August 4, 2003

Dr. Ronald L. Simard
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SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION RESPONSES TO NUCLEAR ENERGY INSTITUTE (NEI) COMMENTS ON DRAFT REVIEW STANDARD (RS)-002, "PROCESSING APPLICATIONS FOR EARLY SITE PERMITS," SECTIONS 15 AND 17.1.1

Dear Dr. Simard:

This letter provides the responses of the U.S. Nuclear Regulatory Commission (NRC) staff to the comments on the subject document provided in your letter to me dated June 13, 2003. Enclosed with this letter are item-by-item NRC staff responses to the comments provided in the enclosure to your letter. The responses reflect the staff's positions on your comments, and they will be addressed as appropriate in the development of the final RS-002 scheduled for completion by the end of 2003.

Regarding the comment in your letter on generic early site permit item 7(ESP-7), the NRC staff sent a response (letter dated June 20, 2003), to your letter dated April 10, 2003. The staff's position continues to be that dose consequence analyses are required to address 10 CFR 52.17(a)(1) and 10 CFR 50.34(a)(1). However, an applicant using a plant parameter envelope (PPE) approach may use plant parameter values as surrogate design inputs to the dose assessments.

With regard to quality assurance (QA), the staff's position on equivalence with Appendix B is unchanged from that documented in our letter to you dated February 3, 2003. While the staff will not write findings solely based on deviations from Appendix B, staff reviewers of an ESP application and staff assigned to inspect an applicant's quality controls need a framework for evaluating QA measures. Appendix B provides the regulatory standard for this purpose. If, as your letter suggests, the quality of an applicant's information is either not in dispute or is readily verifiable even though the applicant's measures are not equivalent to those in Appendix B, the staff review and inspection will confirm that fact.

If you have any questions regarding this letter or the staff's responses to your comments, please contact Mr. Michael L. Scott, Early Site Permit Project Manager, at (301) 415-1421.

Sincerely,

/RA/

James E. Lyons, Program Director
New, Research and Test Reactors Program
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

Project No. 689

Enclosure: As stated

cc w/encl: See next page

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NRC Staff Responses to Comments of the Nuclear Energy Institute on Draft Review Standard RS-002, Sections 15.0 and 17.1.1

NOTE: This document reproduces verbatim the Nuclear Energy Institute (NEI) comments provided by letter dated June 13, 2003. The staff's response follows each NEI comment. All section numbers in the U.S. Nuclear Regulatory Commission (NRC) responses herein refer to sections in RS-002 unless otherwise specified.

1. Section 15.I.2 – After the words "PPE values" in the third and fourth sentences, add the words, "and associated information in the ESP application." To determine site acceptability, the NRC staff will use the PPE in combination with associated information elsewhere in the ESP application.

Staff response: The staff agrees with the comment and will add the suggested words to Section 15.0.

2. Section 15.I.3 – This section is numbered incorrectly.

Staff response: The staff will correct the subsection numbering as noted in the comment.

3. Section 15.I.3 – As is being demonstrated in connection with the pilot ESP applications, the full six-part NRC review of the radiological consequences of potential design basis accidents is not required to support NRC granting of an ESP. The guidance should be revised to reflect that it would be appropriate to perform the full six-part review only if sufficient design information is available and provided in the ESP application, and the ESP applicant requests an NRC determination that the criteria of 10 CFR 50.34(a)(1) are met for the specified combination of site and design.

Staff response: The staff does not agree with the comment. The full six-part NRC review of the radiological consequences of potential design basis accidents as stated in Section 15.I.3 is required for the staff to make a determination regarding the acceptability of the proposed site using the radiological consequence evaluation factors identified in 10 CFR 50.34(a)(1). This requirement is specified in 10 CFR 52.17(a)(1). Additional details on the staff's basis for this position are given in the NRC staff's letter to NEI dated February 5, 2003 on the subject of guidance for satisfying requirements of 10 CFR 52.17(a)(1).

