important for ensuring that future plant licensing will benefit from lessons learned from past and ongoing Part 52 activities and will meet the original intent of Part 52 to provide for predictable, stable and efficient licensing for new plants. We appreciate the opportunity to provide the enclosed comments, recommendations and responses for NRC consideration. As indicated above, the balance of industry comments will be provided by September 30, 2003.

If you have any questions concerning the industry's major comments and recommendations, or our responses to the seven questions posed in the NOPR, please contact me (rls@nei.org or 202-739-8128) or Russ Bell (rjb@nei.org or 202-739-8087).

Sincerely,



Ronald L. Simard

Enclosures:

1. Description of Major Issues Related to the Notice of Public Rulemaking on 10 CFR Part 52.
2. Industry Responses to NOPR Section IV Questions

c: James E. Lyons, NRC/NRR

September 16, 2003

Enclosure 1
Description of Major Issues Related to the Notice of Public Rulemaking on 10 CFR Part 52

Issue 1 – Applicability of 10 CFR Part 50 and Other NRC Requirements (Proposed 10 CFR 52.5, 52.19, 52.28, 52.111, 52.215 and 52.249)

Comment:

The current version of 10 CFR Part 52 specifically identifies those portions of Part 50 that must be addressed by an applicant under Part 52. In contrast, Section 52.5 of the proposed Notice of Public Rulemaking (NOPR) would broadly sweep in all of the requirements of 38 sections of Part 50 onto applicants, holders and licensees for all seven of the licensing processes described in Part 52. Similarly, proposed Sections 52.19, 52.28, 52.111, 52.215 and 52.249 would impose all or a portion of the Part 50 requirements on all or some of the licensing processes in Part 52. This approach will place inappropriate and conflicting requirements on Part 52 applicants, holders, and licensees.

By incorporating numerous provisions in Part 50 without tailoring those provisions for Part 52 applicants, holders, and licensees, the proposed rule lacks the specificity that is required by good regulation, and leaves open to interpretation many of the rules and regulations being referenced by this rule change. Of the 38 items of 10 CFR Part 50 being referenced by the revised 10 CFR Part 52.5, most of these items are inapplicable in whole or part to at least some of the applicants under Part 52. For example, proposed §52.5 references reporting requirements in 10 CFR 50.72 and 52.73 that clearly are not appropriate for Part 52 activities, except for COL holders. Similarly, proposed §52.5 references numerous design and administrative requirements in Part 52 that clearly are not appropriate for ESPs, such as:

- Applicability of §50.71 without qualification would be inappropriate because §50.71(b) would require financial information to be submitted on an annual basis by ESP holders even though such information has no applicability for an ESP holder.

- Applicability of §50.57(a)(1) would require that construction be substantially complete prior to issuance of the operating license. This would clearly not be pertinent in a Part 52 combined license context.

- Applicability of §50.56, *Conversion of construction permit to license; or amendment of license*, is unnecessary and inappropriate because construction permits are not issued or converted under Part 52, and the requirement does not comport with proposed §52.227(a)(1).

Furthermore, proposed Sections 52.19 and 52.111 would impose all of the requirements in Part 50 on applicants for an ESP or design certification. Such a

requirement is clearly inappropriate and ignores the extensive history that distinguishes certified designs from licensed designs in the 1989 rulemaking that created Part 52. For example, proposed Sections 52.19 and 52.111 would require an applicant for either an ESP or design certification to satisfy the technical and financial qualification requirements in Part 50 - - this is clearly unwarranted (and, we assume, is unintended by the NRC). Similarly, there are numerous other provisions in Part 50 that simply are inapplicable and inappropriate if applied to ESP and design certification applicants.

Proposed Section 52.28 would impose all of the requirements in 10 CFR 50.80 upon applicants who seek to transfer an ESP. However, Section 50.80 includes requirements for technical and financial qualification that are not applicable to an ESP applicant, and therefore should not be imposed upon an applicant for transfer of an ESP.

Standing in contrast to the ambiguity of the examples provided above is proposed Section 52.209. As discussed in the supplementary information accompanying the proposed rule, Section 52.209 is proposed to "remove any ambiguity" regarding the implementation timing of Section 50.120 training requirements. Section 52.209 clarifies, for purposes of Part 52 combined licenses, that Section 50.120 requirements must be satisfied prior to fuel load, rather than prior to the granting of the license. The proposed approach of Section 52.209 – namely, adding specific language to Part 52 to clarify how particular provisions in Part 50 should be applied to Part 52 licensees and applicants is one way to address that issue. This is an example of the kind of tailored provisions that could be developed in lieu of generic provisions such as proposed in Section 52.215.

The inconsistencies of the proposed rule within itself highlights the need to step back and rethink this rulemaking's sweeping approach to addressing the applicability of Part 50 requirements.

In a letter to the NRC dated November 13, 2001, NEI stated, "The industry proposes that additional General Provisions be added to part 52 in addition to an appropriate provision on Written Communications. This approach is preferable to including cross-references in part 52 to part 50 General Provisions because these provisions typically must be tailored to apply appropriately to the variety of licensing processes in part 52." In particular, we proposed specific language for new general provisions on Employee Protection and Completeness and Accuracy of Information.

The NOPR states, "The Commission disagrees with this proposal to create over 35 new general provisions that are tailored to 10 CFR Part 52 because it would appear to be an inefficient and burdensome addition." The industry believes that the effort to develop clear and fully appropriate regulations does not constitute an unnecessary burden; rather, the use of cross-references to inappropriate regulations creates far worse burdens to the licensees that are unnecessary and unknown. The effort necessary to establish clear and fully appropriate regulations is the minimum requirement of good regulation.

We have cited only a few examples of the conflicts created by the proposed 52.5, 52.19, 52.28, 52.111, 52.215 and 52.249. To fully document the conflicts and ambiguities would require more time than can is available within the allotted period for comments. The examples cited provide ample evidence that the proposed approach is flawed.

Due to the sweeping nature of these proposed changes, the full impact of the changes is not yet well understood by either industry or the NRC, and the proposed changes would lead to a host of unintended consequences that have not been sufficiently considered (and may not be predictable for many years to come). These proposed changes introduce significant uncertainty into the licensing process established under Part 52, and impose unnecessary regulatory burden associated with the confusing and conflicting requirements embodied in this change.

