

February 20, 2004

Marilyn C. Kray
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SUBJECT: EXELON GENERATION COMPANY, LLC - NRC INSPECTION OF APPLICANT AND CONTRACTOR QUALITY ASSURANCE ACTIVITIES INVOLVED WITH PREPARATION OF THE APPLICATION FOR AN EARLY SITE PERMIT, REPORT 0520007/2004001

Dear Ms. Kray:

On January 16, 2004, the Nuclear Regulatory Commission (NRC) completed a special team inspection of Quality Assurance (QA) procedures and controls associated with preparation of the application for an early site permit (ESP) for the Clinton site at your offices in Kennett Square, Pennsylvania. The enclosed report presents the results of that inspection.

The team concluded that the QA procedures and controls used by you, your primary contractor, CH2M HILL, and CH2M HILL's sub-contractors were equivalent in substance to the criteria contained in Section 17.1.1, Early Site Permit Quality Assurance Controls of RS-002, "Processing Applications for Early Site Permits."

An open item identified during this inspection involved the validation of data obtained directly from publically accessible internet web sites for reference in the application. The team was concerned that data posted to web sites may not be subject to the same degree of review and verification as data obtained directly from the sponsoring organization, or that malicious computer data tampering could impact the integrity or reliability of the web site data. This issue is identified as Open Item 52-007/2004-01-01, "Validation Requirements for Web Site Data Used in License Applications."

The report contains an additional open item regarding an issue that was identified during a 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. 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 issue is identified as Open Item 52-007/2004-01-02, "Applicability of 10 CFR Part 21 to ESP applicants."

The open items will be resolved during completion of the licensing review for the Early Site Permit, and will be closed in the final NRC Safety Evaluation Report (SER), or during a follow-up inspection prior to issuance of the final SER.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system(ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

Sincerely,

/RA/

Cynthia D. Pederson, Director
Division of Reactor Safety

Docket No. 52-007

Enclosure: As Stated

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Sincerely,

/RA/

Cynthia D. Pederson, Director
 Division of Reactor Safety

Docket No. 52-007

Enclosure: As Stated

*Concurrence via email

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U. S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No. 52-007

Report No. 52007/2004001

Licensee: Exelon Generation Company, LLC

Facility: Early Site Permit for the Clinton site

Location: 200 Exelon Way
Kennett Square, PA 19348

Dates: January 12 - 16, 2004

Inspectors: R. Gardner, Sr. Project Manager, Division of Reactor Safety, RIII
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Enclosure

EXECUTIVE SUMMARY

Clinton Early Site Permit NRC Inspection Report 520007/2004001

This special team inspection reviewed aspects of applicant and contractor QA and quality control (QC) activities involved with preparation of the application for the Clinton Early Site Permit.

The team concluded that the QA measures used by the applicant, Exelon Generation Company, LLC; the primary contractor, CH2M HILL, and sub-contractors were equivalent in substance to the criteria contained in Section 17.11 of RS-002, Early Site Permit Quality Assurance Controls.

An open item identified during this inspection involved the validation of data obtained directly from publically accessible web sites for reference in the application. The inspectors were concerned that data posted to web sites may not be subject to the same degree of review and verification as data obtained directly from the sponsoring organization, or that malicious computer data tampering could impact the integrity or reliability of the web site data. This issue is identified as Open Item 52-007/2004-01-01, "Validation Requirements for Web site Data Used in License Applications."

An additional open item was identified regarding an issue that was generated during a 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. 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 issue is identified as Open Item 52-007/2004-01-02, "Applicability of 10 CFR Part 21 to ESP applicants."

The resolution of the open items will be determined during completion of the licensing review for the Early Site Permit, or during a follow-up inspection prior to issuance of the final SER.

Enclosure

Report Details

Status

On September 25, 2003, Exelon Generation Company, LLC (EGC) submitted an application for an early site permit (ESP) in accordance with 10 CFR 52, Subpart A, Early Site Permits.

The site selected for the ESP is a parcel of land on the Clinton Power Station (CPS) site in DeWitt County, Illinois, approximately 6 miles east of Clinton, Illinois. An existing nuclear facility licensed by the NRC is located on the CPS site. The existing facility is CPS Unit 1 (NRC Docket No. 50-461).

A Site Safety Analysis Report (SSAR) supports EGC's application for the ESP. The SSAR contains information about site safety and includes site description, design parameters, population profile, and an assessment of site features affecting the plant design. This inspection (in accordance with Inspection Procedure 35006) was conducted to ascertain whether the applicant's Quality Assurance (QA) controls, as applicable to ESP activities, provided reasonable assurance of the integrity and reliability of ESP data or analyses that would affect the function of safety-related structures, systems or components (SSCs) for a future plant built at the site.

Quality Assurance

1. QA Manual/Control Documents

a. Inspection Scope:

For specific organizations with quality assurance/quality control (QA/QC) responsibilities, the team reviewed the QA manuals, or applicable QA control framework documents, to determine if requirements for quality-related activities were consistent with the guidance contained in Section 17.1.1, "Early Site Permit Quality Assurance Controls," of Review Standard (RS)-002, "Processing Applications for Early Site Permits."

b. Observations and Findings

Exelon

The team reviewed the Exelon procedure that provided general guidance for the quality measures to be applied to ESP activities for the subcontractors. Procedure AP-AA-1000, "Early Site Permit Project Quality Assurance Instructions," Revision 0, stated that activities related to the development of the application would be conducted in accordance with 10 CFR Part 52. The Exelon Nuclear Quality Assurance Topical Report was determined not to be applicable to ESP activities. However, certain criteria of 10 CFR Part 50, Appendix B, were determined to be applicable. As detailed in the Organization section of this inspection report, Exelon delegated ESP activities. The subcontractors that conducted ESP activities were working under their own quality assurance measures, by direction provided in procurement documents, or were working under the quality assurance measures required by the lead subcontractors. The

team found the guidance provided by the Exelon procedure AP-AA-1000 was adequate for overall guidance for the conduct of ESP activities. Detailed below are the specific subcontractor quality measures that were applied to ESP activities.

CH2M HILL

CH2M HILL had the lead for compiling the necessary information needed for the Site Safety Analysis Report (SSAR). Activities conducted by CH2M HILL included seismic analysis, QA audit activities, the environmental report and contract preparation. The team reviewed the project quality plan (PQP) developed by CH2M HILL for the Exelon ESP project. Document DEL-012-4, "Project Quality Plan for Exelon Early Site Permit," Revision 4, delineated the quality program for the development of the ESP application. The document stated that CH2M HILL shall develop the application in accordance with the requirements of 10 CFR Part 52. The document described the project organization, quality objectives and criteria, and project quality processes. The project quality processes were broken down to Appendix B criteria that were applied to ESP activities conducted by CH2M HILL. In addition, CH2M HILL developed procedures that amplified guidance on the conduct of ESP activities. The procedures were reviewed by the team and found to provide adequate detail and guidance.

The PQP stated that while Exelon retained the overall responsibility for the completeness and accuracy of the information to be provided in support of obtaining an ESP application, the initial gathering and analysis of this information was delegated to CH2M HILL. The document further stated that the purpose of the PQP was to provide adequate controls such that the Exelon ESP application was prepared under quality practices commensurate with the intended use of the application and its content. To that end, only certain elements of the criteria set forth in 10 CFR 50, Appendix B, and other quality standards were applied as necessary. As stated in RS-002, Section 17.1.1, an applicant may determine the applicable quality measures to be applied. The team reviewed the quality measures CH2M HILL established as applicable and determined that the measures applied were adequate for the activities conducted in support of the Exelon ESP activities.

Parsons Energy & Chemicals Group

The overall scope of work conducted by Parsons included review and assessment of existing site data; review and assessment of Plant Parameter Envelope (PPE) data; preparation of site plot plan and facility description sections for the SSAR; preparation of the SSAR text for mechanical, structural, and electrical sections; and documentation for the effluents and design basis accident sections of the SSAR.

The scope of work provided by Parsons included preparation of the SSAR in support of the ESP application, in accordance with the Parsons Project Administration Manual (PAM), Revision 0. The PAM stated that the

requirements of Appendix B, American National Standards Institute (ANSI) N45.2, and the American Society of Mechanical Engineers (ASME) NQA-1 would be met. Parsons conducted work under this document and supplementary procedures. The team noted that the PAM provided adequate guidance and quality assurance measures for the scope of work.

Parsons was audited by the Nuclear Utility Procurement Issues Committee (NUPIC). The team reviewed NUPIC audit number 17828, dated November 5, 2001. The audit found Parsons to have an acceptable Appendix B quality assurance program. A subsequent NUPIC audit, number 18640, was conducted in October 2003. While the official report had not been issued, the preliminary audit findings were available. No significant deficiencies were identified. The team noted that these audits were not related to Parson's ESP activities.