4. Section 15.II, last paragraph – The exposure acceptance criteria specified in 10 CFR 50.34(a)(1) are required to be met at the COL stage. A lower acceptance criterion is not appropriate and should not be applied to ESP applications that do not reference an NRC certified design. Doing so will not provide reasonable assurance that 10 CFR 50.34(a)(1) will be met at COL because meeting the exposure acceptance criteria would remain strongly dependent on the plant design selected for the site. Also, applying a lower acceptance criterion would not be consistent with past NRC practice, e.g., a lower acceptance criterion was not applied during design certification reviews to account for siting uncertainties.

Staff response: While the application of a lower exposure acceptance criterion is consistent with past staff practice in certain licensing actions, the staff will delete the guidance cited in the comment. The staff emphasizes that early site permit (ESP) applicants, particularly those who reference a plant parameter envelope (PPE), bear the burden of ensuring sufficient margin is provided in the design parameters provided in the ESP application to compensate for uncertainties in those parameters. The margin should be large enough such that the actual design submitted at the combined license (COL) stage, coupled with the site characteristics as described in the ESP, will comply with NRC regulations.

5. Section 15.III.1.4 – The guidance should indicate that staff re-confirmation that site-specific x/Q values are within those of the certified design referenced in a COL application is not necessary if this confirmation was accomplished in the ESP. In particular, this may be the case for an ESP that is based on a specific certified design and reflects the plant location on the site and fission product release points.

Staff response: The staff agrees with the comment and will change Section 15.0 as indicated in the comment.

6. Section 15.III.1.5 – This item should be deleted. At the COL stage, if site-specific x/Q values are within those of the referenced certified design, no NRC review is required or appropriate to confirm that the criteria of 10 CFR 50.34(a)(1) are met. This is consistent with Section III.1.3, which states that, "If site-specific x/Q values are within those specified in the design certification, no further radiological consequence evaluation is needed."

Staff response: For the case of an ESP that references one or more standard designs, as noted in item 15.III.1.3 in Section 15.0, the dose consequence analyses to show compliance with 10 CFR 52.17(a)(1) will have been performed at the design certification stage, with confirmation at the ESP stage that the site-specific χ/Q values are bounded by those of the referenced certified design(s). Therefore, the dose consequence calculations in item 15.III.1.5 at the COL stage using site-specific χ/Q values are used for the information of the staff and to supplement the licensing basis. The staff will move item 15.III.1.5 to a footnote in Section 15.0 and will revise the item to make clear that it is for information and not for review.

7. Section 15.III.2.2 – The site-specific x/Q values are site characteristics, not PPE values.

Staff response: The staff agrees with the comment and will change Section 15.0 as indicated in the comment.

8. Section 15.III.2.2 – As we identified in our April 10, 2003, letter on ESP-7, we disagree with the NRC staff that ESP applications must include dose consequence analyses. As described in our December 20, 2002, analysis of this issue (attached), providing dose consequence analyses is not necessary for compliance with Section 10 CFR 52.17(a)(1). The determination that 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 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 requirements and compliance with Section 52.17(a)(1) is dependent on the site characteristic x/Q, including any assumptions on 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.

We note that at its March 7 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.

Pending final resolution of the differing industry and NRC staff views on this issue, to allow the ESP demonstration process to go forward, ESP applicants have indicated that they will provide radiological dose consequence analyses consistent with the draft review guidance to the extent design basis accident information is available for the designs on which the plant parameters envelope is based.

Staff response: The staff's position remains as documented in letters to NEI dated February 5, 2003 and June 20, 2003. In summary, the staff's position is that dose consequence analyses are required to address 10 CFR 52.17(a)(1) and 10 CFR 50.34(a)(1), but that an applicant using a PPE approach may use plant parameter values as surrogate design inputs to the dose assessments. The text in Section 15.0 referenced in the comment is consistent with this position.

