



NUCLEAR ENERGY INSTITUTE

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May 20, 2002

James E. Lyons
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U.S. Nuclear Regulatory Commission
Mail Stop O-11 D17
Washington, DC 20555-0001

Dear Mr. Lyons:

The purpose of this letter is to respond to your letter of February 22, 2002, on early site permit (ESP) issues; to provide further information on the ESP-related points raised in our April 24 public meeting on these issues; and to help us prepare for the next public meeting on May 28. We see great value in these discussions in helping us meet several mutual objectives:

- efficient and timely resolution of generic ESP implementation issues in advance of the first applications
- coordination of submittals and NRC/applicant interactions in a way that makes the most efficient use of NRC and industry resources
- development of an efficient and predictable ESP review process in a way that emulates the successes with license renewal

To help meet the first objective, in our April 24 discussion, and in the April 1 public meeting with NRC senior management, we proposed a mechanism for identifying, tracking and close-out of generic ESP issues. The intent is to provide a description of each generic ESP issue, identify aspects warranting discussion, and track the resolution status of the issue to closure. Enclosed is the list of issues identified to date that we provided during the April 24 meeting, along with the updated issue status summary on assuring quality of ESP applications, topic ESP-3. In your February 22 letter, you indicated that this is the issue that the NRC staff is most concerned with at this time. The attached summary describes the industry's approach to ensuring quality of ESP applications and is provided as a basis for our discussion of this issue planned for May 28.

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As discussions of additional topics are scheduled, ESP issue status summaries are expected to be useful in preparing for those discussions and tracking progress toward appropriate resolutions. Following our May 28 discussions, we will update the summary on assuring ESP application quality to document areas of common understanding and areas where further discussion is needed. We will provide the updated issue summary to the NRC staff for informal review and comment on the updated issue status.

Such a mechanism for tracking and documenting the resolution status of generic ESP issues is important to provide timely feedback to ESP applicants and support preparation of ESP submittals. While many of the issues documented in this way may also be addressed in SECY documents, NRC inspection guidance or industry guidance, these documentation vehicles do not lend themselves to the short time frames required to support the target submittal schedules of ESP applicants.

In the April 24 meeting, the NRC staff elaborated on plans outlined in the February letter for developing ESP inspection guidance. We understand that the ESP inspection guidance will take the form of a new Inspection Manual Chapter 2511A. Because of the significant differences between the ESP process under 10 CFR Part 52 and existing Part 50 process for Construction Permits, we agree that the extent to which existing guidance can be applied to ESPs is limited, and that new guidance is needed. New guidance for ESPs is needed primarily due to the focus of existing pre-CP inspection guidance (IMC-2511) on plant design, procurement and construction – activities not associated with ESP.

In our April 24 discussion, we provided the following comments and recommendations concerning the proposed IMC-2511A:

Expectations regarding NRC interactions prior to ESP submittals

As we have expressed to the staff, there is a significant lack of guidance to support preparation of ESP applications. Accordingly, we agree that substantial pre-submittal interactions with NRC will be important to identify and address issues associated with developing first-ever ESP applications and to simplify follow-on NRC reviews.

We expect the great majority of these issues will be common to all three lead ESP applicants. It is our intent and that of the lead ESP applicants to collectively address these issues with NRC primarily through NEI-led interactions with the

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ESP Task Force (ESPTF). Applicant-specific interactions would take place on an as-needed basis as determined by the applicant and the NRC. The two examples of applicant-specific interactions that were identified during the April 24 discussion are the Corporate Management (“Kick-off”) Meeting and NRC visits to become familiar with ESP-relevant site features.

Dealing with generic issues identified in the enclosure via the ESPTF is consistent with license renewal experience, the need to use resources effectively and the goal that ESP applications maximize use of common information and approaches. In addition, this approach provides a mechanism for meaningful interactions in the absence of specific regulations, regulatory guidance or other bases for assessing ESP application or information prior to formal submittal.