The PAM provided administrative directives to project personnel and included the quality plan implemented for the project. The PAM identified organizational structure and interfaces, outlined project personnel responsibilities, and defined design control, interface control, and client-specific requirements. The PAM recognized the need for controls and procedures for the work being performed under this task based on the use of the data being generated. The Parsons PAM stated that it would be used for those portions of the work, such as calculations, where Appendix B requirements would be applicable. The PAM provided details of what specific areas were applicable.

In Attachment II of the PAM, the procedures relating to areas covered by Appendix B were identified. The team found the procedures to be adequate to cover the areas of ESP activities that were the responsibility of Parsons.

Testing Services Corporation

Testing Service Corporation (TSC) provided engineering, technical and laboratory services associated with geotechnical activities. Geotechnical activities included site borings, sample collection, testing and inspection of soil and rock as used in engineering design and construction. The team reviewed the quality assurance manual prepared by TSC for ESP activities. The quality manual was essentially a compilation of the work to be conducted by TSC. The TSC quality manual included a description of the TSC organization, the resumes of personnel that conducted geotechnical activities, data reports and records, calibration records and procedures, and procedures related to sample testing and onsite inspections. The TSC quality manual stated that the manual was prepared in accordance with section 9.1 of the American Society for Testing and Materials (ASTM) D3740, "Standard Practice for Minimum Requirement for Agencies Engaged in the Testing and/or Inspection of Soil and Rock as Used in Engineering Design and Construction."

CH2M HILL developed procedure 300.345f.018-1, "Exelon Early Site Permit Application Workplan for Subsurface Explorations," Revision 4, to outline the quality measures to be used by TSC and other geotechnical subcontractors in

the conduct of ESP activities. The scope of the procedure was intended to be consistent with the industry guidance on the ASTM standards.

A TSC licensed professional engineer was designated as being responsible for ensuring internal quality reviews of conducted work activities. A copy of the internal quality review check sheet was included in the TSC quality assurance manual.

Other subcontractors were involved in similar work. These subcontractors included Stratigraphics and GEOVision. These subcontractors were also required to follow procedure 300.345f.018-1.

The team's review of the procedure and TSC quality manual found the documents to provide a thorough description of the conduct of work and adequate quality assurance measures.

Geomatrix

Geomatrix conducted Exelon ESP activities such as seismic source characterization, probabilistic seismic hazards analysis (PSHA), the analysis of site hazard for rock conditions, and safe shutdown earthquake (SSE) ground motion development and assessment of their effects.

CH2M HILL developed procedure 300.345f.017-1, "Workplan for Seismic and Geotechnical Studies and Investigations," Revision 3, to outline the quality measures to be employed by Geomatrix in the conduct of ESP activities. The scope of the procedure was detailed as to the specific work to be conducted, such as seismic hazard and geotechnical studies. The procedure stated that the work would be conducted in accordance with the PQP. Additionally, the scope of work covered by the procedure was intended to be consistent with the guidance provided in Regulatory Guide (RG) 1.70, "Standard Format and Content of Safety Analysis Reports," and RG 1.165, "Identification and Characterization of Seismic Sources and Determination of Safe Shutdown Earthquake Ground Motion." The team noted that the procedure provided adequate guidance for the scope of work conducted.

GRL Engineers Incorporated

The team reviewed the GRL quality assurance manual. GRL conducted standard penetration test (SPT) measurement work. The team reviewed documentation that provided the extent of quality assurance measures applied to ESP activities. Measurements performed by GRL were in accordance with ASTM standard D-4945 concerning dynamic measurements. Measurement gages and signal processing equipment were in compliance with the standard for dynamic measurements. The preparation and review of engineering calculations were conducted in accordance with the GRL quality assurance plan. The team reviewed the GRL quality assurance plan and found the plan to be adequate for the ESP activities conducted by GRL.

c. Conclusions

The team concluded that the quality assurance implementing documents employed by the lead subcontractors and other subcontractors met the guidance in Section 17.1.1 of RS-002. Additionally, the supporting procedures had adequate guidance for the specific work to be conducted by the subcontractors.

2. QA Control Implementation

For selected organizations having QA/QC responsibilities, the team reviewed QA organizations and responsibilities, implementing procedures, contractual requirements, and work records to assess implementation in the following areas:

2.A. QA Organization

a. Inspection Scope

The team reviewed selected organizations having QA/QC responsibilities applicable to ESP activities at the proposed site. The team interviewed cognizant applicant and contractor personnel, and reviewed applicant, contractor, and sub-contractor procedures to verify that adequate controls existed regarding ESP QA/QC activities.

b. Observations and Findings

Exelon

The applicant stated that the Exelon Nuclear Quality Assurance Manual had been reviewed and determined to not be applicable to siting and construction activities. The applicant developed procedures specific to ESP activities such as the ESP quality assurance instruction, ESP advanced plant department description, ESP project manual, and Exelon acceptance review of the contractor prepared ESP application. The team reviewed the program procedures and noted that the procedures met the guidance in Section 17.1.1 of RS-002. The applicant had adequately described the ESP organization and personnel responsibilities. In addition, the team noted the following regarding the ESP organization and Exelon oversight responsibilities:

Section 4.2.1 of the Exelon ESP Project Quality Assurance Instruction indicated that Exelon was responsible for the establishment and execution of a project quality assurance plan for an ESP project but that Exelon would typically delegate to others, such as contractors, the work of establishing and executing the QA plan. The document further indicated that Exelon management would ensure that persons and organizations performing quality assurance functions had sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions; and have direct access to levels of management as may be necessary to perform these functions.

The team interviewed Exelon quality assurance audit personnel that conducted audits of ESP activities and reviewed personnel training records. The applicant indicated that Exelon project staff received on-the-job training related to ESP activities. However, no formal training plans were developed and no training records were maintained. The applicant stated that personnel were assembled for the project such that their experience precluded the need for formal training. The team reviewed the resumes of pertinent Exelon personnel associated with the ESP project. The resumes demonstrated satisfactory experience and education for each of the individuals selected for review.

CH2M HILL

The team reviewed the CH2M HILL Project Quality Plan (PQP), Revision 4. The applicant indicated that the PQP was prepared by CH2M HILL, and reviewed by Exelon, to provide quality controls such that the Exelon ESP application was prepared under quality practices commensurate with the intended use of the application and its content. Procedures were prepared by CH2M HILL for those quality functions described in the PQP. The team reviewed several procedures in detail to ensure the procedures were adequate to perform the stated procedure purpose.

The team reviewed CH2M HILL procedure Del-013-2, "Document Creation, Peer and Technical Review," Revision 2. This procedure provided guidance regarding the creation of project documents. The team determined that the procedure adequately identified the organizational roles and responsibilities regarding document authorship, review and approval. Furthermore, the team noted that the procedure provided the following specific requirements relating to Peer Reviews and Independent Reviews:

- Section 3.1 noted that Peer Reviews would be conducted by qualified CH2M HILL personnel to check documents for content. Further, Section 4.0 identified that peer reviewers would be designated in writing and trained on the review process. The team reviewed the peer reviewers selected by CH2M HILL to conduct a peer review of the ESP application prior to release to Exelon. The team noted that the reviewers were designated in writing and that required training had been provided and documented.
- Section 4.0 identified that the Seismic Work Plan and Seismic Report required an independent review. The applicant provided documented evidence that the required review had been performed. The team reviewed resumes of each member of the seismic review board and determined that board members had extensive education and experience in seismic analyses.

The team reviewed training and qualification records for CH2M HILL personnel and other subcontractors involved in Exelon ESP related activities. In addition, the CH2M HILL organization structure and personnel responsibilities were reviewed. No issues were identified.

Testing Services Corporation (TSC)

CH2M HILL subcontracted to TSC to obtain geological testing support such as site borings, sample collection, and piezometer installation. TSC developed a project-specific QA manual and a work plan to identify the scope of work activities, and quality requirements. The team reviewed the TSC QA manual and the project work plan to assess the adequacy of the specified QA measures, particularly those associated with test control and test equipment calibration. The team noted that the TSC quality assurance manual addressed training, work assignment, and competency evaluation of TSC personnel. The manual indicated that reviews of test results and conformance to work procedures were independent of the organizations performing field and lab work. Furthermore, the team noted that the QA manual provided the following specific requirements relating to testing, field oversight, and quality reviews:

- Section 10, "Internal Quality Systems Review," indicated that quality deficiencies would be reported to the TSC Vice President. Actions would then be taken to determine the need to modify policies and/or procedures to address the deficiencies. Additionally, deficiency remediation reports would be forwarded to the TSC Vice President and kept on file.
- Section 6, "Description of Calibration and Verification Procedures and Records," indicated that TSC would perform calibration and verification of required equipment at specified intervals. Additionally, a calibration and verification file for each piece of equipment was kept on file.

Geomatrix

CH2M HILL subcontracted to Geomatrix to support CH2M HILL's ESP efforts in performance of probabilistic seismic hazard and/or sensitivity analyses for the Clinton site. Consistent with the requirements specified in CH2M HILL procedure DEL-014-2, "Control of Subcontractor Quality," Revision 2, Geomatrix utilized the CH2M HILL Project Quality Plan for contract quality requirements.