9. Section 15.III.2.3 – ESP applications based on the PPE approach, including the pilot applications, will not address the timing, nature and quantities of fission products released from the fuel to the containment. This information is not germane to the demonstration that the criteria of 10 CFR 50.34(a)(1) are met, or otherwise necessary to support required NRC staff reviews and findings for ESP. Rather, this information is design-related and site-independent by nature and thus appropriately subject to NRC safety review in a design certification or combined license proceeding. Because ESP applications based on the PPE approach will not include this information, this review guidance should be deleted.

Staff response: This section states that the staff reviews such information if available. The section further states that this information will help the staff determine whether the proposed PPE values are not unreasonable. RS-002 is applicable not only to the pilot ESP applicants but also to future ESP applicants who may not choose to use a PPE. The existing draft text is therefore appropriate and flexible enough to accommodate lack of availability of the referenced design-related information.

10. Add new Sections 15.III.2.7 and 15.III.2.8 as follows:

    15.III.2.7 – If a COL application references an ESP and a certified design, the staff reviews the site-specific x/Q values specified in the ESP to confirm that the site-specific x/Q values are within the bounds of those x/Q values provided in the reactor design certification based on the proposed plant design, the plant location on the site, and the fission product release points.

    15.III.2.8 – At the COL stage, in the event that the site-specific x/Q values exceed the bounds of those specified in a referenced design certification, the staff verifies that the applicant has demonstrated that the radiological consequences associated with the bounding DBAs using its site-specific x/Q values continue to meet the radiological consequence evaluation factors identified in 10 CFR 50.34(a)(1).

Staff response: The staff agrees with the comment and will add text similar to that provided in the comment to Section 15.0.

11. Section 15.IV.1 – The guidance should also reflect the scenario identified in Section 15.II.1.6. It is possible that x/Q values specified in the ESP will not be bounded by those of the certified design referenced, and that the COL application would contain additional analyses to support the determination that the acceptance criteria of 10 CFR 50.34(a)(1) are nonetheless met.

Staff response: The staff agrees with the comment and will change Section 15.0 as discussed in the comment.

12. Section 17.1.1 – General Comment – We agree with the NRC staff that ESP applicants must implement quality controls "to provide reasonable assurance of the integrity and reliability of data that supports the site safety assessment and would be used as input in design or construction of SSCs important to safety." We believe that to verify the appropriate quality of ESP information, NRC inspections should focus on understanding the quality controls established by the ESP applicants and direct assessment of ESP information and its sources.

    For two reasons, we do not agree that NRC quality assurance inspections should focus on determining that the quality controls employed by ESP applicants are "equivalent in substance" to those of 10 CFR Part 50, Appendix B. First, as we have expressed in public meetings, our December 20, 2002, letter on ESP-3, and in comments on IMC-2501, Appendix B (or equivalent) controls are not necessary to assure the integrity and reliability of ESP information. And second, as the NRC staff has acknowledged, ESP applicants are not required to implement Appendix B or equivalent controls and are not required to submit QA plans for NRC review. Thus it is inappropriate for NRC inspections to focus on whether or not an ESP applicant has quality controls that are equivalent to those of Appendix B.

    We are concerned that undue focus on equivalence with Appendix B controls will result in time consuming and unproductive discussions of the adequacy of quality controls when the quality of the ESP information itself is either not in dispute or is readily verifiable.

We are heartened that the guidance states that "the staff will not base its regulatory finding on the ESP application solely on the equivalence of the applicant's QA controls to 10 CFR Part 50, Appendix B, controls." We offer specific comments below consistent with the intent to focus on assuring the integrity and reliability of ESP information.

Staff response: The staff agrees with the first paragraph of the comment, including the statement that NRC inspections should focus on understanding the quality controls established by the ESP applicants and direct assessment of ESP information and its sources.

In response to the second paragraph of the comment, the staff notes NEI's continuing disagreement with the staff's position on the equivalence of quality assurance (QA) measures to those of 10 CFR Part 50 Appendix B. The guidance in Section 17.1.1 on this subject is consistent with the staff positions that were documented in draft RS-002, Attachment 2, Note 7, and the staff's letter to NEI dated February 3, 2003, on the subject of quality assurance for ESP applications.