Recommended Action:

In addition to the burdens and uncertainty discussed above, the proposed approach to address the applicability under Part 52 of Part 50 and other NRC requirements is inconsistent with the purpose of Part 52. Part 52 was never intended to be a stand-alone regulatory regime, complete with administrative and technical requirements. Rather, Part 50 and other NRC requirements are to be used as they apply and are technically relevant to Part 52 applicants, holders and licensees. This principle was established in the 1989 Statements of Consideration for Part 52. While the focus in Section II.e, *Applicability of Existing Standards*, is on design certification, the basic principle is the same for all of the licensing processes provided by Part 52. The Commission stated:

> ...the standards set out in 10 CFR Part 20, Part 50 and its appendices, and Parts 73 and 100 will apply to new designs where those standards are technically relevant to the design of the proposed facility. Application of Parts 20, 50, 73 and 100 to the certification of new designs, as reflected in Section 52.48, should go a long way toward establishing the regulatory standard that new designs must meet and thereby provide the regulatory stability that is an essential prerequisite to realizing the benefits of standardization.

Instead of proposed Section 52.5, we recommend the following provision consistent with the principle established by the Commission in the 1989 rulemaking:

Section 52.5 – Applicability of NRC requirements.

> **Unless otherwise specifically provided for in this part, a licensee, holder of, or applicant for an approval, certification, permit, site report, or license issued under this part shall comply with all requirements in 10 CFR Chapter I as they apply and are technically relevant to the particular licensing action.**

This general provision, or equivalent, would obviate the need for process-specific Sections 52.19, 52.111, 52.215 and 52.249. We do envision that the Section 52.215 requirement for COL holders to comply, after the Section 52.231(g) finding, with requirements applicable to holders of operating licenses would be established in a license condition of the COL.

Adopting this or an equivalent provision would efficiently address the issue of applicability of Part 50 and other regulations, as well as the NRC staff concern that developing general provisions tailored for the various Part 52 processes would be too burdensome.

Coupled with this approach, we recommend that the NRC engage stakeholders to develop guidance that clarifies the implementation of the alternative Section 52.5 proposed above. For example, such guidance would make clear that requirements applicable to licensees would generally not be applicable to design certification applicants. It should be noted that we do not believe the problems created by the approach reflected in the proposed rule can be similarly solved by guidance because guidance cannot be used to modify a regulation.

If the NRC does not adopt the above approach, we strongly recommend that the portions of this rulemaking that address the applicability of Part 50 and other regulations be deleted so that the balance of this important rulemaking may go forward. As the balance of this rulemaking goes forward, we urge the NRC staff to engage stakeholders in a full consideration of the impacts of the sweeping approach proposed in the NOPR to address the applicability of Part 50 and other NRC requirements, and to consider alternatives to it. The outcome of those stakeholder interactions could be implemented via direct final rulemaking after the current lessons learned rulemaking on Part 52 is completed.

Issue 2 – NRC ITAAC Verification (10 CFR 52.229)

Comment:

As described in NEI's July 12, 2002, letter to the Commission, *Federal Register* notifications of successful ITAAC completion required by Section 52.229 are a central element in the NRC staff ITAAC verification process and thus to the workability of the overall Part 52 ITAAC process.

ITAAC requirements are clearly laid out in the design certification rules (Section IX of Appendices A, B and C). All of these rulemakings were conducted several years after the original Part 52 rulemaking, reflecting the need to clarify the existing requirements on ITAAC that are in the present Part 52. However, the NOPR's proposed language only partially adopts the wording of Section IX of the current design certification rules for the three certified designs. In particular, it omits the sentence in Section IX which states, *"[T]he NRC staff shall verify that the inspections, tests, and analyses referenced by the licensee have been successfully completed and, based solely thereon, find the prescribed acceptance criteria have been met."* This sentence provides vital clarification

and amplification of the existing provision in 10 CFR 52.99 that states that the NRC staff "shall find that the prescribed acceptance criteria are met."

Section 52.229(e) should use the same language as the design certification rules. Use of differing language is likely to lead to confusion and the potential for conflict. Furthermore, omission of the sentence in question could lead to substantial uncertainty regarding the intent and scope of the ITAAC, and therefore would be contrary to the intent of Part 52.

Clarity on this point and conformance with the design certification rules is critically important to the workability of the ITAAC process and thus to Part 52 overall. Affirming the requirement that NRC staff determinations on ITAAC matters are to be made and documented as the information necessary to support them becomes available is important to ensure a stable, predictable and manageable Part 52 ITAAC process. As construction proceeds, periodic sign-offs on completed ITAAC will build public and investor confidence in the quality of construction, as well as in the Part 52 process itself. Without periodic ITAAC sign-offs, there would be no NRC staff conclusions on the satisfaction of ITAAC until all ITAAC are decided at once at the end of construction. Such a process would be a step backward toward Part 50 licensing where little was certain until the plant was fully constructed and the operating license hearing was completed.

While proposed Section 52.229(e) is inadequate, we note that the intent of Part 52 and the Commission is reflected in the staff's draft Construction Inspection Program Framework Document (May 2003). In that document, the staff clearly acknowledges the May 6, 2003, SRM and states that staff intends to publish its determinations on ITAAC acceptability in the *Federal Register.* This is consistent with the direction of the Commission and existing requirements, and should be reflected in the final Part 52 rule.

Recommended Action:

Subsequent to the original Part 52 rulemaking in 1989, in connection with the design certification rulemakings, the industry and NRC had extensive discussions regarding the NRC staff ITAAC verification process. As a result of those interactions, the final design certification rules each contain ITAAC provisions (Section IX.B.1) that deal explicitly with the nature of NRC staff ITAAC verification and sign-offs. With one slight change to avoid confusion with the Commission's ITAAC finding under Section 52.103(g), we recommend that Section 52.229(e) be conformed to match the language established in the design certification rules, as indicated below. Doing so ensures that the Commission intent regarding NRC staff ITAAC sign-offs is uniformly reflected throughout Part 52, including current and future design certification appendices.

> *"The NRC staff shall ensure that the required inspections, tests, and analyses in the ITAAC are performed and, prior to operation of the facility, shall conclude that the prescribed acceptance criteria are met. The NRC staff shall verify that the inspections, tests, and analyses referenced by the licensee have been successfully completed and, based solely thereon, ~~find~~ **conclude** the prescribed acceptance criteria have been met.*

> *At appropriate intervals during construction, the NRC shall publish notices of the successful completion of ITAAC in the Federal Register."*

We further recommend that Section IX.B.1 of the DCRs be modified as indicated above to match Section 52.229(e) and avoid confusion with the Commission's ITAAC finding. NEI believes that its proposed language is consistent with the historical intent of 10 CFR Part 52, the existing provisions in the design certification rules, and the directions of the Commission in the SRM.