Geomatrix and CH2M HILL jointly developed a Seismic Workplan that outlined a program of seismic hazard and geotechnical studies and investigations implemented as part of the Exelon ESP. The workplan included a requirement that an independent seismic Board of Review review the implementation plan for the seismic hazard work, the interim results of the work, and the conclusions reached during the work. The team verified the independence of the board members and reviewed board member resumes.

c. Conclusions

Based on a review of the ESP QA Project Quality Plan, ESP QA implementing procedures, training records, qualification records, organizational responsibility documents and interviews with personnel directly involved in ESP activities, the team determined that the ESP QA organization met the guidance outlined in Section 17.1.1 of RS-002.

2.B. Design Control

a. Inspection Scope

The team reviewed the implementation of QA design control attributes applicable to ESP activities at the proposed site. The inspectors interviewed cognizant applicant and contractor personnel, and reviewed applicant, contractor, and sub-contractor procedures to verify that adequate controls existed regarding ESP design control activities.

b. Observations and Findings

The Exelon ESP application identified CH2M HILL as the primary contractor providing personnel, systems, project management, and resources for the Exelon ESP project. Further, CH2M HILL procured engineering services and support for specific design control activities from subcontractors, which included Parsons Power Group Inc., Geomatrix Consultants, GRL Engineers, Inc., and others discussed below. The team reviewed and verified the adequacy of design control activities for each of these companies as follows:

Exelon

The team reviewed Exelon procedure AP-AA-1000, "Early Site Permit Project Quality Plan Instructions," Revision 0, which described the elements of the ESP quality assurance plan prepared by contractor CH2M HILL. The procedure identified pertinent elements of criteria stated in 10 CFR Part 50, Appendix B, that applied to controls for the ESP application and responsibilities for establishment and execution of a project quality plan for the ESP by others such as contractors or consultants. The procedure stated that Exelon management retained overall responsibility for the project including the responsibility of attaining quality objectives and that persons and organizations having quality assurance functions have the organizational freedom to identify quality problems. Additionally, the procedure stated that individuals performing audits of the plan have the experience, training, or background to assess the quality of the product being provided by the contractor. The team reviewed resumes and training records of Exelon individuals involved with QA plan oversight and audit and found them adequate.

The QA plan, as written by contractor CH2M HILL, and implemented by CH2M HILL and other contractors, is further discussed in the sections below.

CH2M HILL

Exelon delineated the ESP work scope and quality requirements for CH2M HILL in Exelon Contract No. 01001380. The purchase order included a general description of the CH2M HILL work scope. This included the identification of specific sections of the ESP application for which CH2M HILL was responsible for performing design control activities supporting analyses, evaluations, and procurement, and for ensuring that personnel involved with the project were

trained and knowledgeable of the QA design control requirements. Additionally, CH2M HILL was responsible for implementing procedural controls to identify and correct deviations from quality standards. The team reviewed CH2M HILL procedures and interviewed the responsible project and QA managers.

The team reviewed document DEL-012-4, "Project Quality Plan (PQP)," Revision 4, which delineated the quality program for development of an ESP application and outlined the ESP organization, program, and procedural requirements. Responsibilities were also defined regarding traceability and appropriateness of information prior to its use in any design document. The following sections of the PQP, as they related to the design control area for the ESP, were reviewed:

- Section 2.0 described the project quality processes including organizational authority, responsibilities for completeness and accuracy of information, and gathering and analysis of information to support ESP application development.
- Section 2.2 described ESP design control elements related to 10 CFR Part 50, Appendix B. The section provided for quality processes in the communication of quality requirements of the PQP to the project leads and training of personnel used to perform activities affecting quality.
- Section 2.3 described development planning to determine required review, verification, and validation activities related to the ESP project. The section also provided for determination of functional and performance requirements and applicable statutory and regulatory requirements. Additionally, it established criteria for approval of development inputs and outputs, and review and control of development changes including computer software control.

The team reviewed additional CH2M HILL ESP project procedures as follows:

- DEL-055-0, "Project Analyses and Calculations," Revision 0, established the requirements for controlling the issuance and revisions of computations and resulting data. The procedure further described analyses and calculation documentation requirements, verification methods, and change control.
- DEL-042-0, "Control of Software," Revision 0, provided guidance on the assessment of computer software acquired, developed, and utilized in generating calculations, or analysis of data, intended for use in the ESP application. The procedure further described controls for software procurement, evaluation, maintenance, and validation and verification.
- DEL-014-2, "Control of Sub-Contractor Quality," Revision 2, described the process used to maintain communications between CH2M HILL and sub-contractors regarding implementation of quality requirements for the ESP application. The process included a review of sub-contractor quality plans, observation of field activities, control of computer software, control

of measuring and test equipment, corrective action documentation, and audits.

- DEL-017-0, "Test Control Program," Revision 0, provided guidance on meeting the requirements for implementing and assessing tests of structures, systems, and components. Responsibilities were also defined regarding test development, review, and documentation.
- DEL-018-2, "Control of Measuring and Test Equipment," Revision 2, described the requirements for and implementation of controls for calibrated meters and equipment. The procedure included guidance for selection, use, calibration, and non-conformance reporting of measuring and test equipment for CH2M HILL and sub-contractors.

The team concluded that the design control measures described in the CH2M HILL PQP and other reviewed procedures and documents were adequate.

Parsons Power Group

Parsons Power Group provided engineering services in preparing the site safety analysis report in the ESP application for Exelon. The team interviewed the Parsons project manager and reviewed procedures that included design criteria and input, engineering calculations, computer program verification and validation, computer program verification and validation related to nuclear safety-related software, design review and approval, and computer program error reporting.

Organizational responsibilities and lines of communication between the different engineering disciplines were established in each of the reviewed procedures. This included designation of personnel that originated the initial design or input and the associated reviewers. Procedure EP-1, "Design Criteria/Input," delineated guidelines for the review of specifications to produce design criteria and documentation used for the design of the project. Procedures for review of calculations, including spreadsheet/database utilities and computer analyses, were delineated in Parsons Procedures Manual EP-3, "Engineering Calculations."

Verification and Validation (V&V) procedures for computer programs, including procedures for internal software and purchased software, were detailed in procedure EP-4, "Computer Program Verification and Validation." The validation procedures were prepared to assure that the software performed its desired function and established general criteria to determine the verifier's responsibilities and independence.

The team concluded that the design control measures described in the Parsons Power Group procedures and documents were adequate.

Geomatrix Consultants Inc.

Geomatrix performed seismic and geologic data collection, site response studies, and safe shutdown earthquake determinations for the ESP application. The team reviewed documentation related to calculations and analyses; software validation, verification and control; and the Geomatrix purchase order. Company personnel resumés and QA training records were also reviewed by the team. The team noted that Geomatrix personnel were trained and performed work under CH2M HILL PQP procedures regarding software verification controls and documentation and review of calculations and analyses.

Geomatrix utilized software developed or modified by the company to perform calculations related to the seismic analysis in the ESP application. The team reviewed a Geomatrix memorandum which provided additional information regarding the verification and validation performed on the modified software. The memorandum explained procedures for software V&V performed by Geomatrix. The memorandum also included a summary description of the V&V presentation provided by Geomatrix personnel to the NRC team on January 16, 2004. During the presentation, Geomatrix personnel described the V&V procedures utilized for two of the software codes used to perform the seismic hazard analysis and explained to the team the software modifications necessary to perform the ESP calculations.

As further described in the memorandum, Geomatrix performed verification activities for their software prior to the start of the ESP project. In order to perform the ESP calculations, modifications to the Geomatrix computer codes were necessary to accept ground motion models and seismic source parameters developed by the Electric Power Research Institute (EPRI). The EPRI probabilistic seismic hazard analysis (PSHA) for the Seismic Owners Group (SOG) was considered acceptable to characterize the seismic hazard for nuclear power plants and to develop the Safe Shutdown Earthquake (SSE) ground motion, as stated in Regulatory Guide 1.165, "Identification and Characterization of Seismic Sources and Determination of Safe Shutdown Earthquake Ground Motion." Geomatrix used the EPRI-SOG-1989 model to verify and validate the accuracy of the codes and the output results.

In November 2002, to verify and validate the accuracy of their software results, Geomatrix used the original Clinton site EPRI-SOG PSHA calculations as the benchmark case. Geomatrix compared the output curves using EPRI-SOG software with the output curves using the Geomatrix software. Results were documented in the ESP SSAR, Appendix B, Section 3.2.1, and were reviewed by the team.

The team concluded that Geomatrix complied with the CH2M HILL PQP and that the design control measures utilized by Geomatrix for seismic studies incorporated in the ESP application were adequate.

Other Sub-Contractors

The team reviewed the purchase orders, a sample of personnel qualifications, and the description and methods of work performed, including applicable quality assurance design controls, for selected sub-contractors. The team concluded that the QA design control measures for the four companies listed below were adequate.

GRL Engineers, Inc.