The staff expects that an ESP applicant will use a QA control framework equivalent in substance to that described in Appendix B. RS-002 provides one method for demonstrating that the ESP QA controls are equivalent in substance to Appendix B. The staff selected the Appendix B framework for the review of an ESP application based on several factors, including:

1) the extensive staff experience with the review of Appendix B implementation at existing facilities and the proven effectiveness of the Appendix B framework over many years of nuclear power plant operation

2) consistency with QA controls that will be required at the COL stage for design of structures, systems, and components (SSCs) important to safety

3) the lack of another objective standard for measuring the adequacy of ESP QA controls

However, an applicant's failure to use a framework equivalent to Appendix B would not, in and of itself, result in rejection of an application. The staff believes that Section 17.1.1 allows sufficient flexibility for an applicant to propose alternate QA measures, and that no change to the text is necessary as a result of this comment.

Also, in the second paragraph of the comment, NEI states, in part, that the NRC staff has acknowledged that ESP applicants are not required to submit QA plans for NRC review. While this is correct, the staff again notes that it will need to evaluate each applicant's QA measures. If a description of the measures is not submitted with the ESP application, information to conduct these evaluations will be requested after the application is docketed. The evaluations will be supplemented by inspection activities.

13. Page 17.1.1-2, first full paragraph – We agree that NRC staff findings should be based on "whether or not the applicant has provided adequate controls to provide reasonable assurance of the integrity and reliability of data that supports the site safety assessment and would be used as input in design or construction of SSCs important to safety." We do not agree that "Therefore, any deviations of the applicant's QA controls from [controls equivalent to Appendix B] will be evaluated for their effect on the integrity and reliability of data supporting the ESP application." While we understand that Appendix B may be used by the staff as a guide, evaluating the effects of departures from Appendix B is

inappropriate and unnecessary, especially when the integrity and reliability of ESP information is not in question.

We have the same comment where this same language is used in the second paragraph under Section II on page 17.1.1-7.

Staff response: The staff's reasoning for expecting equivalence to Appendix B is discussed in the response to NEI comment 12. Given this expectation, lack of such equivalence in an application indicates the need for the staff to evaluate whether the integrity and reliability of the ESP information are in question.

The staff must base a conclusion that data is satisfactory for future use on the controls exercised by the applicant in obtaining and analyzing site data. Absent a QA control framework equivalent in substance to Appendix B, the staff will seek other objective evidence that data is accurate and reliable.

The staff has developed inspection guidance to determine the impact of a QA measure that is not equivalent in substance to the corresponding provision in Appendix B. In summary, the guidance in Inspection Procedure 35006, "Early Site Permit Quality Assurance Controls Assessment and Conclusion," states that a QA control deviation would be considered a substantive finding (and thus grounds for denying the application) if any of the following criteria are met:

1) An activity important to safety related to site characterization data or analysis was not performed as required.

2) An activity important to safety related to site characterization data or analysis was performed incorrectly.

3) The applicant lacks objective evidence to establish that the activity important to safety related to site characterization data or analysis was adequately completed.

In particular, under the third criterion, the staff, in its review, will attempt to identify objective evidence that a site characterization activity was adequately performed. The applicant's use of QA controls equivalent in substance to those in Appendix B would provide this evidence. However, absent these controls, the staff would attempt to obtain other forms of objective verification that activities were adequately performed. If the failure to implement adequate QA controls results in insufficient objective evidence that an activity was adequately performed, the staff could identify a substantive finding with regard to site characterization data or analysis.

The staff believes that no change is needed to Section 17.1.1 as a result of this comment.

14. Page 17.1.1-2, last paragraph – The second sentence should be revised as follows: "The regulations of 10 CFR 52.39 set forth an ESP process that has finality, in that the staff shall not revisit, absent significant new information, ~~should not need to revisit~~ site information as part of its review of a COL application.

