

17. EARLY SITE PERMIT QUALITY ASSURANCE MEASURES

17.1 Introduction

The applicant (Exelon) chose not to supply information on the quality assurance (QA) measures it applied to the early site permit (ESP) activities described in its application. The applicant, responding to a request for additional information (RAI) from the U.S. Nuclear Regulatory Commission (NRC), subsequently submitted information on the QA measures Exelon and its principal contractors applied to ESP activities. The NRC staff conducted an inspection of the applicant's QA measures between January 12 and 16, 2004. Subsequently, the staff performed an in-office technical review to evaluate whether the applicant and its principal contractors had applied adequate QA measures. The staff also conducted a review to determine whether the applicant adequately applied the guidance in Section 17.1.1, "Early Site Permit Quality Assurance Controls," of Review Standard (RS)-002, "Processing Applications for Early Site Permits," Attachment 2, to demonstrate the integrity and reliability of the data obtained during ESP activities.

Under Title 10, Section 52.18, "Standard for Review of Applications," of the *Code of Federal Regulations* (10 CFR 52.18), the staff must review ESP applications in accordance with the applicable regulations of 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," and its appendices, as well as 10 CFR Part 100, "Reactor Site Criteria," as they apply to construction permits. The current regulations do not require ESP holders or applicants to implement a QA program compliant with the requirements of Appendix B to 10 CFR Part 50. However, the applicant is expected to implement QA measures equivalent in substance to the measures described in Appendix B to 10 CFR Part 50. This will provide reasonable assurance that any information derived from ESP activities which could be used in the design and/or construction of structures, systems, and components (SSCs) important to safety will support satisfactory performance of such SSCs once they are in service. Therefore, the staff evaluated quality measures for those activities associated with the applicant's generation of site-related information that could be used as input to the design of future SSCs to ensure that these measures can provide reasonable assurance of the integrity and reliability of the information, assuming that the applicant's QA measures are equivalent in substance to the criteria of Appendix B to 10 CFR Part 50.

In accordance with 10 CFR 52.79(a)(1), if an application for a combined license (COL) references an ESP, it must contain information sufficient to demonstrate that the design of the facility falls within the parameters specified in the ESP. Therefore, the ESP applicant must provide reasonable assurance of the reliability and integrity of the data contained in or supporting the ESP application, which in turn supports the COL application.

Conformance with the QA measures described in RS-002, Attachment 2, Section 17.1.1, provides reasonable assurance that the applicant used adequate QA measures to support its ESP application. The staff focused its review on whether the applicant's QA measures adequately addressed the guidance in Section 17.1.1 of RS-002, Attachment 2, for each applicable element (as determined by the applicant). The staff performed much of its evaluation in an inspection conducted in January 2004 and documented in Inspection Report 0520007/2004001 (ADAMS Accession No. ML040540622). For any element the applicant determined was not applicable, the staff verified that the ESP activities did not rely on

QA measures associated with that element. The review focused on the applicant and its primary contractor, CH2M HILL. Inspection Report 0520007/2004001 includes details on additional subcontractors involved in the Exelon ESP activities. Section 17.7 of this SER discusses the adequacy of the QA measures these additional subcontractors used.

In response to an RAI, the applicant submitted the description of the QA measures it applied to the ESP activities. The staff reviewed Exelon's general guidance to its subcontractors for the quality measures applied to ESP activities. Exelon's Instruction AP-AA-1000, "Early Site Permit Project Quality Assurance Instructions," Revision 0 (hereafter referred to as the instruction), states that activities related to the development of the application would be conducted in accordance with 10 CFR Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants." Exelon's subcontractors conducted their ESP activities in accordance with their own QA measures, by direction provided in procurement documents, or in accordance with the primary contractor's required QA measures.

17.1.1 Technical Information in the Application (Organization)

Exelon's application did not initially supply information about its QA organization, but the applicant subsequently provided this information in response to an RAI. The applicant's instruction identifies certain criteria of Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. The instruction states that the applicant would apply elements from these criteria or verify that the controls applied to the ESP activities reflect these elements. The applicant considered organization to be a criterion having elements associated with the control of ESP activities.