GRL performed standard penetration tests in accordance with the GRL quality assurance plan and Section 6.1 of ASTM D4945, "Standard Test Method for High-Strain Dynamic Testing of Piles," for dynamic measurements. The work performed was monitored by a CH2M HILL field supervisor who verified that work was performed in accordance with the seismic field work plan. CH2M HILL reviewed the GRL quality manual following completion of the work performed by GRL and found that the manual met the requirements of the Exelon quality plan.

Stratigraphics

Stratigraphics performed cone penetrometer measurements and testing used for geotechnical aspects of the ESP. The work was monitored by CH2M HILL and performed in accordance with the CH2M HILL PQP and project quality field work plans.

Testing Services Corporation (TSC)

TSC performed site borings and sample collections in accordance with the TSC Quality Manual. The manual was reviewed and approved by CH2M HILL who found it to be prepared in accordance with the criteria required in the PQP and in ASTM D3740, "Standard Practice for Minimum Requirement for Agencies Engaged in the Testing and/or Inspection of Soil and Rock as Used in Engineering Design and Construction."

University of Texas (UT)

UT performed soil sample resonant column and torsional shear (RCTS) testing. The team reviewed the UT testing report which detailed procedures for preparing, reviewing, calibrating, and system performance checks. The procedures were designed to meet ASTM D3740. UT engineering personnel were trained, and were supervised during performance of the tests.

The UT quality assurance program policies contained in the report were in accordance with those previously approved by the U.S. Department of Energy for the Yucca Mountain Project soil and rock tests, also performed by the University of Texas. Documentation presented by UT described technical and test procedures for the RCTS testing performed in their soil dynamics laboratory. An overview of the test program, theoretical background of RCTS tests,

discussion of the dynamic test results and reports, and validation procedures were also reviewed by the team.

QA Measures for Control of Publically Accessible Internet Data

The team noted that the applicant used publically accessible internet web sites to obtain information referenced in various parts of the ESP application. For example, the ESP application referenced internet web sites controlled by the United States Department of Commerce Census Bureau and the National Oceanic and Atmospheric Administration (NOAA). This data was used, in part, to establish population distributions and growth estimates as well as the meteorological profile for the planned ESP site. During the inspection, the applicant provided a matrix of internet web sites used in the application and their associated disclaimer information. However, objective evidence that demonstrated that the applicable web site data was identical to the official data controlled by the web site sponsoring organization was not available.

In reviewing the Census Bureau and NOAA web sites used by the applicant, the team noted that each of these agencies offered certification services to verify that data supplied to users was identical to the agency officially archived data. NOAA indicated in publication Environmental Information Summary C-1, "Weather records in Private Litigation," that, in accordance with 28 U.S.C 1733, only properly authenticated copies or transcripts of records can be admitted as evidence in a court of law.

The team was concerned that data posted to web sites may not be subject to the same degree of review and verification as data obtained directly from the sponsoring organization or that malicious computer data tampering could impact the integrity or reliability of the web site data. This issue is identified as Open Item 52-007/2004-01-01, "Validation Requirements for Web site Data Used in License Applications."

c. Conclusions

The QA procedures and design controls used by Exelon, CH2M HILL, and sub-contractors were readily available. Applicant and contractor personnel involved with the ESP project were cognizant and knowledgeable of the QA design control requirements contained in the applicable procedures and had received adequate training or had adequate experience in their areas of responsibility. Additionally, the inspectors verified that procedures existed for the review of calculations, drawings, specifications, and other design control documents. Pending resolution of the open item, the inspectors concluded that the ESP application QA controls in the design control area were adequate to meet the guidance contained in Section 17.1.1 of RS-002.

2.C. Procurement Control

a. Inspection Scope

The team reviewed the implementation of QA controls for procurement of services by the applicant and the applicant's contractors and sub-contractors. The team reviewed purchase orders, work scope technical requirements, project plans, supplier quality assurance programs and methods used by the purchasing organization to qualify suppliers of safety-related services.

b. Observations and Findings

Organization

The authority and responsibilities of persons and organizations performing quality management functions were identified in Section 1.3 of the Project Quality Plan (PQP). The primary function of the Exelon project manager was to direct the project team to complete the ESP application. The CH2M HILL Project Manager had the overall responsibility for completing the ESP application and for satisfactorily addressing technical issues and questions that would arise in the period following submittal of Exelon's ESP application to the NRC. The CH2M HILL Quality Assurance Manager was responsible for the quality elements of the ESP application. The Site Safety Analysis Report Lead had overall responsibility for the technical content and completion of the report. Individuals carrying out these responsibilities were interviewed by the team. Based on these interviews and review of project documentation, it was determined that the staffing for these positions was consistent with the descriptions in the PQP. Other positions described in Section 1.3 of the PQP included assignment of responsibilities to lead technical positions for key project areas. Based on the team's review of overall project documentation, these positions were determined to be accurately described in the PQP.

Procurement Authorization

The Exelon Project Manager served as the contract administrator in authorizing all services procured under the ESP application contract. During review of the Exelon Services and Material Agreement contract file governing the ESP application contract, the team interacted with the project manager and the contract specialist and found them knowledgeable in pertinent details of contract administration.

The CH2M HILL Project Manager and QA Manager were interviewed regarding authorization of subcontract procurement. CH2M HILL procurement was authorized by the CH2M HILL Project Manager in coordination with the CH2M HILL procurement officer located in the CH2M HILL Tucson, Arizona office.

Based on review of procurement purchase orders and interviews with authorizing contract personnel, the team found the authorizing individuals to be knowledgeable of Exelon's quality assurance requirements.

Contract Specifications

The team reviewed the Exelon Services and Material Agreement which authorized the scope of work to be performed by the primary contractor. The purchase order, dated April 22, 2002, defined the scope of work to be performed. Quality requirements for the contract, incorporated as part of the contract, stipulated that the scope of work should ensure that tasks would be accomplished with the appropriate level of quality controls being applied to individual tasks, such that the quality of the data would not be called into question during its subsequent use in the combined operating license (COL) process as set forth in 10 CFR Part 52. The contract required as a deliverable a written detailed description of the quality control practices employed and the corresponding data or information for which these controls were applied.

CH2M HILL was selected as the primary contractor for preparing the ESP application. The CH2M HILL proposal specified that the existing CH2M HILL QA program, which implements its Quality Management System (QMS), would be implemented for the ESP task to the extent applicable and that all reports and records required by the application would be reviewed and approved by CH2M HILL prior to being forwarded to Exelon.

The CH2M HILL proposal, subsequently incorporated within the terms of the contract, committed to develop and implement specific procedures to verify and validate the processes and results of all data collection and report generation processes to ensure that all relevant data had been identified and applied to the appropriate reports in an accurate and appropriate manner. Such project specific procedures would be developed for all geotechnical and seismic field investigation activities in accordance with NQA-1, Part II, Subpart 2.20, "QA Requirements for Subsurface Investigations for Nuclear Power Plants." All computer modeling activities would be completed in accordance with NQA-1, Part II, Subpart 2.7, "QA Requirements for Computer Software for Nuclear Facility Applications."

The following CH2M HILL purchase orders (PO) for tasks related to preparation of the ESP application were reviewed by the team:

CH2M HILL Purchase Orders Reviewed		
Organization	PO Dated	Scope of Activities
Parsons	August 12, 2002	Engineering services in support of preparation of the ESP application
Geomatrix	October 2, 2003, as amended through October 2, 2003	Seismic work
Stratigraphics	August 7, 2002	Subsurface field investigations

GRL Engineers	September 4, 2002	SPT energy measurement services
University of Texas at Austin	July 14, 2003	Resonant column/cycle torsion tests on soil samples

Project Control

The CH2M HILL proposal specified that special procedures for controlling processes used in data collection and report generation would be developed and approved in accordance with the CH2M HILL controlled document program. These special procedures, together with existing procedures from CH2M HILL's QMS Manual, would be assembled in a Project Procedures Manual for use by the ESP Project Team. Documents pertaining to the quality systems and those used to direct work relating to contractual requirements would be controlled. The document control program was applied to internally generated documents such as manuals, procedures, plans, work instructions, forms, drawings and records, as well as documents of external origin, to ensure control of document creation and management. The document management system was designed to ensure that only those procedures that had been reviewed and approved by project management were available at the point of use.

Based on review of the purchase orders and related discussions with the CH2M HILL project manager, the team found that CH2M HILL executed the procurement functions effectively and in a manner consistent with the Exelon contract.

Audits

The ESP application contract identified the CH2M HILL internal audit program as the primary process for evaluating the level of implementation and effectiveness of processes used in data collection and report generation. The audit program was integrated with the CH2M HILL documentation program, training program, corrective action program, and management program for controlling procurement activities. The audit process evaluated project activities by reviewing procedures against contract requirements for compliance and documenting and addressing "non-conforming" steps or outputs through the corrective action program.