Staff response: The staff will revise the referenced text to state: "The regulations of 10 CFR 52.39 provide for finality of determinations made at the ESP stage, in that matters resolved in

the ESP proceeding remain resolved at the COL stage, except under certain limited conditions specified in the regulations."

15. Page 17.1.1-2, last paragraph – Modify the last sentence as follows: "Therefore, the staff plans to evaluate quality controls for activities associated with generation of ESP ~~this design~~ information to assure the controls are adequate to provide reasonable assurance of the integrity and reliability of the information ~~using the criterion that these controls be equivalent in substance to Appendix B to 10 CFR Part 50~~."

Staff response: The staff will revise the sentence referenced in the comment to read: "Therefore, the staff plans to evaluate quality controls for activities associated with generation of this design-related information to assure the controls are adequate to provide reasonable assurance of the integrity and reliability of the information, using the criterion that these controls be equivalent in substance to Appendix B to 10 CFR Part 50." See the response to NEI comment 12 for the reason the staff will not remove the "equivalent in substance" phrase as recommended in the comment. The staff considers site characterization data that will be used for the future design of SSCs to be design-related information.

16. Page 17.1.1-3, third paragraph – Modify the last sentence as follows: "The scope of the review includes determination that the applicant has implemented quality controls that provide reasonable assurance of the integrity and reliability of data that supports the site safety assessment and would be used as input in design or construction of SSCs important to safety ~~of the equivalence between the applicant's proposed QA controls and the corresponding criteria of Appendix B to 10 CFR Part 50~~.

Staff response: The staff will revise the text referenced in the comment to read: "The scope of the review includes determination of the equivalence between the applicant's QA controls and the corresponding criteria of Appendix B to 10 CFR Part 50. The applicant's implemented quality controls should provide reasonable assurance of the integrity and reliability of data that support the site safety assessment and would be used as input in design or construction of SSCs important to safety." See the response to comment 12 as to why the staff will not remove the phrase "the equivalence between the applicant's proposed QA controls and corresponding criteria of Appendix B to 10 CFR Part 50" as recommended in the comment.

17. Page 17.1.1-3, fourth paragraph – Modify the last sentence as follows: In such cases, the NRC staff will evaluate the applicant's controls to assure they are adequate to provide reasonable assurance of the integrity and reliability of data that supports the site safety assessment and would be used as input in design or construction of SSCs important to safety ~~for adequacy, with the expectation that they will be equivalent in substance to those stated below~~.

Staff response: The staff will revise the sentence to read: "In such cases, the NRC staff will evaluate the applicant's controls to assure they are adequate to provide reasonable assurance of the integrity and reliability of data that support the site safety assessment and would be used as input in design or construction of SSCs important to safety, with the expectation that they will be equivalent in substance to those stated below." See the response to comment 12 as to why the staff will not remove the phrase "equivalent in substance to those stated below [in Appendix B]" as recommended in the comment.

18. Section I Quality Controls (pp. 17.1.1-3–7) – ESP applicants have established and implemented quality controls that provide for the integrity and reliability of ESP information. ESP applicant quality controls are not required to be equivalent to those of Appendix B, and, as indicated above, Appendix B or equivalent controls are not necessary to assure the integrity and reliability of ESP information. In particular, because of the limited scope of activities associated with ESPs, we do not agree that ESP applicants must establish controls, and be subject to equivalence reviews, in all 18 areas of Appendix B. Examples of Appendix B review areas that may not be germane to ESP activities include:

    - Criterion 8, "Identification and Control of Materials, Parts and Components"
    - Criterion 9, "Control of Special Processes"
    - Criterion 13, "Handling, Storage and Shipping"
    - Criterion 14, "Inspection, Test and Operating Status"
    - Criterion 15, "Nonconforming Materials, Parts or Components"

    The guidance in Section I should be revised to reflect that based on the limited scope of activities performed for ESP, applicants need not have quality controls in place in all 18 areas of 10 CFR Part 50, Appendix B.