In this regard, the February 22 outline of the envisioned IMC-2511A correctly identifies that, “[i]n general, the NRC’s enforcement policy would not apply prior to the submission of an ESP application.” Indeed, while we all agree on the value of interactions with NRC in advance of the three pilot ESP submittals, as acknowledged by the staff on April 24, there is no requirement for such interactions. We appreciate the staff’s desire to proceduralize its activities to ensure consistency of ESP reviews. We also appreciate the staff’s interest in early interactions to support completion of ESP inspection guidance and otherwise prepare for first-ever ESP reviews. However, we question the development of guidance that calls for pre-application “inspections,” “audits” and resolution of “nonconforming” issues in the absence of applicable regulations or bases for such activities. The NRC should not establish guidance for inspections that it does not have the authority to perform.

Rather, we recommend that IMC-2511A identify the ESP review activities to be performed by the NRC, but indicate that these activities may either be performed on a voluntary, information only, basis prior to submitting an ESP application, or after in accordance with 10 CFR 52.18 and other applicable NRC regulations. Whether performed before or after submittal, we expect that feedback from NRC review activities prior to submittal would be documented, provided to the ESP applicant and addressed as appropriate in the ESP submittal. To the extent the applicant conforms its submittal to the advance feedback provided by the NRC in a particular area, it will be expected that, absent significant new information, the NRC will find that aspect of the ESP application to be acceptable during their review.

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We believe IMC-2511A should not establish a general NRC inspection requirement for applicant-specific pre-ESP inspections, audits, etc. For the three pilot applicants, such interactions will take place primarily through NEI and the ESP task force as described above, with applicant-specific interactions as appropriate. Future applicants would be expected to follow the approaches of the lead applicants, including guidance we envision developing based on lead ESP experience, obviating the need for formal pre-ESP inspections by the NRC. Moreover, while significant advance interactions are fundamental to the pilot ESP projects, similar interactions may not be part of the project planning for all future applicants. For purposes of supporting adequate NRC resource planning, future ESP applicants would be expected to identify during initial scoping interactions with the NRC the extent to which pre-

submittal interactions are envisioned. Accordingly, IMC-2511A should reflect that pre-ESP interactions are optional – even encouraged – but not required.

Opportunity to provide additional input to development of IMC-2511A

The NRC staff indicated that IMC-2511A would be developed over the next several months, and we appreciate the opportunity to provide input to the staff at this early stage. In light of the first-time implementation of the ESP process and the need for development of ESP applications to mirror development of corresponding NRC inspection guidance, it is important that we continue to share our respective views and expectations. In particular, we request that the industry (and other stakeholders) have additional opportunity to provide input and comments on IMC-2511A when it is in a more advanced, yet still draft, form.

Timing of public information meetings by NRC

The NRC staff held public information meetings on the Part 52 ESP process on July 25-26, 2001, and March 28, 2002. In addition, the NRC staff has indicated its intent to hold public information meetings in the vicinity of the sites identified by ESP applicants approximately one year in advance of an ESP application.

We and the ESP applicants fully support public information meetings to ensure that people living near the identified sites have a full understanding of what an ESP is, what it is not, and to identify when opportunities will be provided to participate in the process. Indeed, to ensure local communities are fully informed, the ESP applicants have been implementing communications plans in connection with their selection of ESP candidate sites.

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During our April 24 meeting, we suggested that NRC public information meetings might be more effective if held closer to the scheduled date for submittal of ESP applications when more information is likely to be available regarding the envisioned ESP applications, conduct of NRC inspections and reviews, and other topics likely to be of interest to affected persons. While indicating no change in its intent to hold public information meetings one year in advance, the NRC staff agreed to work with ESP applicants on the content and precise timing of such meetings to ensure appropriate coordination with ongoing communications plans. The NRC staff also observed that experience with holding initial meetings of this type may indicate their optimum timing for future ESP applicants. In this regard, we recommend that IMC-2511A reflect that public information meetings in the vicinity of ESP candidate sites will be held at some point *up to one year in advance*, to provide flexibility for the staff to adjust the timing based on experience for maximum effectiveness.