The following audits were conducted in conjunction with ESP activities:

CH2M HILL Audits		
CH2M HILL Internal	Document Control	June 11, 2002
	Record Control	September 17, 2002

	Review Process	February 4, 2003
	Record Control	February 4, 2003
CH2M HILL External	Geomatrix	September 18, 2002
	Testing Services Corporation	September 23, 2002
NUPIC	Parsons	October 23-25, 2002 October 2003
Exelon	CH2M HILL	July 25, 2002 March 12, 2003 August 31, 2003

The ESP Project Team consisted of representatives from Exelon, CH2M HILL, Parsons Energy and Chemical group (Parsons) and Geomatrix. All of these organizations were audited during preparation of the ESP application. The adequacy of these audits are addressed in Section 2.G. of this report.

Tasks performed by organizations not represented on the ESP Project Team were performed in conjunction with field investigations at the ESP site during the period of July 22 through August 28, 2002. During this period, CH2M HILL and Exelon quality personnel provided full surveillance coverage of subcontractor activities. Based on the audit and surveillance coverage identified above, the team concluded that oversight of contract activities for the preparation of the ESP application was adequate.

Peer Review

Prior to forwarding the ESP application to Exelon, CH2M HILL conducted an internal independent technical assessment of the data and reported findings. The assessment evaluated the collection process, performed verifying calculations, and reviewed the methodologies applied in developing the information to be submitted in support of the ESP application.

c. Conclusions

Based on review of the procurement documents associated with services supplied by Exelon's contractors and subcontractors in support of the Clinton ESP application, and discussions with project personnel, the team concluded that procurement activities for ESP activities important to safety were adequately controlled. In particular, the team determined that all activities were conducted in accordance with quality requirements invoked by contract specifications to ensure that quality assurance measures provided reasonable assurance of the integrity and reliability of site data used to support the ESP application.

2.D. Supplier Contractor Surveillance

a. Inspection Scope

The team reviewed project documentation and interviewed key project personnel with respect to activities conducted at the proposed ESP site to assess the adequacy of monitoring and control of ESP-related activities performed by contractors and suppliers.

b. Observations and Findings

The term “surveillance,” as used in this report, refers to observation by ESP quality project personnel of activities performed at the proposed Clinton ESP site. The bulk of these activities were performed during the period July 22 through August 28, 2002. Field activities performed during this period included the following:

- Three deep soil borings were advanced using mud rotary drilling methods. Soil sampling was conducted. Rock coring was advanced up to 30 feet into the bedrock in the deep boring. (Technical Services Corporation)
- Three groundwater piezometers were installed. (Technical Services Corporation)
- Four cone penetrometer test (CPT) soundings were advanced. Two of these included seismic wave CPT tests for measurement of shear wave velocity soil profile, in addition to the normal CPT side and end resistance measurements. The other two were piezocone CPT soundings, involving end, side, and pore pressure measurements. (Stratigraphics)
- One suspension logging test was conducted to log the shear wave velocity of the subsurface profile. (GEOVision)
- Each of the boring and sounding locations was surveyed for horizontal coordinates. Elevations of each location were measured by differential leveling. (Chastain)

Contractors performing ESP related activities were identified in the “ESP Project Activity Matrix,” which was provided to the NRC staff. Contractors on site during the field activities included:

- Testing Services Corporation, responsible for site borings, sample collection, and piezometer tests
- GRL Engineers, responsible for SPT measurements
- GEOVision Geographical Services, responsible for suspension logging tests to determine shear and compressional wave velocities

- Homer Chastain and Associates, responsible for collection, review, and preparation of the data for inclusion in the ESP application.

The CH2M HILL purchase orders for each of these contractors were reviewed by the team. With the exception of Technical Services and GRL Engineers, the contractors worked in accordance with the CH2M HILL PQP. Technical Services and GRL Engineers conducted activities in accordance with their internal quality plans. All quality plans were reviewed by the team.

In conjunction with the governing quality plans, site activities were controlled by a task-specific Geotechnical Field Workplan, prepared by CH2M HILL. The workplan was prepared by the CH2M HILL auditor. The workplan was reviewed/approved by the CH2M HILL senior geotechnical engineer assigned to the ESP project. This individual's qualifications included 30 years of geotechnical design and consulting experience with a PhD in Civil Engineering from the University of Michigan, as attested on his resume.

During the period of field activities, the CH2M HILL auditor was onsite full time and observed activities in progress on a daily basis. His field log for each of the days in which the subsurface investigations were conducted was reviewed by the team. The log documented the period from July 22, 2002 when the Technical Services Corporation drill rig arrived at the site through August 28, 2002, after the contractors had departed and the auditor secured the site.

In addition to surveillance activities which occurred during the performance of subsurface investigations, CH2M HILL conducted an audit while boring was in progress (July 31 - August 1, 2002). The audit was conducted by the CH2M HILL Project QA Manager, with technical assistance by the CH2M HILL senior geotechnical engineer. The scope of the audit included contractor compliance with the Geotechnical Field Workplan, in addition to applicable quality requirements.

The field notes documented a site visit by Geomatrix during field activities and a visit subsequent to field activities by a representative from the University of Texas. This individual was responsible for the resonant column/cyclic testing that was performed, the results of which are documented in the ESP application. The field notes also documented a site visit by NRR and Region III staff on August 7-8, 2002, to observe ongoing field activities. NRC staff observations for this visit were documented by staff memorandum dated September 9, 2002 (ADAMS Accession No. ML022530396).

c. Conclusions

Based on review of ESP program documentation which included the Field Geotechnical Workplan, the audit of field activities in progress, and documented daily surveillances, the team concluded that contractor activities involved with the subsurface investigation at the proposed ESP site were effectively controlled by responsible CH2M HILL project personnel.

2.E. Corrective Action

a. Inspection Scope

The team reviewed applicant and contractor procedures and instructions covering the identification and correction of the causes of significant deviations relating to site testing and data evaluation, and other ESP activities important to safety. The corrective action programs, and the identified problems, were reviewed for the identification and resolution of generic deviations and documentation of corrective actions.

b. Observations and Findings

The Exelon ESP project quality assurance instructions provided for controls on the identification and correction of ESP project conditions adverse to quality. Any conditions adverse to quality pertaining to the actions or functions specific to Exelon would be addressed either in accordance with the corrective action program identified in the PQP, or in accordance with the Exelon Nuclear corrective action program.

The PQP provided for the identification and correction of conditions adverse to quality. The PQP stated that for the identification of a significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to the appropriate level of management. The CH2M HILL QA Manager was responsible for the corrective action program, the implementing procedures, and for processing corrective actions. The team determined through interviews with the QA Manager and review of relevant documentation, that he possessed adequate training and qualification including knowledge of the corrective action process and the resolution of condition reports.

The team reviewed CH2M HILL project procedure DEL-015-2, "Corrective Action Program," Revision 2. The procedure provided instructions for establishing and operating a corrective action program and established processes and methods to be used to resolve issues. Documentation was required for the determination of the root cause of issues, the development and implementation of effective corrective action plans, and the performance of follow-up activities to determine if the corrective action had been effective in resolving the issue. The team determined the guidance in DEL-015-2 was adequate for the conduct of a corrective action program.

The team reviewed all of the corrective action reports (CARs) that were generated during Exelon ESP activities including subsequent actions to obtain resolution of identified issues. The team also discussed some observations with the CH2M HILL QA Manager. For the majority of the condition reports, the proposed corrective action and subsequent resolution were found to be adequate to address the identified problem. The team did note that all of the condition reports were generated by the auditor performing the audit. None of the condition reports were generated by personnel that conducted ESP activities. The team also noted an instance in which CH2M HILL had not initially documented the root cause of an adverse condition. This deficiency was identified to CH2M HILL by the applicant and subsequently corrected. In addition, the team noted that the CAR form had the corrective action approved by the project manager with a proposed resolution date. However, the form only had a “yes” or “no” response for when the corrective actions were completed. The team pointed out that it would have been useful if procedure DEL 015-1 included instructions to insert the date when the corrective action was completed. Finally, an Exelon audit identified many adverse findings related to procedural deficiencies identified during the early stages of ESP activities. Exelon ensured the findings were corrected. The team determined that the findings identified above did not have a significant impact on ESP activities and were adequately resolved.

c. Conclusions

The team verified that the applicant and associated subcontractors followed the guidance in the governing procedures and documents and adequately implemented a corrective action program. The corrective action program met the guidance in Section 17.1.1 of RS-002.

2.F. QA Record Control

a. Inspection Scope

For specific organizations with QA/QC responsibilities, the team conducted reviews to verify that procedures and instructions for the generation, control, and use of QA records addressed appropriate attributes of QA record control. To accomplish this inspection, project procedures were reviewed to determine records management requirements applicable to QA records to verify that the applicant’s records management requirements were consistent with the guidance in Section 17.1.1 of RS-002. Records management requirements applicable to the applicant’s prime contractor and subcontractors were also reviewed. Audit reports were reviewed for issues and corrective actions related to records. Procedures for turnover of contractor documents to the applicant were reviewed.

b. Observations and Findings

Exelon

Exelon Procedure AP-AA-1000, "Early Site Permit Project Quality Assurance Instruction," Revision 0, listed the ESP PQP elements, including Quality Assurance Records. The Instruction stated that the PQP shall include controls for the identification, retention, and maintenance of ESP project records.