Staff response: The staff will revise Section 17.1.1 to more clearly acknowledge that some of the review criteria therein may not be applicable, depending on the type and extent of ESP activities. The staff has not determined that any criteria would always be inapplicable to an ESP application, and the guidance in Section 17.1.1 must be broad enough to deal with a broad range of eventualities.

The staff's reasoning for considering the equivalence of an applicant's QA measures to those of 10 CFR Part 50 Appendix B is contained in the staff's response to comment 12.

19. Page 17.1.1-7, first paragraph under Section II – Modify the third sentence as follows: The applicant is expected to demonstrate that quality controls ~~equivalent in substance to 10 CFR Part 50, Appendix B,~~ have been implemented that provide reasonable assurance of the integrity and reliability of data that supports the site safety assessment and would be used as input in design or construction of SSCs important to safety.

Staff response: The staff response to the "equivalent in substance" issue is covered in the response to comment 12. However, the staff agrees that the statement "to provide reasonable assurance of the integrity and reliability of data that supports the site safety assessment and would be used as input in design or construction of SSCs important to safety" would clarify the sentence. Therefore, the staff will revise the first paragraph under Section II on page 17.1.1-7, as recommended in the comment, to read: "The applicant is expected to demonstrate that quality controls equivalent in substance to 10 CFR Part 50, Appendix B, have been implemented and that these controls provide reasonable assurance of the integrity and reliability of data that supports the site safety assessment and would be used as input in design or construction of SSCs import to safety."

20. Page 17.1.1-7, second paragraph under Section II – Same comment as Comment 13, above.

Staff response: The staff does not propose any revision to the second paragraph under Section II on page 17.1.1 for the same reasons given in the staff's response to comment 13.

21. Section II Acceptance Criteria (pp. 17.1.1-7–21) – As stated earlier, it is not appropriate to establish acceptance criteria for the purpose of determining that ESP applicant quality controls are equivalent to those of 10 CFR Part 50, Appendix B. This is because Appendix B or equivalent controls are not necessary to assure the integrity and reliability of ESP information, and ESP applicants are not required to implement Appendix B or equivalent controls.

    In particular, the NRC staff should not perform reviews for conformance with acceptance criteria in areas of Appendix B that are not applicable due to the limited scope of ESP applicant activities (see previous comment).

    Even in Appendix B areas expected to be addressed by ESP applicant quality controls, Section II includes acceptance criteria that may not be applicable or appropriate based on the nature of the ESP applicant's organization and the limited scope of ESP activities. We believe many of these have no applicability to assuring the integrity and reliability of ESP data and should be eliminated from RS-002.

    At minimum, the guidance should be modified to reflect that based on the nature of the ESP applicant's organization and the limited scope of ESP activities, applicants need not have quality controls in place in all 18 areas of 10 CFR Part 50, Appendix B, and that not all of the acceptance criteria identified in Section 17.1.1 may be applicable and appropriate for review. Moreover, we recommend that NRC quality-related inspections and associated acceptance criteria focus on performance-based assessment of ESP data and its actual handling, rather than on review of ESP applicant quality controls for equivalence to Appendix B.

Staff response: For the staff response to the discussion in the first paragraph of the comment, see the staff's response to comment 12. In response to the discussion in the remaining paragraphs of the comment regarding inapplicability of some criteria in the guidance, see the staff's response to comment 18. The staff has not identified any criteria that would always be inapplicable to an ESP. As discussed in the response to comment 18, the staff will modify the review guidance to clarify that some of the review criteria provided in the guidance may not be applicable, depending on the type and extent of ESP activities.

In response to the concern that the staff should conduct performance-based assessments rather than focus on equivalence to Appendix B: see the staff's response to comment nos.12 and 13. The staff will focus on assessment of handling and QA controls for ESP data, using Appendix B as a framework and reference for that assessment.

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