Issue 3 – Vendor Design Change Process

Comment:

Section IV. *Specific Requests for Comments*, Item 6, poses the following question:

> *"Should the final rule include a revision to the current Sec. 52.63 (proposed Sec. 52.127) to allow the original design certification applicant to petition the Commission for rulemaking to amend the design certification rule to incorporate ``beneficial changes," including improvements in safety, and/or design changes that would ``significantly improve efficiency, reliability and economics." Refer to letters from Steven A. Hucik, GE Nuclear Energy (March 30, 2002) and Ronald L. Simard, Nuclear Energy Institute (March 22, 2002)."*

The industry continues to support the incorporation of a vendor change process into 10 CFR Part 52. Experience with previously certified designs indicates a need for a process by which the design certification applicant can request the NRC to amend a design certification. This is driven by the need for economic competitiveness and the desire to reflect increases in design maturity that occur after design certifications are completed. A 10 CFR Part 52 design change process would allow for the realization of the benefits of continued first-of-a-kind-engineering that may occur after Design Certification has been granted. Such a process would allow for the improvement of a certified design by improving design completeness and by incorporating improvements in technology.

Such a process is consistent with that provided under Subpart L of Part 72 which provides the requirements for spent fuel storage casks certified by the NRC. Upon NRC approval of the spent fuel cask design, the applicant is granted a Certificate of Compliance (CoC) in accordance with the provisions of § 72.238 and the CoC is incorporated into the list of approved cask designs contained in § 72.214. Part 72 includes provisions in § 72.244 for CoC holders to apply for an amendment to the CoC. Specifically, § 72.244 states the following:

> *Whenever a certificate holder desires to amend the CoC (including a change to the terms, conditions or specifications of the CoC), an application for an amendment shall be filed with the Commission fully describing the changes desired and the reasons for such changes, and following as far as applicable the form prescribed for original applications.*

The NRC requirements for issuance of amendments to CoCs are contained in § 72.246 which states:

> *In determining whether an amendment to a CoC will be issued to the applicant, the Commission will be guided by the considerations that govern the issuance of an initial CoC.*

Based on similarities associated with use of standard certified designs for power reactors in accordance with Part 52 and NRC-approved certified cask designs for storage of spent fuel in accordance with Part 72, it is reasonable that similar provisions be provided for amending certified designs in both Part 52 and Part 72.

Currently, Part 52 allows plant-specific changes in a certified design to be made by the COL applicant in individual licensing proceedings (through the "50.59-like" process and by requesting NRC approval of the more significant changes). However, this process introduces unwanted uncertainty and economic risks for the COL applicant, and a vendor design change process would provide more certainty earlier in the licensing process. Additionally, Part 52 allows the design certification applicant to apply for a new design certification that incorporates the changes. However, given the cost of a new design certification, this method is not commercially viable for making the kinds of changes envisioned under this proposal. The following are several examples of the types of beneficial design changes that could be applied to the certified ABWR under a vendor change process envisioned by the industry.

Item	Design feature	DCD		Type	Benefit by the change
		Tier1	Tier2		
Control Rod Drive	Apply Seal-less Fine Motion Control Rod Drive with magnetic coupling	X	X	Apply latest technology	Maintainability and Reliability
Thermal power	Power uprate by measurement uncertainty recapture	X	X	Apply revised rule	Economics
Fuel Type	Adopt 10X10 fuel instead of 8X8 fuel		Tier2*	Apply latest technology	Improve efficiency
Seismic Analysis Condition	Apply analysis of hard rock site		X	Change of design condition	Economics
Fire Protection	Add assessment against NFPA804		X	Apply new codes	Reduce license burden
Solid Waste Management system	Deleting incinerator for dry combustible waste		X	Design change	Improve environmental impact

We recommend that the NRC revise Part 52 to allow the design certification applicant to request the NRC to amend a design certification through rulemaking. Such a process will reduce the unnecessary regulatory burdens associated with the existing change

processes in Part 52, without impacting safety. Additionally, such a change process would provide the NRC with full authority to review and approve all generic changes, while preserving the rights of the public to participate in the rulemaking that approves the changes.

Recommended Action:

Modify existing Section 10 CFR 52.63 (proposed Section 52.127) as follows.

(a)(1) Notwithstanding any provision in 10 CFR 50.109 **and except as provided in paragraph (d) of this section**, while a standard design certification is in effect under § 52.55 or 52.61, the Commission may not modify, rescind, or impose new requirements on the certification, whether on its own motion, or in response to a petition from any person, unless the Commission determines in a rulemaking that a modification is necessary either to bring the certification or the referencing plants into 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. The rulemaking procedures must provide for notice and comment and an opportunity for the party which applied for the certification to request an informal hearing which uses the procedures described in § 52.51 of this subpart.

...

d) **The applicant for the standard design certification issued under this Subpart may file a request for an amendment to the design certification by way of notice and comment rulemaking. The Commission shall grant the amendment request if it determines that the amendment will comply with the Atomic Energy Act and the Commission's regulations in effect at the time of the amendment. If the amendment request entails such an extensive change to the design certification that an essentially new standard design is being proposed, an application for a design certification shall be filed in accordance with § 52.45 and 52.47 of this part. The amendment will apply to construction permits or combined licenses that reference the standard design certification and that are issued after the effective date of the amendment.**

Issue 4 – Requirements for Prototype Plants (52.211)(b)(1)

Comment:

Proposed 10 CFR 52.211 would add a requirement that the same testing that would be required for a design certification applicant must be performed by a COL applicant that seeks a license for a non-evolutionary custom plant. The proposed rule would require either (A) analysis, testing or experience, or (B) full-scale prototype testing. Additionally, the Commission has stated that, for design certification of advanced reactors, it favors the use of a full-scale prototype in lieu of the other alternatives. (51 Fed. Reg. 24643)

As discussed in our previous letter (R. Simard, November 13, 2001), we believe it is unnecessary to apply these requirements to COL applicants, and that the

potential requirement for a full-scale prototype testing is particularly inappropriate. NEI renews our objections to the proposed 52.211 on the same basis as was previously articulated.