Exelon procedures associated with records retention were reviewed. Procedure RM-AA-101-1004, "Standard Records Retention Schedule," Revision 2, provided general guidance on retention of records. Records were classified as Lifetime or Nonpermanent according to criteria in the procedure. The procedure required review of nonpermanent records to determine an appropriate retention period; a documented review had not yet occurred for ESP records. Exelon stated that they intend to retain ESP related QA records until and unless they decide to use the ESP in support of a combined license (COL) application. If the decision is made to reference the ESP in a COL application, the ESP records will be turned over to the COL project.

The team reviewed Exelon requirements imposed on contractors for turning over ESP quality records to Exelon. Procedure AP-AA-1000, Section 4.2, paragraph 17, required that Exelon Nuclear, at ESP project completion, take possession from the lead contractor of all applicable ESP project documentation in accordance with Exelon Nuclear records retention and storage processes. Exelon stated that CH2M HILL does not have an explicit written internal requirement regarding turnover of records to Exelon. However, Article 27 of the Services Agreement, dated April 19, 2002, between Exelon and CH2M HILL required the contractor to provide Exelon all information and documentation within the contractor's scope of services and which is required by Exelon for design, construction, licensing, quality assurance, operation, or maintenance of the services or of the facility for which the services are intended.

CH2M HILL

The PQP was prepared by CH2M HILL for Exelon. Section 2.17, which addressed QA records, stated that records required for the quality program shall be controlled and that sufficient records shall be maintained to furnish evidence of activities affecting quality. The PQP also listed the types of records required to be controlled as quality records.

CH2M HILL Project Procedure, Del-021-2, "Quality Assurance Records", Revision 2, established instructions for identifying, storing, retrieving, protecting, retaining, and disposing of project QA records. This procedure outlined responsibility for QA records for project managers, the document control manager, and record keepers. It also provided a listing of categories of quality assurance records, and provided requirements for storage and protection, retrieval, and disposition of quality records. For example, it required that record

keepers consider security, fire, and environment (heat and humidity) prior to storing records.

Records retention requirements for CH2M HILL were also reviewed. Section 3.5 of CH2M HILL procedure Del-021-2 stated that retention time of all quality records shall be defined. It referred to the CH2M HILL online records management retention schedule, which contained specific retention requirements for project files (records documenting substantive project documentation, including calculations, reference material, preliminary drawings and reports, project contracts, documentation of any client requirements, etc.). These records are to be maintained for the active length of a project plus 6 years. Work products and deliverables are to be retained for periods of 6 to 15 years after the active period of a project, depending on the type of record. The team also reviewed the CH2M HILL Quality Record Log for ESP deliverables. This log showed specific CH2M HILL retention periods for ESP records that appeared to be consistent with those specified in the online records management retention schedule. CH2M HILL personnel interviewed stated that services agreements (contracts) with clients govern retention requirements for records developed by CH2M HILL associated with clients' projects. Several line entries in the online retention schedule related to project records contained language consistent with these statements.

CH2M HILL project procedure Del-056-0, "Document Control," Revision 0, provided guidance on document control. This procedure described assignment of a document control authority and provided document control requirements, including requirements for electronic media storage and backup, and creation and maintenance of a document log.

CH2M HILL project procedure Del-013-2, "Document Creation, Peer and Technical Review," Revision 2, provided guidance on document creation and the peer and technical review process. This procedure provided requirements for the control of distribution of documents and approval of documents. The team noted that the procedure gave responsibility to the project manager to determine who has the authority to approve documents within a specific area or project.

CH2M HILL project procedure Del-055-0, "Project Analyses and Calculations," Revision 0, established requirements for developing, analyzing, and verifying computations; for controlling issuance and revisions of these computations and resulting data; and for identifying permit interface activities. Section 3.9 of this procedure stated that documentation generated during the analyses and calculations (e.g., assumptions, reference material, calculations, analyses, verifications) shall become quality records and shall be processed in accordance with the Quality Assurance Records project procedure.

Interviews with cognizant Exelon and CH2M HILL staff indicated that responsibility for quality records had not been turned over to Exelon. At the time of the inspection, the records resided on a secured computer server in the CH2M HILL offices in Idaho Falls, Idaho. The CH2M HILL Document Control Manager (DCM) stated that she controlled access and storage of the records. She stated

that the server containing the documents was housed in a secure room that was locked at night and that the room contained a fire suppression system. She stated that security, fire, and environmental considerations were taken into account in the storage of the records. She also stated that the electronic records were backed up nightly. The team noted that there did not appear to be any documented process or form in place for controlling access to the records other than the need to go through the DCM.

Audit reports were reviewed for records management issues. An internal CH2M HILL audit, dated September 30, 2002, identified that records control procedure Del-021-1 did not conform to the project record management process. The audit was halted and the procedure revised. A follow-up audit conducted on February 4, 2003, found that record and control processes were in place and effective at documenting, filing, and storing records, but that there were process improvement opportunities in record management. Del-021 was found to satisfy all requirements for identification, storage, protection, retrieval, retention, and disposition. Four recommendations were made: (1) that lists and processes found in the original instruction be updated and incorporated into the record control procedure, (2) that only one entry be created for each form type to indicate retention requirements, (3) that project task leads screen their activities and identify records created to ensure a complete set of project records is identified, and (4) that all records be archived immediately upon project close out in the long-term storage facility. The team questioned whether a follow-up to this audit had occurred and whether the recommendations had been implemented. Exelon personnel indicated that some of the recommendations were being implemented (in particular, regarding screening for records), though they added that there was no documentation of the follow-up because the items were only recommendations.

A CH2M HILL internal audit, dated June 11, 2002, of document and record control identified several nonconformances. Of relevance to records management was a nonconformance that the project instruction did not address documentation requirements. CH2M HILL records indicated that corrective action was taken to incorporate issuance and control of documents in project processes, and follow-up verification was approved by the QA Manager on August 2, 2002. Another nonconformance stated that the authority of individuals responsible to review and approve documents was unclear. Corrective actions were identified to revise project instructions to inform users of authorized report reviewers and of the document approval process. The QA Manager approved the follow-up verification of these corrective actions on March 19, 2003.

Finally, the team reviewed the reports of the final review of the seismic sections of the SSAR and supporting documents and the CH2M HILL peer review and found that the results of the reviews were documented.

Regarding work done by CH2M HILL subcontractors for seismic and geotechnical studies, the team reviewed the CH2M HILL seismic workplan, "Workplan for Seismic and Geotechnical Studies and Investigations," 300.345f.017-1, Revision 3. This workplan outlined the program of seismic

hazard and geotechnical studies and investigations that was implemented as part of the Exelon ESP application for the Clinton ESP site. This document governed work done by GEOVision Geophysical Services, Geomatrix Consultants, Inc., Statigraphics, Homer Chastain and Associates, and GRL Engineers, Inc. The work plan contained a section on Quality Assurance which stated that the seismic and geotechnical work would be carried out in accordance with the PQP for the project. Section 4.2 of this workplan stated that results of all tasks within the scope of the workplan would be summarized in one or more reports that would include information necessary for the Site Safety Analysis Report and the Environmental Report. The workplan also provided expectations for the content of the reports. Among the required contents were results of analyses, field explorations, and laboratory testing. The plan also required descriptions of methods and assumptions for each work area, as well as inclusion of supporting information such as reference lists, boring logs, and seismic velocity measurements.

Testing Services Corporation

TSC performed site borings, sample collection, and piezometer installation. The team reviewed their "Soils and Aggregate Testing Laboratory Quality System Manual," dated March 12, 2001. The TSC quality manual included provisions for control of quality records.

Parsons

Parsons assembled the SSAR. Section 11.0, "Quality," of the Parsons Project Administration Manual for the CH2M HILL project was reviewed. Subsection 11.9 of this document required maintaining project records to furnish evidence of "QA activities affecting quality." It stated that accumulation, control, and maintenance of QA records relating to the project shall be controlled with the project documentation or by the Nuclear Quality Assurance Manual as appropriate.

c. Conclusions

The team concluded that procedures and instructions for generation, control, and use of QA records met the guidance in Section 17.1.1 of RS-002. The applicant and contractor procedures addressed the types of records required, standards for quality of records, and measures for protection and preservation of records.

2.G. Audits

a. Inspection Scope

The team verified that the applicant (and each contractor with QA/QC responsibilities) had detailed procedures/instructions covering the preparations for, and the conduct of, audits. The team reviewed completed audits to verify that these controls had been adequately implemented.

b. Observations and Findings

Exelon

Exelon's ESP quality assurance instructions stated that Exelon may perform audits of the lead subcontractor's implementation of the PQP. The PQP included guidance for subcontractors to conduct audits. The audit conducted by Exelon personnel applied guidance from existing Nuclear Oversight (NOS) Department procedures. The team reviewed the qualifications of the Exelon personnel that conducted the audit. All audit personnel had adequate qualifications.

