

July 18, 2005

Ms. Marilyn Kray
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SUBJECT: CLINTON EARLY SITE PERMIT (ESP) QUALITY ASSURANCE ASSESSMENT
AND RESOLUTION OF CONFIRMATORY ITEM (CI) 17.3-1 AND
OPEN ITEM (OI) 17.1-1

Dear Ms. Kray:

Consistent with Nuclear Regulatory Commission (NRC) inspection procedures 35006A and 35012A for inspections supporting the review of early site permit (ESP) applications, the Plant Support Branch (IPSB) has completed a review of the quality assurance (QA) measures applied to ESP activities conducted by the applicant. The review was conducted to determine whether QA measures employed by the applicant had been conducted without substantive deviation from the NRC guidance contained in Review Standard-002, Section 17.1.1.

The staff performed an inspection between January 12 and 16, 2004, as documented in Inspection Report 52007/2004001 (ADAMS Accession No. ML040540622). The inspection focused on site characterization and procurement activities for the development of the ESP application and included a selective review of established procedures and instructions. Our examinations included a selective review of the applicant's activities and records relating to surveillance of contractors, such as audits, inspections, and reviews, and of the applicant's assessments pertaining to the acceptability and timeliness of contract implementation of delegated parts of the QA measures framework.

NRC Inspection Report 52007/2004001 documented Open Item 52007/2004001-01, "Quality assurance measures used to authenticate and verify data retrieved from Internet Web sites that support information in the site safety analysis report (SSAR) that would affect the design, construction, or operation of structures, systems, and components (SSCs) important to safety." This was also documented in Section 17, "Early Site Permit Quality Assurance Measures," of the draft safety evaluation report for the Clinton ESP application (ADAMS Accession No. ML050630183) as Confirmatory Item 17.3-1, "Verification of information obtained from the Internet."

The staff conducted a followup inspection of both items on May 19, 2005, at the applicant's offices in Kennett Square, Pennsylvania. The staff determined, through review of supporting documentation, that the applicant provided adequate quality assurance measures to authenticate and verify data retrieved for Internet Web sites that support information in the

SSAR that would affect the design, construction, or operation of SSCs important to safety. Specifically, Exelon's primary contractor (CH2MHILL) had technically qualified personnel review data retrieved from Internet Web sites, using a documented process. The data was subsequently reviewed again by subject matter experts during an independent review that was conducted once the SSAR was completed.

An additional open item (52007/2004001-02, "Applicability of 10 CFR Part 21 to ESP Applicants") was identified in NRC Inspection Report 52007/2004001, regarding an issue that was generated during an NRC workshop held on August 27, 2003, to discuss the NRC's Construction Inspection Program Framework Document. During that workshop, Exelon representatives stated Exelon's position that 10 CFR Part 21 does not apply to ESP applicants. The NRC staff attending the workshop disagreed with this position, but indicated that this issue would be further evaluated and that a final NRC position on this matter would be communicated at a later date. This was identified in the draft safety evaluation report (DSER) as Open Item 17.1-1, "Address 10 CFR Part 21 for ESP Activities."

A June 22, 2004, letter to the Nuclear Energy Institute (NEI) (ADAMS Accession No. ML040430041) and meeting summaries for two public meetings with NEI on generic ESP issues (September 9, 2004, ADAMS Accession No. ML042360430; November 10, 2004, ADAMS Accession No. ML043290195) documented the NRC position regarding the applicability of 10 CFR Part 21 to ESP applicants and holders.

The NRC position was that safety-related design and analysis or consulting services should be procured and controlled, or dedicated, in a manner sufficient to allow the ESP holder and its contractors, as applicable, to comply with the reporting requirements of 10 CFR 50.55(e) and Part 21. If this was not done, the ESP holder would not be in compliance with 50.55(e) upon issuance of the ESP nor would its suppliers of such services be in compliance with Part 21 at that time.

The staff determined through a review of supporting documentation that the applicant had adequately implemented the requirements of Part 21 for safety-related design and analysis or consulting services supplied by the primary contractor and subcontractors that supported information in the SSAR that would affect the design, construction, or operation of SSCs important to safety. Specifically, Exelon revised its QA instructions to incorporate Part 21 requirements. The contracts were revised to invoke Part 21 requirements for outstanding work being conducted by subcontractors. Additionally, for closed contracts, letters were sent to the respective subcontractors requesting notification from a responsible company representative that Exelon had been informed of any outstanding defect or noncompliance with the services supplied. There were none.

Accordingly, the staff concludes that the QA measures for the Clinton ESP application are consistent with NRC ESP QA guidance.

M. Kray

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Should you require additional information, please contact John Segala, of my staff, at 301-415-1858.

/RA/

William D. Beckner, Program Director
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Office of Nuclear Reactor Regulation

Docket No. 52-007

cc w/atts: See next page

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