The fact that the current §52.79 does not reference the prototype testing requirements in Section 52.47(b)(2)(i) was no mere oversight - - it was intentional. The Statements of Consideration for both the proposed 10 CFR Part 52 (i.e., 53 Fed. Reg. 32060, August 23, 1988) and the final 10 CFR Part 52 (i.e., 54 Fed. Reg. 15372, April 18, 1989) clearly indicate that design certification and licenses are to be treated differently with respect to prototype testing. Note that these references are more recent than the 51 FR 24646 (July 8, 1986) utilized in the NRC's justification for retaining this proposed requirement. For example, in issuing the proposed (1988) and final (1989) versions of 10 CFR Part 52, the Commission stated the following:

- "Certification of a reactor design which differs significantly from a reactor design which has been built and operated may be granted only after the design has been shown to be sufficiently mature." (53 Fed. Reg. at 32063-64)

- In order to demonstrate maturity, "prototype testing is likely to be required for certification of advanced non-light water designs." (54 Fed. Reg. at 15375)

- In contrast, the NRC recognized that it may "license the prototype for commercial operation." (54 Fed. Reg. at 15374)

- Furthermore, the NRC expressly rejected a proposal that would allow a Combined License to be issued only for a standard design, stating: "The final rule does not contain this restriction because there may be circumstances in which a combined license would properly utilize a non-standard design and because such a restriction would mean, among other things, that every prototype would have to be licensed in a fully two-step process." (54 Fed. Reg. at 15383)

- Thus, "[i]t is well to remember also that, under the rule, prototype testing is only required for certification or an unconditional final design approval, if at all." (54 Fed. Reg. at 15374).

Additionally, the original Commission policy statement on Regulation of Advanced Nuclear Power Plants (51 FR 24643, July 8, 1986) clearly indicated the intent of the revised licensing process was to minimize complexity and uncertainty in the licensing process. The addition of a prototype plant testing requirement neither minimizes the complexity nor the uncertainty, but rather adds to the uncertainty by adding a significant additional step (currently representing an unknown quantity) prior to the licensing of a plant of a new design. Moreover, exercising the proposed COL requirement for prototype testing would create a logical disconnect. Absent a license, a prototype commercial plant cannot be built in the United States. However, under the proposed rule, absent construction of a prototype, the design could not be licensed. This "Catch-22"

situation would effectively close an important path for bringing to market nuclear plant designs with innovative safety features. For these reasons, it would be inappropriate to establish or impose § 52.47(b)(2)(i)(B) (prototype testing) on COL applicants.

The Commission has stated that prototype testing will likely be required for design certification of advanced reactors. However, there are significant differences between certified and custom designs. A certified design is effective for 15 years, may be incorporated by reference by any license applicant without further review and approval by the NRC, and is subject to broad protection against backfits under the change control process in 10 CFR 52.63 (proposed §52.127).

In contrast, the arguments for prototype testing for *certification* of advanced reactors do not apply to *licensing* of advanced reactors. Unlike a design certification, licensing represents approval of only a single facility. Licensing of subsequent facilities, even if identical in design, is still subject to NRC review and approval including possible design changes to account for any unfavorable results of startup and power ascension testing and operating experience from previously licensed facilities. Furthermore, unlike a design certification, the NRC has fairly broad authority under 10 CFR 50.109, "Backfitting," to impose backfits on a licensed facility to account for any unfavorable results of startup and power ascension testing and operating experience. Finally, in lieu of prototype testing, the NRC has authority to impose special license conditions that might not be necessary or appropriate if applied to all plants with a standard design (e.g., a license condition can require special design, procedural, or testing provisions to provide adequate protection of safety until the design is demonstrated to be safe through testing or operation). Therefore, there is no compelling reason for a full-scale prototype test facility prior to prior to licensing of an advanced reactor.

In addition, it is simply unnecessary to impose on COL applicants the requirements of § 52.47(b)(2)(i)(A) to demonstrate safety features via analysis, testing and/or experience. This is because the COL applicant is already subject to 10 CFR 50.34(b)(4) requirements to provide sufficient information of this type to support the required NRC safety determination on the design. Additionally, at COL issuance, the NRC has authority to establish license conditions, including conditions on successful demonstration of unique design features.

NRC guidance and past precedent both indicate that a full-scale prototype testing facility need not precede licensing of a new type of reactor. For example, NRC Regulatory Guide 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants - LWR Edition" which provides the standard format and content for safety analysis reports, explicitly states that special, unique, or first of a kind design features may be verified through startup test.

> "14.1.2 Plant Design Features That Are Special, Unique, or First of a Kind
>
> A summary description of preoperational and/or startup testing planned for each unique or first-of-a-kind principal design feature should be included in the PSAR [Preliminary

> Safety Analysis Report]. The summary test descriptions should include the test method and test objectives."

Similarly, NUREG-0800, "Standard Review Plan" Section 14.2, Paragraph III.8 recognizes that the initial test program in Final Safety Analysis Reports may include provisions for "testing for special, unique, or first-of-a-kind design features." Thus, NRC guidance clearly allows for testing of unique and first-of-a-kind design features through the startup and power ascension test program, and does not require prototype testing prior to issuance of a license for a plant involving such features.

Recommended Action:

Part 52 need not be modified to reference the testing and analysis requirements for design certification of an advanced reactor. reference the testing and analysis requirements for design certification of an advanced reactor. Through its existing requirements and regulatory authority, the NRC is assured of (1) adequate information to support required COL reviews and safety determinations, and (2) satisfactory demonstration of innovative design features during startup and power ascension testing. The proposed new COL application requirements are unnecessary and should not be included in 10 CFR Part 52.

Issue 5 – Format for 10 CFR Part 52

Comment:

The NRC has proposed to reorganize 10 CFR Part 52 to establish a separate subpart for each of the seven licensing processes currently described in 10 CFR Part 52. The purpose for this change is to show that all of the processes in the subparts have equal standing. The proposed reorganization would result in numerous changes in existing section numbers.

We are concerned that this proposed format change would introduce administrative burdens. Numerous existing documents reference the original Part 52 section numbers, including the Design Control Documents and statement of considerations for the three existing certified designs. If these documents are not changed, it will introduce the potential for confusion since the section numbers referenced in these documents would not correspond to the section numbers in the revised rule.

In the alternative, these documents would need to be revised to reference the new section numbers. Such revisions would introduce unnecessary administrative burden that we believe can be avoided. For example, it would not be a good use of NRC or industry resources to engage in rulemaking to revise the existing DCDs to reference new section numbers in Part 52. Also, the NRC's proposed numbering system would make it difficult for NRC and stakeholders to refer to and use numerous existing documents that provide historical perspective on the objectives of Part 52 and resolution of key policy and process issues consistent with those objectives.