Procedures were in place for the conduct of audits regarding internal CH2M HILL activities, including project subcontractors. Audit deficiencies were documented in the applicant's corrective action process (see Section 2.E of this report for details on corrective action). Some contractors were not audited since they were operating under their own previously accepted 10 CFR Part 50, Appendix B, quality processes (Parsons), including subcontractors whose portions of the ESP project were of short duration.

The team reviewed the results of audit number 1209977, dated September 11, 2002, that documented an internal audit to assess the adequacy and implementation of the CH2M HILL quality assurance program. The audit was performed using the process developed by NUPIC. The NUPIC approved Checklist, Revision 10, was used as a guide. Of the five CARs that were generated, three were administrative in nature. One finding stated that training requirements were not pre-defined, as required by the CH2M HILL quality assurance plan. Another CAR addressed a finding that two out of six root causes were not stated on the corrective action document.

In addition to the internal audit, Exelon conducted a performance assessment. The team reviewed the October 10, 2003, memorandum, "Transmittal of ESP Project Quality Assessment Report." The report detailed the assessment performed of the ESP quality program. The quality assurance areas assessed included the project quality plan structure, the quality assurance organization, document controls, design controls, record controls, contractor surveillances, audits, and the corrective action program. This assessment was conducted following completion of work related to ESP activities and compilation of the ESP application.

The Exelon assessment concluded that the project quality controls were adequately implemented as described in the quality framework documents and provided reasonable assurance of ESP application quality. Ten findings and four enhancements were identified during the assessment.

The team discussed the process used to conduct the assessment with the Exelon lead corporate assessor for NOS. A unique template was developed to conduct the assessment from existing NOS procedures. The subsequent report was also issued to the ESP subcontractors involved.

The team reviewed the findings and enhancements detailed in the report. None of the items had a direct impact on data or calculations and were generally of an administrative nature.

CH2M HILL

The PQP provided that planned audits shall be conducted to verify compliance with the quality assurance program to determine the effectiveness of the program. Procedure DEL-016-2, "Quality Audit Program," Revision 2, outlined the administration and implementation of the audit program. Procedure guidance covered personnel responsibility, internal auditor training requirements, development of an audit schedule, and audit documentation. Procedure Del-016-2 referenced procedure DEL-015-2, "Corrective Action Program," Revision 2, to address processing of audit findings.

The team reviewed the qualifications of the CH2M HILL personnel that conducted audits. All audit personnel had adequate qualifications.

The team reviewed the following audits conducted by CH2M HILL:

- The team reviewed a memorandum dated June 11, 2002, that documented the results of an internal audit of document and record control of the ESP application project. The audit concluded that the document control system had not clearly addressed all requirements for the internal control of the creation, approval, revision and distribution of documents but that the processes and procedures established were capable of doing so with some modifications. There were six corrective action reports (CARs) that were generated.
- The team reviewed a memorandum dated August 1, 2002, that documented the results of an internal audit of the work plan for subsurface investigation. The audit concluded that the work plan adequately addressed the activities at the work site and that it provided sufficient guidance to workers and contractors. Five CARs were generated that were related to the work instructions utilized, most of which were minor in nature.
- The team reviewed a memorandum dated September 19, 2002, that documented the results of an internal audit of Geomatrix, Incorporated. The audit concluded that Geomatrix generally conformed to the requirements of the PQP and the work plan. One CAR was generated that was administrative in nature.
- The team reviewed a memorandum dated September 23, 2002, that documented the results of an internal audit of Testing Services Corporation, a soil testing subcontractor to CH2M HILL. The audit concluded that Testing Services Corporation's quality program was consistent with the ASTM D3740 guidance. Two CARs were generated. One of the CARs stated that the dates for calibration provided on some

certificates in the quality manual were outside the periodicity range for the equipment calibration. However, a valid certificate was available at another office. The other CAR was administrative in nature.

- The team reviewed a memorandum dated February 4, 2003, that documented the results of an internal audit of the peer review plan. The audit concluded that the peer review process as documented in the peer review plan was adequately documented and implemented. One CAR was generated and was considered administrative in nature.
- The team reviewed a memorandum dated May 28, 2003, which documented CH2M HILL's response to an internal audit of software controls. Two CARs were generated and were considered administrative in nature.

Board of Review

An independent board of review assisted the project team during the seismic work. The board of review was used to review the implementation plan for the seismic hazard work, the interim results of the work, and the conclusions reached during the work.

The team reviewed the memorandum, "Exelon Early Site Permit Application Final Review of Seismic Sections of SSAR and Supporting Documents," dated September 25, 2003, that was the board of review's product. The review involved checking Sections 2.5 and 3.4 of the SSAR and providing feedback. The team reviewed the qualifications of the members of the board of review and found their qualifications to be adequate.

Independent Review of the SSAR

In addition to the routine audits and performance assessments detailed above that were conducted, Exelon had Sargent & Lundy (S&L) and Idaho National Engineering and Environmental Laboratory (INEEL) perform an independent review of draft SSARs. Exelon developed a guidance document, "Independent Technical Evaluation of Draft Early Site Permit Application," dated November 8, 2002, for the conduct of the independent review. The scope of the review included all documents and information, including reference material, that formed the entire submittal of the ESP application. S&L conducted an overall review. The focus of the INEEL review was the geotechnical report and supporting information.

c. Conclusions

The team concluded that the internal audits, performance assessment and independent reviews of the SSAR were conducted in accordance with procedures, at an appropriate frequency, by qualified personnel and were of sufficient scope and depth to meet the guidance in Section 17.1.1 of RS-002.

3. 10 CFR Part 21 Applicability

The team identified one open item regarding an issue which was not addressed during the inspection but which will require follow up action at a later time. The open item involves the applicability of 10 CFR Part 21, "Reporting of Defects and Noncompliance," to the Exelon ESP project. The open item stems from an NRC workshop held on August 27, 2003, on the NRC's Construction Inspection Program Framework Document. During that workshop, an Exelon representative asked a question about NRC Inspection Procedure 35002, "Early Site Permit Pre-Docketing Quality Assurance Controls Meeting," that referred to 10 CFR Part 21 reporting requirements. The Exelon representative stated that he did not believe that 10 CFR Part 21 applied to ESP applicants. During that meeting, the NRC staff stated that it believed that 10 CFR Part 21 does apply to ESP applicants but that the staff would evaluate Exelon's statements after the workshop and respond to Exelon's question in more detail. This issue is identified as Open Item 52-007/2004-01-02, "Applicability of 10 CFR Part 21 to ESP applicants."

Management Meetings

Exit Meeting Summary

The inspectors presented the inspection results to members of the applicant's management at the conclusion of the inspection on January 16, 2004. The licensee acknowledged the findings presented.

Documents containing proprietary materials were reviewed during the inspection. The team assured the applicant's management that proprietary information would be properly controlled.

SUPPLEMENTAL INFORMATION

KEY POINTS OF CONTACT

Applicant

Marilyn Kray, Vice President, Project Development
Rod Krich, Vice President, Licensing Projects
Tom Mundy, Director, Project Development
Eddie Grant, Licensing Contact

CH2M HILL

Amy Lientz, Project Manager
Kristie Hicks, Document Control Manager
Don Chapman, QA Manager
Marilyn Paarmann, Reference Lead
Bernie Holcomb, Emergency Plan Lead
Pat Ervin, Purchasing Planning Lead
Don Anderson, Seismic Lead
Matt Gavin, Field Work Lead
Louise Melchor, Emergency Report

Sub-Contractors

John Ioannidi, Parsons Project Manager
Robert Youngs, Geomatrix Project Manager

LIST OF ITEMS OPENED, CLOSED AND DISCUSSED

Opened

52-007/2004-01-01, Validation Requirements for Web Site Data used in License Applications
52-007/2004-01-02, Applicability of 10 CFR Part 21 to ESP Applicants

DOCUMENTS REVIEWED

Procedures Used to Implement QA Measures - Exelon Nuclear

- RM-AA-102, Control of Documents (Rev. 2)
- RM-AA-101, Records Management Program (Rev. 6)
- LS-AA-117, Written Communications (Rev. 1)
- SM-AA-1017, Supplier Performance Monitor (Rev. 0)
- AD-AA-101, Processing of Procedures and T&RM's
- LS-AA-125, Corrective Actions (CAP) Procedures
- AP-AA-1000, Early Site Permit Project Quality Assurance Instruction (Rev. 0)
- AP-AA-1001, Acceptance Review of Contractor Prepared, Early Site Permit Application (Rev. 0)
- AP-AA-100, Early Site Permit Project Manual (Rev. 0)
- AP-AA-10, Process Description, Advanced Plant Process Description (Rev. 0)
- DD-16, Department Description, Advanced Plant Process Description (Rev. 0)
- RM-AA-101-1004, Standard Records Retention Schedule (SRRS) (Rev. 2)