We look forward to a series of productive interactions related to ESP applications and reviews. If you have any questions, please give me a call at 202-739-8128 (or rls@nei.org), or you can contact Russ Bell at 202-739-8087 (or rjb@nei.org).

Sincerely,

Ron Simard

Enclosure

c: Renaldo Jenkins
Document Control Desk

Topics for Discussion in Support of ESP Applications and Reviews

<u>ESP Discussion Topic</u>	<u>Target Discussion Time Frame</u>
1. ESP application template	April 2002
2. ESP inspection guidance	April 2002
3. QA requirements for ESP information	April 2002
4. Nominal NRC review timeline	April 2002
5. Mechanism for documenting resolution of ESP issues	April 2002
6. Use of bounding plant parameter envelope approach	May/June 2002
7. Guidance for satisfying §52.17(a)(1) requirement for description and safety assessment of the facility	May/June 2002
8. Use of a bounding approach for providing fuel cycle and transportation info required by NEPA (Tables S-3 & S-4)	May/June 2002
9. Criteria for assuring control of the site by the ESP holder	May/June 2002
10. Use for ESP of relevant findings from 10 CFR 51, Subpart B, Appendix B (License Renewal GEIS)	May/June 2002
11. Criteria for determining the initial duration of an ESP (10-20 years)	May/June 2002
12. Guidance for satisfying NEPA requirement to evaluate severe accident mitigation alternatives	May/June 2002
13. Guidance for seismic evaluations required by 10 CFR 50, Appendix S	May/June 2002
14. Applicability of Federal requirements concerning environmental justice	July 2002 and beyond
15. Appropriate level of detail for site redress plans	July 2002 and beyond
16. Guidance for ESP approval of "complete" emergency plans	July 2002 and beyond
17. Use of existing site/facility information (PRM-52-1)	July 2002 and beyond
18. NEPA -required review of alternatives (PRM-52-2)	July 2002 and beyond

TOPIC# ESP - 3

TOPIC: QA requirements of ESP information

DESCRIPTION: This topic focuses on the quality assurance requirements for preparing an ESP application. NRC is proposing to use IMC-2511 which has two Inspection Procedures (IP-35002 and IP-35016) related to QA.

QUESTION(S) FOR DISCUSSION:

- What are the NRC's expectations regarding the use of a quality program for preparing the application? What problem or concerns is the NRC staff trying to address by requesting that portions of an ESP application be prepared under Appendix B? When can a non-Appendix B quality program be used to address those concerns?
- Can an existing quality program be utilized if it is from a subsidiary company?
- Would NRC reviews prior to submitting an ESP application focus on quality-related issues only (i.e., pedigree of data collected), or would NRC also perform technical reviews of results obtained?

PRELIMINARY INDUSTRY POSITION:

In its February 22, 2002 letter, the staff indicated that the issue it is most concerned with at this time relates to the quality assurance (QA) program that will be used by ESP applicants to collect the data and assemble the ESP application. In the April 24 meeting, the staff indicated it had expected applicants to prepare ESP applications pursuant to a 10CFR50 Appendix B Quality Assurance Program.

As stated in 10CFR50 Appendix B "Nuclear power plants and fuel reprocessing plants include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. This appendix establishes quality assurance requirements for the design, construction, and operation of those structures, systems, and components. The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems, and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying."