Recommended Action:

We propose an alternative approach to reformatting the rule. The alternative would accomplish the goal of moving Appendices M, N, O and Q into the body of Part 52 while avoiding the potential for confusion and undue administrative burden. The alternative approach is to include the appendices M, N, O and Q in the body of Part 52 as separate Subparts D, E, F and G. This would accomplish the stated intent of providing equal standing to all of the processes covered by Part 52, while preserving the original basic numbering system of the current Subparts A, B and C, which has been previously referenced in numerous documents.

Issue 6 – Lessons Learned from the Pilot Early Site Permit Applications

Comment:

Based on experience with the pilot ESP applications, modification of proposed Section 52.17(a)(1) is needed to 1) reflect the acceptability of using bounding design parameters in lieu of actual facility information (i.e., the plant parameters envelope (PPE) approach) and 2) clarify the nature of dose consequence analyses that are to be provided as part of ESP applications.

While the industry and the NRC staff generally agree on the acceptability of the PPE approach for ESP applicants who have not selected a specific design for their site, proposed Section 52.17(a)(1) does not adequately reflect this ESP option. For example, the proposal to clarify that an ESP application should describe "the specific number, type and thermal power level of the facilities or range of possible facilities, for which the site may be used" is not consistent with understandings reached concerning the PPE approach. Under the PPE approach, an ESP applicant does not seek approval of the site for a range of possible facilities; rather, bounding design information is used as a surrogate for actual facility information to support the ESP review and approval is sought for a reactor or reactors that fall within the site characteristics specified in the ESP. Alternative rule language is recommended below that explicitly provides that ESP applications may based on bounding design parameters if the PPE approach is used.

Depending on the approach selected by an ESP applicant, the radiological consequence analyses that can meaningfully be performed and provided for NRC review are different. ESP applications based on a specific design may[1] present complete radiological consequence analyses that demonstrate Part 100 radiological dose criteria are met for the proposed site/design combination. If the ESP applicant has not selected a specific

[1] Section 52.17(a)(1) should not require complete radiological consequence analyses even for applicants that seek approval of the site for a specific facility because the specified facility may not be a certified design, If the ESP application is based on a specific, non-certified design, the design-specific information necessary for complete radiological consequence analyses may not yet be available. NRC review and approval of accident sequences, release histories and related design-specific information would be expected in a design certification or combined license proceeding, not in an ESP proceeding.

design, complete radiological consequence analyses, which require knowledge of design-specific accident sequences, release histories, etc., cannot be meaningfully accomplished. Instead, the focus for these ESP applicants should be on the site-related aspects of radiological consequence analyses, i.e., determination of site atmospheric dispersion characteristics.

Section 52.17(a)(1) does not require complete radiological consequence analyses for ESP but does clearly state that site characteristics comply with Part 100. Thus, as described in our analysis of this issue contained in a letter to NRC dated December 20, 2002, we conclude that providing complete dose consequence analyses is not necessary for compliance with Section 52.17(a)(1). The NRC staff identified during recent pilot ESP interactions that it does not agree with the industry interpretation and interprets Section 52.17(a)(1) to require complete radiological consequence analyses in all cases. The recommended rule language below is proposed to clarify and resolve this issue.

The determination that Part 100 radiological dose consequence criteria are met can only be made when both the site and design are known and interface issues can be evaluated. The pilot ESP applicants are using the PPE approach and have not specified a particular design as the basis for their applications. Thus the radiological consequence analyses that the pilot ESP applicants have been requested by the staff to provide will be based on generalized design information and will not yield a meaningful finding; design-specific analyses will be required to be submitted in any combined license application referencing the pilot ESPs.

For an ESP application, the acceptability of the site with respect to Part 100 radiological dose consequence criteria and compliance with Section 52.17(a)(1) is dependent on the site characteristic atmospheric dispersion factors (X/Q), including any assumptions related to the structures, systems and components (SSCs) that bear significantly on the calculation of X/Q such as elevated release point, and building locations associated with assumed wake effects. At COL, the site X/Q is combined with the release history information provided in a design certification, or approved during the COL review of an uncertified design, to determine whether Part 100 requirements are met for the site/design combination.

As stated in its February 5, 2003, letter to NEI, the staff disagrees with the industry perspective and interprets Section 52.17(a)(1) to require complete radiological consequence analyses to be prepared by all ESP applicants, reviewed by the NRC and subject to public hearing. We believe the primary reasons cited by the staff for coming to this conclusion are flawed. In particular, the staff concludes that all ESP applicants must demonstrate compliance with the radiological consequence criteria in Part 100. As discussed above, this is not possible if a specific facility is not proposed, and in any event, is not required. Section 52.17(a)(1) clearly requires only that site characteristics comply with Part 100. We interpret this language to permit a focus for ESP on site characteristics that bear significantly on the acceptability of the site, namely the site atmospheric dispersion characteristics (X/Q). In its February 5 letter and in SECY-03-0105, the staff indicates that evaluation of the acceptability of the site with respect to Part 100 dose criteria as envisioned by the industry cannot be divorced from design considerations because determination of X/Q depends on factors such as release elevation, building wake effects and distance to the site boundary. As we have identified to the staff, ESP applicants lacking design-specific information would use conservative

assumptions for design dependent factors to permit calculation of X/Q. In fact, Regulatory Guide 1.145 requires a ground-level release with no credit for building wake effects to be conservatively assumed when calculating X/Q.

The fact that ESP applicants who do not specify the design to be built can select generalized design parameters that, when combined with the site X/Qs, show that Part 100 radiological consequence criteria are met does not mean that such analyses should be provided in ESP applications. At best, such generalized analyses show that Part 100 can be met, not that Part 100 is met.

Moreover, requiring analyses to be developed for ESP, reviewed by the NRC and subject to public hearing that are not conclusive with respect to Part 100 compliance and thus will be required to re-submitted and re-reviewed at COL imposes unnecessary regulatory burden. It would waste scarce applicant and NRC resources and is inconsistent with the need to focus on matters that will be resolved with finality in the ESP.

We note that at its March 7, 2003 meeting, the ACRS indicated strong support for this view, in particular that radiological dose consequence analyses in the absence of a specific design would not be meaningful and should not be required of ESP applicants.