The instruction states that Exelon is responsible for the establishment and execution of an ESP project QA plan. Exelon typically delegates to others, such as contractors or consultants, the work of establishing and executing the QA plan, or part thereof, but retains overall responsibility.

The instruction further states that an appropriate level of Exelon management will have overall responsibility for the ESP project. Exelon management will have authority and responsibility to establish a program such that the persons and organizations performing QA functions have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; to verify implementation of solutions; and to have direct access to such levels of management as may be necessary to perform these functions. The instruction also states that individuals performing audits should possess experience, training, or background at least sufficient to assess the quality of the product provided by the contractor.

The CH2M HILL "Project Quality Plan for Exelon Early Site Permit" (hereafter referred to as the Project Quality Plan (PQP)) describes the organizational, programmatic, and procedural requirements intended to result in a complete and accurate application and states that the contractor will use, where appropriate, the pertinent elements of Appendix B to 10 CFR Part 50.

The PQP states that, while Exelon retains the overall responsibility for the completeness and accuracy of the information to be provided in support of obtaining an ESP, it delegated the initial gathering and analysis of that information to CH2M HILL. The PQP also establishes and

communicates the authority and duties of persons and organizations performing quality management and provides an organization chart.

17.1.2 Regulatory Evaluation (Organization)

While the applicant is not required to develop an organization to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002, Attachment 2, contains guidance for the staff to use in evaluating an ESP applicant's organization. The applicant's instruction outlines the elements of an organization that the applicant applied to its ESP activities.

Paragraph 17.1.1.1 in RS-002, Attachment 2, Section 17.1.1, provides the QA measures that constitute an acceptable organization. An acceptable organization should include (1) an organization description and charts of the lines, interrelationships, and areas of responsibility and authority for all organizations performing quality-related activities, including the applicant's organization and principal contractors, (2) the relative location of the QA organization, degree of independence from the organization performing ESP activities, and authority of the individuals assigned the responsibility for performing QA functions, and (3) the organizational provisions that exist for ensuring the proper implementation of QA controls.

17.1.3 Technical Evaluation (Organization)

17.1.3.1 Exelon

The PQP identifies the authority and responsibilities of persons and organizations performing quality management functions. The Exelon project manager is primarily responsible for directing the project staff to complete the ESP application.

The Site Safety Analysis Report (SSAR) Lead had overall responsibility for the technical content and completion of the report. The NRC staff interviewed individuals carrying out these responsibilities. Based on these interviews and the review of project documentation, the staff determined that the applicant's staffing for these positions is consistent with the descriptions in the PQP. The PQP also describes the assignment of responsibilities to lead technical positions for key project areas. Based on its review of the overall project documentation, the staff determined that the PQP accurately describes these positions.

The applicant developed procedures specific to ESP activities, as detailed in Inspection Report 0520007/2004001. The staff reviewed the program procedures and noted that the procedures meet the guidance in Section 17.1.1 of RS-002, Attachment 2. The applicant adequately described the ESP organization and personnel responsibilities.

The instruction indicates that Exelon is responsible for the establishment and execution of a project QA 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 instruction further indicates that Exelon management would ensure that persons and organizations performing QA functions had sufficient authority and organizational freedom to (1) identify quality problems, (2) initiate, recommend, or provide solutions, and (3) verify implementation of solutions. The instruction also indicates that Exelon management would ensure that persons and

organizations performing QA functions had direct access to any level of management necessary to perform these functions.

The staff interviewed Exelon QA audit personnel who conducted the audits of ESP activities and reviewed their personnel training records. The applicant indicated that Exelon project staff received on-the-job training related to ESP activities. However, the applicant did not develop formal training plans or maintain training records. The applicant stated that it assembled personnel for the project whose experience precluded the need for formal training. The staff reviewed the resumes of several Exelon ESP project personnel. The resumes demonstrate satisfactory experience and education for each of the individuals reviewed.