Although an Early Site Permit (ESP) has been referred to as a "partial construction permit" for the purposes of public interaction and hearings, an ESP does not authorize construction or operation of any nuclear related structure, system, or component. The ESP Application does not present or evaluate safety-related functions of structures, systems, or components. An ESP Application includes a Safety Assessment of the Site, an Environmental Report, and an Emergency Plan (either complete or major features). The Environmental Report and Emergency Plan do not affect safety related functions of structures, systems, or components. The Safety Assessment primarily evaluates site environmental parameters that may be used as design input parameters during the Combined

License process; most likely the ESP values will be compared to facility design values to ensure appropriate application of the selected design. The Safety Assessment will contain an analysis and evaluation of the major structures, systems, and components of the facility that bear significantly on the acceptability of the site under the radiological consequence evaluation factors; this will be done through the use of a Plant Parameter Envelope rather than physical feature descriptions when the applicant has not yet chosen a reactor technology. The requirement in 10 CFR 50.34(a)(7) to provide in the Construction Permit Application a description of the applicant's Appendix B Quality Assurance Program must be understood in the context of a 10 CFR 50 Construction Permit which authorized construction and a permit application which included information directly related to the design, fabrication, construction, and testing of the structures, systems, and components important to safety; 10 CFR 50.34(a)(7) is not applicable to the ESP process.

The industry is concerned that the term "Appendix B Quality Assurance" is being used too broadly by the NRC staff to cover issues and processes which, while important, are appropriately associated with "standard or generally accepted industry practices" and "quality control." Although this may seem like semantics, compliance issues could arise if we are not precise in our use of terms. The industry certainly agrees that the accuracy of the ESP application is a key element in supporting a timely NRC review.

As a subset of "accuracy," the processes that control the pedigree of data (e.g. correctness, appropriate use of data, source of data, accuracy and uncertainty) and data assessment (e.g. computer codes, engineering reviews) are important. The ESP application will present data from many sources (e.g. U.S. Geological Survey, National Oceanic and Atmospheric Administration's National Climate Data Center, U.S. Army Corps of Engineers, National Institute of Standards and Technology, U.S. Census Bureau, EPA, USDA, U.S. Fish and Wildlife Service). Such sources are generally accepted as reliable, but are not subject to 10 CFR 50 Appendix B Quality Assurance Programs. Likewise data collected at operating nuclear stations may be used in the ESP Application. Although this data would have been subject to appropriate nuclear site procedures, "Appendix B Quality Assurance" may not have been applied because the data may not be related to any existing safety related structures, systems, or components.

It is clearly the applicant's responsibility to provide an accurate submittal. If data sources and methods different than those accepted by the NRC in their guidance documents (e.g. Standard Review Plans) are used, justification will be provided for their use. Each applicant will have a Quality Plan that outlines the processes to be used in the ESP projects to ensure an accurate and quality submittal. In some cases, programs and procedures implementing 10 CFR 50 Appendix B requirements may be used; in all cases, quality will be assured. Examples of data managed under Appendix B versus standard industry practices are discussed below.

ESP applicants will utilize quality assurance programs and practices that are consistent with 10CFR Part 50, Appendix B, requirements for completing analyses and studies that could be used directly in future design of safety related systems, structures or components for a new nuclear power plant. For example, the collection of data for calculating the seismic response of a potential nuclear power plant site and all manipulation of that data to determine the site's expected seismic response would be performed under a program that implements 10 CFR Part 50, Appendix B, requirements. Similarly, analysis of meteorological data to define site specific bounding environmental conditions

that would establish the future design envelop, such as definition of the site design basis tornado, probable maximum precipitation, and design basis wind loadings would also be performed under a program that implements 10CFR Part 50, Appendix B, Quality Assurance requirements.

Collection and analysis of data necessary to evaluate the overall suitability of the site for construction and operation of a nuclear power plant will be completed in accordance with standard practices for performing environmental and siting studies. For example, analysis of census and demographic data, analysis of ecological data, and analysis of potential effects of cooling water discharges on the environment would be performed in accordance with the normal standards for completing such evaluations.

NRC STAFF POSITION:

In the April 24 meeting, the staff indicated it had expected applicants to prepare ESP applications pursuant to a 10CFR50 App B Quality Assurance Program. The staff indicated that to the extent that ESP applicants were not planning to apply Appendix B to certain ESP activities, additional discussions were necessary to understand the alternative quality processes envisioned.