Recommended Action:

NEI recommends the following changes to Section 52.17(a)(1):

§ 52.17(a)(1) The application must contain the information required by § 50.33 (a) through (d), the information required by § 50.34 (a)(12) and (b)(10), and to the extent approval of emergency plans is sought under paragraph (b)(2)(ii) of this section, the information required by § 50.33 (g) and (j), and § 50.34 (b)(6)(v) of this chapter. The application must also contain a description and safety assessment of the site on which the facility is to be located. The site safety assessment must contain an analysis and evaluation of the ~~structures, systems and components of the facility~~ **site atmospheric dispersion characteristics** that bear significantly on the acceptability of the site under the radiological consequence evaluation factors identified in § 50.34(a)(1) of this chapter. Site characteristics must comply with Part 100 of this chapter. **If the application seeks approval of the site for a specific facility, the application may present the required analyses and request an NRC finding in the early site permit that radiological dose criteria of Part 100 are met for the proposed site – design combination.**

The application should describe the following; **bounding design information may be provided in the case of an application that does not seek approval of the site for a specific facility:**

(i) The ~~specific~~ number, type, and thermal power level of the facilities~~, or range of possible facilities~~,, or range of possible facilities~~,~~ for which the site may be used;
(ii) The boundaries of the site;
(iii) The proposed general location of each facility on the site;
(iv) The anticipated maximum levels of radiological and thermal effluents each facility will produce;

(v) The type of cooling systems, intakes, and outflows that may be associated with each facility;
(vi) The seismic, meteorological, hydrologic, and geologic characteristics of the proposed site;
(vii) The location and description of any nearby industrial, military, or transportation facilities and routes; and
(viii) The existing and projected future population profile of the area surrounding the site.

We further recommend that proposed 52.211(a)(1)(i) be modified as follows:

(a) Early site permit
(1) If the application references an early site permit, the application need not contain information or analyses submitted to the Commission in connection with the early site permit, but must contain, in addition to the information or analyses otherwise required:
(i) Information sufficient to demonstrate that the design of the facility falls within the site **characteristics** specified in the early site permit and that the requirements of Part 100 are met, **unless this information was approved in connection with the early site permit**.

Issue 7 – Update of Emergency Planning Information Approved in an ESP

Comment:

Proposed Section 52.39(b) would require that an applicant for a construction permit, operating license, duplicate license or combined license who has filed an application referencing an ESP shall update and correct the emergency planning information that was provided under §52.17(b). The applicant would be required to discuss whether the new information materially changes the bases for compliance with the applicable requirements. New information which materially changes the bases for the Commission's determination on the matters in §52.17(b) would be subject to litigation during the licensing proceeding in the same manner as other issues material to those proceedings.

The purpose of the ESP is to provide licensing stability. To achieve that stability, NRC regulations stipulate that while the ESP is in effect, the Commission may not change or impose new requirements, including emergency planning requirements, unless it determines that a modification is necessary either to bring the permit or the site into compliance with the Commission's regulations and orders applicable and in effect at the time the permit was issued, or to assure adequate protection of the public health and safety or the common defense and security. We object to the NRC staff proposal because it would significantly erode the finality of emergency planning information approved in the ESP that is explicitly intended by Section 52.39(a).

During the term of a license, a licensee is allowed per Section 50.54(q) to change the emergency plans without Commission approval if the changes do not decrease the effectiveness of the plans, and the plans, as changed, continue to meet the requirements of Appendix E to Part 50. Just as Section 50.54(q) is appropriate for

control of changes to emergency plans approved in a license, the "decreased effectiveness" standard is the proper standard for determining when updates to emergency planning information approved in the ESP should be subject to NRC review and litigation in the licensing proceeding. Provided the applicant evaluations are performed and demonstrate that updates or modifications to the emergency planning information approved in the ESP do not decrease the effectiveness of the plans, the information approved in the ESP, and updates and modifications thereto, should be considered resolved within the meaning of Section 52.39(a). Summaries of the updates and modifications to the information approved in the ESP would be provided in the application, and the applicant's complete evaluations would be available for NRC inspection. Changes to emergency planning information approved in the ESP that decrease the effectiveness of the plans, and any new emergency planning information provided for in the application, would be subject to NRC review and hearing.

The proposal to subject to litigation new information that "materially changes the bases" for the approval of emergency planning information in the ESP would result in the re-review and re-litigation of many changes that do not decrease the effectiveness of emergency plans, and even those that enhance effectiveness of plans. Such a standard would undermine the regulatory stability provided by the ESP.

Recommended Action:

The following alternative language is recommended for the final rule concerning the update of emergency planning information approved in the ESP:

Proposed Section 52.39(b)

An applicant for a construction permit, operating license, duplicate design license, or combined license who has filed an application referencing an early site permit issued under this subpart shall update and identify changes to ~~correct~~ the information that was provided under § 52.17(b), including a summary of the evaluation of each. Changes determined to decrease the effectiveness of emergency plans approved in the ESP, and any new emergency planning information provided in the application, are subject to NRC review and approval and ~~discuss whether the new information materially changes the bases for compliance with the applicable requirements. New information which materially changes the bases for the Commission's determination on the matters in § 52.17(b)~~ must be subject to litigation during the construction permit, operating license, duplicate design license, or combined license proceeding in the same manner as other issues material to those proceedings.

Proposed Section 52.211(d)(1)

If the application references an early site permit, the application may incorporate by reference emergency plans, or major features of emergency plans, approved in connection with the issuance of the permit. If the application incorporates by reference an emergency plan or major features of such a plan, the application must include information that updates and identifies changes to ~~correct~~ the information that was provided under § 52.17(b), including a summary of the evaluation of each. Changes

determined to decrease the effectiveness of emergency plans approved in the ESP, and any new emergency planning information provided in the application, are subject to NRC review and approval and ~~corrects the information previously provided under § 52.17(b), and discuss whether the new information materially changes the bases for compliance with the applicable requirements. New information that materially changes the bases for the Commission's determination on the matters in § 52.17(b)~~ must be subject to litigation during the combined license proceeding in the same manner as other issues material to those proceedings.

Enclosure 2 – Industry Responses to Section IV Questions
Part 52 Notice of Proposed Rulemaking

Section IV *Specific Request for Comments* posed questions on seven topics. This enclosure provides the industry responses to those specific requests.

1. *Should the final rule include an updating requirement for other than emergency preparedness information and what portions of the early site permit (ESP) should be subject to the updating requirement? Also, if an updating requirement is adopted, in what manner could an interested person challenge the updated information? (refer to Sec. 52.39(a))*

   Response: No additional update requirements for ESP information are necessary or appropriate beyond an appropriate requirement on COL applicants to update the emergency planning (EP) information approved in any referenced ESP. (See Enclosure 1, Issue 7, for discussion of the alternative approach proposed by the industry regarding an appropriate EP update requirement.)

