

February 3, 2003

Mr. Ronald L. Simard  
Nuclear Energy Institute (NEI)  
1776 I Street, NW, Suite 400  
Washington, DC 20006-3708

SUBJECT: RESOLUTION OF EARLY SITE PERMIT TOPIC 3 (ESP-3), QUALITY  
ASSURANCE REQUIREMENTS FOR ESP APPLICATIONS

Dear Mr. Simard:

The purpose of this letter is to inform you of our understandings and expectations regarding quality assurance (QA) requirements for early site permit (ESP) applications. This topic, which is identified as ESP-3 on the list of Nuclear Energy Institute (NEI) generic ESP issues, was discussed at public meetings between July 17 and December 5, 2002. Subsequently, NEI documented its position on this topic in a letter dated December 20, 2002. The discussion below is our response to the relevant understandings and expectations identified in your letter.

We agree with the points made in your letter that (1) current regulations do not require implementing a Part 50 Appendix B program in support of an ESP application, (2) there is no current requirement for pre-application review of quality processes, and (3) there is no current requirement to describe the applicant's quality assurance program in an ESP application. However, the staff does not otherwise concur with the statements and assumptions in your letter or the NEI white paper (Enclosure 1 to your letter) except as specifically stated below. Also, this letter only addresses quality controls applicable to the site safety area, which is the focus of your letter.

Item 1. Requirement that ESP applicants have a 10 CFR Part 50 Appendix B QA program

The current regulations in 10 CFR Part 52 do not require that a Part 50 Appendix B program be implemented in support of ESP applications. However, ESP activities associated with site safety must be controlled by QA measures sufficient to provide reasonable assurance that future safety-related systems, structures, and components (SSCs) of a nuclear power plant or plants that might be constructed on the site will perform adequately in service. For example, activities associated with data collection, analysis, and evaluation for soil composition, geology, hydrology, meteorology, and seismology determinations should be subjected to QA controls, commensurate with the importance of the respective activities to design, and equivalent in substance to the controls described in Appendix B to 10 CFR Part 50. Further, information derived from recognized authorities, such as the Census Bureau or the National Oceanic and Atmospheric Administration, should be controlled using processes for maintaining data integrity, traceability, document control, evaluation, analysis, and record storage that are equivalent to the processes and controls described in Appendix B to 10 CFR Part 50.

The regulations in 10 CFR 52.39, with certain specific exceptions, require the Commission to treat matters resolved in an ESP proceeding as resolved in making findings for issuance of a construction permit, operating license, or combined license (COL). Because of this finality, conclusions made during the ESP phase will be relied upon for use in subsequent design, construction, fabrication, and operation of a reactor that might be constructed on the site for which an ESP is issued. Therefore, the level of quality used to control activities related to safety-related SSCs should be equivalent in substance in the ESP and COL phases.

For these reasons, applicants must apply quality controls to each ESP activity associated with the generation of design information for safety-related SSCs that are equivalent to those specified in Appendix B for similar activities. The staff plans to evaluate quality controls for such activities using the criterion that these controls be equivalent to controls specified in Appendix B. As a practical matter, the burden on the applicant of demonstrating equivalence will be reduced if the applicant invokes the appropriate Appendix B requirements.

Item 2. Requirement for pre-application review of applicant's quality processes

There is no current requirement for pre-application review of an applicant's quality processes. Such reviews, while not required, are likely to be beneficial to both the staff and the applicant in that they support timely completion of required reviews and early identification of any issues regarding these processes.

Item 3. Pre-application submittal of quality process information at the discretion of future ESP applicants

This point as stated in your letter seems essentially the same as the one made in Item 2. There is no current requirement for pre-application submittal of QA process information.

Item 4. Expectation that pre-application interactions will minimize the need for post-submittal NRC review of quality assurance processes

To the extent that the applicant's QA processes are found to be adequate and effectively implemented in the pre-application period, the need for post-submittal reviews of these processes should be reduced. However, the staff will determine on a case-by-case basis the need for additional review of such processes based on the results of the pre-application reviews. Also, the pre-application review does not preclude post-submittal review of quality processes. The pre-application review is primarily for the benefit of the applicant, to minimize potential QA issues during the ESP application review and any eventual COL or construction permit application review.

Item 5. Use of the phrase "baseline for use"

The phrase "baseline for use" in the staff's November 19, 2002, position paper refers to the need for the staff to determine that QA measures applied to information submitted for review at the ESP stage are adequate, such that the staff can accept the use of this information, as embodied in an ESP, in support of a later construction permit, operating license, or COL application.

Item 6. Requirement that ESP applicants describe their QA programs in their ESP applications

An applicant is not required to provide a description of its QA program in its ESP application. Supporting information for your letter states NEI's belief that NRC Inspection Manual Chapter (IMC) 2501 requires, in Paragraph 05.05, a description of the applicant's QA program. That paragraph states, in part: "Those portions of the ESP application which are applicable to the requirements of 10 CFR Part 50 Appendix B will be inspected and reviewed pursuant to Appendix B (and if provided with the ESP application), the QA program description." The quoted sentence clearly recognizes that the QA program description is not required to be submitted with the ESP application. Regardless of whether the applicant chooses to submit a QA program description with its application, the staff will need to evaluate the applicant's QA controls. If a description of the controls is not submitted with the ESP application, these evaluations will be facilitated through requests for additional information (RAIs) from the staff after the application is docketed. The evaluations will be supplemented by inspection activities.

Item 7. The NRC staff will review the ESP applicant's quality processes and sources of information

The staff agrees with the statements in this item of your letter that recognize the need for staff review of the applicant's quality processes.

The staff has determined that the guidance on reviewing an applicant's QA measures in Note 7 to Attachment 2 of Draft RS-002, "Processing Applications for Early Site Permits" (ML023540313), is consistent with the staff's positions as stated in this letter. However, the staff will review the guidance in RS-002 in conjunction with addressing public comments received on the document, and will revise the QA-related guidance in RS-002 as appropriate in support of development of the final document. The staff plans to revise IMC 2501 and other affected guidance documents as needed.

Please contact Mike Scott, ESP Project Manager, at 301-415-1421 if you have any questions on this matter.

Sincerely,

*/RA/*

James E. Lyons, Director  
New Reactor Licensing Project Office  
Office of Nuclear Reactor Regulation

Project No. 689

cc: See next page

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Please contact Mike Scott, ESP Project Manager, at 301-415-1421 if you have any questions on this matter.

Sincerely,

/RA/

James E. Lyons, Director  
New Reactor Licensing Project Office  
Office of Nuclear Reactor Regulation

Project No. 689

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**ACCESSION NO. ML030160555 \*See previous concurrence**

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Distribution for letter to R. Simard dated February 3, 2003

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