Procedures Used to Implement QA Measures - CH2M HILL

- DEL-012c, Exelon Early Site Permit Application Quality Plan (Rev. 1)
- DEL-012-4, Project Quality Plan for Exelon Early Site Permit (Rev. 4)
- DEL-013-2, Project Procedure, Document Creation, Peer and Technical Review (Rev. 2)
- DEL-014-2, Control of Subcontractor Quality (Rev. 2)
- DEL-015-2, Corrective Action Program (Rev. 2)
- DEL-016-2, Quality Audit Program (Rev. 2)
- DEL-017-0, Test Control Program (Rev. 0)
- DEL-018-2, Control of Measuring and Test Equipment (Rev. 2)
- DEL-021-2, Quality Assurance Records (Rev. 2)
- DEL-027-4, Technical Editing and Formatting Procedure (Rev. 4)
- DEL-042-0, Control Software (Rev. 0)
- DEL-054-0, Handling, Storage, Shipping and Presentation (Rev. 0)
- DEL-055-0, Project Analyses and Calculation (Rev. 0)
- DEL-056-0, Documentation Control (Rev. 0)
- DEL-085-1, Exelon Early Site Permit Application CH2M HILL Peer Review Process Plan(Rev. 1)
- 200.220.059-4, Project Instructions for Exelon Early Site Permit Application (Rev.4)
- 200.245.100, Revision to Quality Plan (Technical Memorandum - 8/21/02)

Procedures Used to Implement QA Measures - Geomatrix

- Workplan for Seismic and Geotechnical Studies and Investigations (Rev.3)

Procedures Used to Implement QA Measures - Parsons

- EP-1: Design Criteria/Input (Rev. 1)
- EP-3: Engineering Calculations (Rev. 0)

- EP-4: Computer Program Verification and Validation (Rev. 2)
- EP-4NS: Nuclear Supplement to EP-4, (Rev. 0)
- EP-9: Design Review and Approval (Rev. 1)
- EP-12(N): Design Verification (Rev. 1)
- EP-14(N): Computer Program Error Reporting (Rev. 0)
- QP-4: Indoctrination and Certification of Personnel Performing Quality Related Activities (Rev. 2)
- Project Administration Manual, Early Site Permit Application for Advanced Nuclear Reactor Design (Rev.0)

Training Documents - CH2M HILL

- Internal Audit Course, A HSE&Q Program Presentation (presentation slides)
- Internal Auditor Training Roster (8/14/02)
- Peer Review Process Training for Exelon ESP Application Roster (12/03/02)
- Peer Review Process Training for Exelon ESP Application Task List (12/05/02)
- ESP Application Documentation Review and Revisions Processes Training Roster (9/17/02)
- CH2M HILL ESP Training Matrix

Training Documents - Geomatrix

- ESP Application, Document Review and Revision Processes Training Roster (9/17/02)
- CH2M HILL Exelon ESP Application Quality Plan, review and signed Geomatrix staff

Training Documents - Parsons

- Indoctrination Records of key personnel

Training Documents - TSC

- TSC Training Record issued by American Association of State Highway and Transport Officials
- TSC Training Record issued by Illinois Department of Transportation, Carol Stream

Audit Documents - Exelon Nuclear

- Supplier Evaluation Services Department, Audit Report No. 1209977 (9/11/02)

Audit Documents - CH2M HILL

- RAI01 613, Assessment of Processes (Audits)
- Internal Audit Report of Geometric, Inc (Memorandum - 9/19/02)
- Internal Audit on Record Control for Exelon (Memorandum - 9/17/02)
- Internal Audit of Document and Record Control of ESP Application Project (Memorandum - 6/11/02)
- Internal Audit of Work Plan for Subsurface Investigation (Memorandum - 6/11/02)

- Internal Audit of Peer Review Plan (Memorandum - 2/04/03)

Audit Documents - Parsons

- PPL Audit # 2003-064 (NUPIC Audit #18640)
- South Carolina Electric & Gas Company Memorandum, NUPIC joint Audit Report (NUPIC AUDIT # 17828)

Purchase Order - Exelon Nuclear

- CH2M HILL

Purchase Orders - CH2M HILL

- University of Texas, Austin (7/14/03)
- Stratigraphics (8/7/02)
- GRL Engineers (9/4/02)
- TSC (8/7/02)
- Geometrix (7/29/02)
- Parsons (7/22/02)

Exelon Nuclear Documents

- Request for Proposal (10CFR52, Subpart A, Early Site Permit Application Preparation for Advanced Nuclear Reactor Designs-1/29/02)
- Services Agreement, Exelon and CH2M HILL, dated 4/19/02
- Exelon Key Personnel Resumes

Contractor Documents - CH2M HILL

- Software Matrix - Exelon ESP Application (200.243.158 updated 1/9/04)
- Response to Exelon Request for Proposal (Section B.2 -1/29/02)
- Field Investigation Daily Log for Projects N. 171881.51.02.01 (7/22/02-10/14/03)
- Review and Approval of GRL Engineers, Inc. Quality Manual (Dec. 30, 2003)
- Final Invoice CH-720843 Memorandum (GRL Engineers, Inc Quality Manual) (9/13/02)
- Exelon Early Site Permit Seismic Sections of SSAR and Supporting Documents (Memorandum - 9/25/03)
- Clinton ESP Seismic Board of Review Conference Call Notes (11/26/02)
- Exelon ESP, Clinton, Illinois Seismic Site Response Comparison (Technical Memorandum - 8/05/03)
- Exelon Early Site Permit Application CH2M HILL Peer Review Action Items(12/13/02)
- CH2M HILL Software Approval (Technical Memoranda)
- CH2M HILL Key Personnel Resumes

Contractor Documents - Geomatrix

- Technical Memorandum, Approval of Software used in ESP Application (01/07/04)

- Geomatrix Consultants, Inc., Seismic Hazard Software Package Verification (1/09/02), prepared for SAICA
- Geomatrix Key Personnel Resumes

Contractor Documents - Parsons

- Technical Memorandum, Approval of Software for use in ESP Application (6/05/02)
- E&C Memorandum, Transmittal of Software Verification Documentation (10/10/02)
- E&C Memorandum, Preparation for Advanced Nuclear Reactors NRCDOSE Software Verification (8/12/02)
- Parsons Key Personnel Resumes

Contractor Documents - GRL Engineering, Inc.

- Quality Assurance and Quality Control Plan (1998, 2001, 2002, 2003)
- GRL to CH2M HILL Memo Re: QA Program, GRL Job No. 27049 - (12/11/03)
- PDA Pile Driving Analyzer Calibrations Records (07/10/01)
- Calibration Data Sheet for SPT Calibration Strain Gauges (07/10/01)
- GRL Key Personnel Resumes

Contractor Documents - TSC

- TSC Soils and Aggregate Testing Laboratory Quality System Manual (2001)
- Review and Approval of TSC Quality Manual

Contractor Documents - Stratagraphics

- Cone Penetrometer Contractor Section Backup(Qualification Information)

Contractor Documents - University of Texas

- UT Report, Linear and Nonlinear Dynamic Soil Properties Determined by Combined Resonant Column and Torsional Shear Tests: Exelon Generating Company ESP Site, Illinois, Vol. 2, Documentation of Calibration and Test Procedures, Geotechnical Engineering Report GR03-4 (5/09/03)
- Memorandum, Quality assurance requirements associated with dynamic laboratory testing at the University of Texas at Austin for the Exelon ESP Project (12/17/03)

LIST OF ACRONYMS USED

ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
CAR	Corrective Action Report
COL	Combined License
CPS	Clinton Power Station
DCM	Document Control Manager
EGC	Exelon Generation Company
EPA	Environmental Protection Agency
EPRI	Electric Power Research Institute
ESP	Early Site Permit
INEEL	Idaho National Engineering and Environmental Laboratory
ISO	International Organization for Standardization
LLC	Limited Liability Company
M&TE	Measuring and Test Equipment
NOAA	National Oceanic and Atmospheric Administration
NOS	Nuclear Oversight
NQA	Nuclear Quality Assurance
NRC	Nuclear Regulatory Commission
NRR	Nuclear Reactor Regulation
NRRL	Nuclear Required Records Lists
NUPIC	Nuclear Utility Procurement Issues Committee
OJT	On-the-Job-Training
PAM	Project Administration Manual
PO	Purchase Order
PPE	Plant Parameter Envelope
PQP	Project Quality Plan
PSHA	Probabilistic Seismic Hazard Analysis
QA	Quality Assurance
QAM	Quality Assurance Manual
QC	Quality Control
QMS	Quality Management System
RCTS	Resonant Column and Torsional Shear
RG	Regulatory Guide
RS	Review Standard
S&L	Sargent & Lundy
SOG	Seismic Owners Group
SPT	Standard Penetration Test
SSAR	Site Safety Analysis Report
SSC	Systems, Structures and Components
SSE	Safe Shutdown Earthquake
TSC	Testing Services Corporation
UT	University of Texas
V&V	Verification and Validation