   Regarding information other than EP information, we agree with the rationale presented by the NRC staff on page 40032 of the NOPR Supplementary Information: "An updating requirement for ESP information other than EP information does not appear to be necessary, inasmuch as it is unlikely that there would be changes to the information previously submitted on the site, such that a significant change to the site characteristics, terms, and conditions would be necessary if requested under the provisions of Sec. 52.39(a)(2).

   If an updating requirement is adopted, and if the site does not conform to the characteristics of the ESP, we again agree with the NOPR Supplementary Information that, "[A]n interested person may submit a petition under Sec. 52.39(a)(2)(ii) alleging that the site does not conform to the ESP." Accordingly, the proposed rule does not include an updating requirement for other ESP information."

2.1 *Should the final rule include revisions to 10 CFR Part 52 to distinguish between site characteristics, site parameters, design characteristics, and design parameters?*

   Response: Yes. The need to clarify and ensure consistent use of these terms throughout Part 52 became evident during industry – NRC interactions regarding the pilot ESP applications. In particular, we recommend two of these terms, "site parameters" and "site characteristics," be defined in Section 52.3 as follows:

- "Site parameters" are the postulated physical, environmental and demographic features of a generalized site assumed for and established in a design certification. A COL application referencing a certified design must contain information demonstrating compliance with the site parameters.

- "Site characteristics" are the actual physical, environmental and demographic features of a site. Site characteristics are specified in an early site permit, and a COL application referencing an early site permit must contain sufficient information to demonstrate that the design of the facility falls within the specified site characteristics.

Consistent with these definitions, the proposed Part 52 rule language should be modified as follows:

Affected Section	Recommended Change
52.17(a)(2)	A complete environmental report as required by 10 CFR 51.45 and 51.50 must be included in the application, provided, however, that such environmental report must focus on the environmental effects of construction and operation of a reactor, or reactors, which have characteristics that fall within the characteristics of the site ~~parameters~~, and provided further that ....
52.18	In addition, the Commission shall prepare an environmental impact statement during review of the application, in accordance with the applicable provisions of 10 CFR Part 51, provided, however, that the draft and final environmental impact statements prepared by the Commission focus on the environmental effects of construction and operation of a reactor, or reactors, which have characteristics that fall within the characteristics of the site ~~parameters~~, and provided further that ....
52.21	In the hearing, the presiding officer shall also determine whether, taking into consideration the site criteria contained in 10 CFR Part 100, a reactor, or reactors, having characteristics that fall within the characteristics of ~~parameters for~~ the site can be constructed and operated without undue risk to the health and safety of the public.
52.24	The early site permit shall specify the site characteristics ~~parameters~~ and the terms and conditions of the early site permit.

52.39(a)(2)	... the Commission shall treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the early site permit (with the exception of the matters in paragraph (b) of this section), unless a contention is admitted that a nuclear reactor does not fit within one or more of the site characteristics ~~parameters~~ in the early site permit, or a petition is filed which alleges either that the site does not conform to the site characteristics in the early site permit, or that the terms and conditions of the early site permit should be modified.
52.39(a)(2)(i)	A contention that a nuclear reactor does not fit within one or more of the site characteristics ~~parameters~~ included in the early site permit may be litigated in the same manner as other issues material to the proceeding.
52.211(a)(1)(i)	Information sufficient to demonstrate that the design of the facility falls within the site characteristics ~~parameters~~ specified in the early site permit;
52.221	If the application references an early site permit and/or a design certification rule, the environmental review must focus on whether the design of the facility falls within the site characteristics ~~parameters~~ specified in the early site permit and any other significant environmental issue not considered in any previous proceeding on the site or the design.
DCR III.E	Design activities for structures, systems, and components that are wholly outside the scope of this appendix may be performed using site-specific characteristics ~~design parameters~~, provided the design activities do not affect the DCD or conflict with the interface requirements.

We note that the discussion accompanying Question #2 on page 40039 indicates that the items identified in Section 52.17(a)(1)(i)-(viii) "appear to be site parameters as [that term] is used in the current rule." Actually, these items are a mixture of site characteristics and design information.

2.2 *Should the final rule include revisions to 10 CFR Part 52 to require the Commission to specify the site characteristics and design parameters when issuing early site permits?*

Response: No. ESPs should specify site characteristics and terms and conditions of the ESP, but not design parameters. This is consistent with the proposed change to Section 52.39(a)(1). However, Sections 52.24, 52.39(a)(2), 52.39(a)(2)(i), 52.211(a)(1)(i) and 52.221 need to be modified as indicated above to properly reflect the information to be specified in ESPs.

Design parameters should not be specified in ESPs for the following reasons:

- Not all ESP applications will contain design parameters; only ESP applications based on the plant parameters envelope (PPE) approach will identify design parameters.

- Under the PPE approach, bounding design parameters are used as a surrogate for actual design information primarily to support environmental review of the ESP application. Bounding design parameters are used to demonstrate and determine the suitability of the proposed site for an unspecified future reactor or reactors. As such, and as recognized by the NRC staff in its letter to NEI dated February 5, 2003, bounding design parameters do not correspond to any specific design and will not be reviewed by the NRC for correctness. The non-specific and unreviewed nature of design parameters used under the PPE approach makes them qualitatively different from site characteristics and inappropriate specify in the ESP.

- Bounding design parameters used in the ESP application and review are independent of the site itself and thus should not be specified in the ESP.

- A COL applicant must either demonstrate compliance with the site characteristics specified in the ESP, or seek approval for deviation from them. Thus it is appropriate to specify site characteristics in the ESP. This is not the case for the bounding design parameters of the PPE. The design proposed by a COL applicant may deviate from the PPE provided that the site characteristics, terms and conditions of the ESP are satisfied. If the deviation from the PPE constitutes a significant new environmental issue with respect to the site, Section 52.211(a)(1)(ii) requires that the COL application must also include information necessary to resolve that issue.

- Bounding design parameters will be identified in the ESP application and presumably in the NRC's Safety Evaluation Report and/or Environmental Impact Statement. Thus this information will be readily available to support COL applicant demonstration that a proposed facility falls within the design parameters used to evaluate environmental impacts.

2.3 *Should the final rule include revisions to 10 CFR Part 52 to require the design certification rule to specify the site parameters and design characteristics for the design?*

Response: No. Characteristics of the standard design and postulated site parameters for the design are already required to be identified in a design

certification application by proposed Section 52.107(a)(1). This information is contained in the generic DCD and thus becomes part of the design certification rule. No change to Part 52 is necessary or appropriate in this regard.

2.4 *Should the final rule include revisions to 10 CFR Part 52 to require a combined license applicant referencing an early site permit to demonstrate that either the design of the nuclear power plant or the site parameters and design characteristics of a referenced design certification rule fall within the design parameters and site characteristics of the early site permit?*

Response: No changes to Part 52 are necessary or appropriate in this regard, except for the clarification to Section 52.211(a)(1)(i) identified above in response to Question 2.1. A COL applicant referencing an early site permit must provide sufficient information to demonstrate that the design of the facility falls within the site characteristics specified in the early site permit. As discussed in response to Question 2.2, ESPs will not specify design parameters, and so there will be no comparison with design parameters at COL. If a design certification is also referenced, the COL applicant must also provide information demonstrating compliance with the site parameters postulated for the design.

2.5 *Should the final rule include revisions to 10 CFR Part 52 to require a combined license applicant referencing a design certification rule to demonstrate that the site parameters and design characteristics of the design certification rule fall within either: (i) The site characteristics of a site, or (ii) the site characteristics and design parameters of a referenced early site permit?*

Response: No changes to Part 52 are necessary or appropriate in this regard. As discussed above in response to Questions 2.2 and 2.4, ESPs will not specify design parameters, and so there will be no comparison with design parameters at COL. A COL applicant referencing a design certification rule will be required to demonstrate that the design of the facility falls within the characteristics of the site, which may be specified in a referenced early site permit.

3. *Are there terms and conditions for an ESP that can only be fulfilled after issuance of the referencing combined license, such that "have been met" should be changed to "will be met," or "have been and will be met"? (refer to proposed Sec. 52.211(a)(1))*

Response: This question is difficult to answer because the staff has not yet identified the terms and conditions it envisions would be attached to an ESP. However, we believe that, yes, there may be terms and conditions for an ESP that can only be fulfilled after issuance of the referencing combined license. For

example, one ESP condition that the NRC has envisioned so far would require the reporting to NRC of any information the ESP holder identifies as having a significant implication for public health and safety. Because sub-surface investigations that might reveal such information may not take place until after a COL is granted, such a condition is one of a continuing nature that cannot be satisfied beforehand.

We recommend that proposed 52.211(a)(1)(iii) be revised to state that COL applications referencing an ESP must contain "[A] demonstration that all terms and conditions of the ESP have been satisfied or that there is reasonable assurance that all terms and conditions will be satisfied during the term of the combined license."

4. *Should the final rule include a requirement in Section 50.34(a) for a construction permit application that references an ESP to demonstrate that the design of the facility falls within the site parameters of the ESP? (refer to proposed Section 52.211(a)(1))*

   Response: It would be appropriate to amend Section 50.34(a) to require a construction permit application that references an ESP to demonstrate that the design of the facility falls within the site characteristics of the ESP. Please refer to the distinctions in these terms described in our response to Question 2.1.

5. *Should the final rule include a requirement in 10 CFR Part 50 to perform testing to qualify advanced reactor designs before licensing? The purpose of this testing requirement would be to demonstrate that new or innovative safety features will perform as predicted in an applicant's safety analysis report, that effects of systems interactions have been found acceptable, and to provide sufficient data for analytical code validation, as required by proposed Section 52.107(b) and 52.211(b).*

   Response: No. See Enclosure 1, Issue #4, for discussion.

6. *Should the final rule include a revision to the current Sec. 52.63 (proposed Sec. 52.127) to allow the original design certification applicant to petition the Commission for rulemaking to amend the design certification rule to incorporate "beneficial changes," including improvements in safety, and/or design changes that would "significantly improve efficiency, reliability and economics." Refer to letters from Steven A. Hucik, GE Nuclear Energy (March 30, 2002) and Ronald L. Simard, Nuclear Energy Institute (March 22, 2002).*

Response: Yes. See Enclosure 1, Issue #3, for discussion.

7. *Should 10 CFR Part 21 apply to: (a) A holder of an early site permit, but only after the holder references the permit in a license application, and (b) an applicant/vendor of a design which is the subject of a design certification rule, but only after the design certification rule is first referenced in a license application. In both cases, the Commission believes that there is no reasonable possibility of a ``substantial safety hazard'' until either the early site permit or design certification rule is referenced. The Commission seeks public comment on the Commission's proposed basis for this proposal, and whether there are other factors and policy considerations, either in support of, or in opposition to, the Commission's proposal.*

Response: No to both (a) and (b). However, after a COL is issued, it would be appropriate to apply Part 21 to the COL holder.

It would not be appropriate to apply Part 21 to a holder of an early site permit or a vendor of a certified design referenced in a COL application, since Part 21 and Section 206 of the Energy Reorganization Act applies to "licensees" and vendors/suppliers/contractors of licensees, not to "applicants."

As indicated in §21.2, "Scope," the regulations of Part 21 apply to entities licensed to possess, use, or transfer within the United States radioactive material, or to construct, manufacture, possess, own, operate, or transfer within the United States, any production or utilization facility or fuel storage facility. This language conforms to Section 206 of the Energy Reorganization Act, which applies to "Any individual director, or responsible officer of a firm constructing, owning, operating, or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954 as amended." An applicant for a combined license does not meet this definition. Therefore, the ESP holder or vendor of the certified design referenced in a COL application does not fall within this definition.

We note, however, that it has been the standard practice for a construction permit applicant to specify Part 21 requirements in its procurement contracts for a plant prior to issuance of the construction permit. This is a good practice, since Part 21 is applicable to such contracts once the CP is issued by the NRC (e.g., from a commercial perspective, it is preferable to specify Part 21 in the initial contract rather than to attempt to backfit the contract to specify Part 21 requirements once the CP is issued). We would expect that this good practice will be implemented by COL applicants as well.

Finally, we believe that it would be inappropriate for the NRC to apply Part 21 to the applicant for a design certification. A design certification is a rule, not a license, and the design certification applicant has no proprietary interest in the design certification rule. Therefore, the design certification applicant should have no responsibilities under Part 21. Furthermore, both Part 21 and Section 206 apply to companies that supply basic components for a nuclear plant. The design certification applicant is not supplying any basic components and therefore should not be covered by Part 21. Instead, an actual vendor would be subject to Part 21 once the COL is issued.