17.1.3.2 CH2M HILL

The staff reviewed the CH2M HILL PQP. The applicant indicated that the PQP, prepared by CH2M HILL and reviewed by Exelon, provides quality controls to ensure that the Exelon ESP application was prepared under quality practices commensurate with the intended use of the application and its content. CH2M HILL prepared procedures for those quality functions the PQP described. The staff reviewed several CH2M HILL procedures in detail, as described in Inspection Report 0520007/2004001, to ensure the adequacy of the procedures to perform their stated purpose. The staff also determined that the procedures adequately identified the organizational roles and responsibilities regarding managerial and administrative controls for the project.

The staff reviewed training and qualification records for CH2M HILL personnel and other contractors involved in Exelon ESP-related activities. The staff also reviewed the CH2M HILL organizational structure and personnel responsibilities. The staff did not identify any issues.

17.1.4 Conclusion (Organization)

As set forth above, the staff reviewed the applicant's QA measures and those of its primary contractor and concluded that both Exelon and CH2M HILL have implemented an acceptable organization which meets the guidance in Section 17.1.1 of RS-002, Attachment 2, and helps provide reasonable assurance that any information derived from ESP activities that could be used in the design and/or construction of SSCs important to safety will support satisfactory performance of such SSCs once they are in service.

17.2 Quality Assurance Program

17.2.1 Technical Information in the Application (QA Program)

Exelon's application did not initially supply information about the QA program, but the applicant subsequently provided this information in response to an RAI. The applicant's instruction identifies certain criteria of Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. The instruction states that the applicant would apply elements from these criteria or verify that the controls applied to the ESP activities reflected these elements. The applicant considered the QA program to be a criterion having elements associated with the control of ESP activities.

The instruction states that Exelon will establish, for each ESP project, a PQP that complies with the requirements of this procedure and includes relevant and instructive elements from the criteria in Appendix B to 10 CFR Part 50 identified herein. This PQP will also include other controls and criteria that the Exelon project management has determined to be necessary or desirable.

The instruction states that the primary contractor retained by Exelon to prepare the ESP application will typically prepare the PQP and associated subtier documentation and Exelon ESP project management will approve these documents. The primary contractor's PQP describes the organizational, programmatic, and procedural requirements intended to result in a complete and accurate application and states that the contractor will use, where appropriate, the pertinent elements of Appendix B to 10 CFR Part 50.

The PQP details the quality processes that define the QA program. Attributes of the QA program include (1) creating the PQP to identify the applicable quality requirements, (2) establishing document and record control programs, (3) selecting personnel for the project based on knowledge, skills, and abilities, (4) conducting or directing audits, (5) reviewing reports, and (6) researching project contract requirements.

17.2.2 Regulatory Evaluation (QA Program)

While the NRC does not require a QA program to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002, Attachment 2, contains guidance for the staff to use in evaluating an ESP applicant's QA program. The applicant's instruction describes the elements of a project QA plan that the applicant applied to ESP activities.

Paragraph 17.1.1.2 in Section 17.1.1 of RS-002, Attachment 2, provides the QA measures that constitute an acceptable level of control for ESP activities. The QA program should include (1) a scope of QA controls adequate to ensure that appropriate quality controls are applied to all site characterization data related to the design and analysis of SSCs important to safety that might be constructed on the proposed site, (2) provisions to ensure proper definition of QA controls, and (3) provisions to ensure the adequacy of personnel qualifications.

17.2.3 Technical Evaluation (QA Program)

This section of the safety evaluation report (SER) documents the staff's evaluation of the applicant and its primary contractor's overall QA program description. The following sections of this SER provide a detailed review and evaluation of each applicable portion of the program.

17.2.3.1 Exelon

The staff reviewed the applicant's instruction, which describes the elements of the ESP QA plan prepared by CH2M HILL. The instruction identifies the pertinent elements of the criteria stated in Appendix B to 10 CFR Part 50 that apply to controls for the ESP application. The instruction also identifies responsibilities for the establishment and execution of the PQP for the ESP by others, such as contractors or consultants. The instruction states that Exelon management retains overall responsibility for the project, including the responsibility for attaining quality objectives, and that persons and organizations with QA functions have the organizational

freedom to identify quality problems. Additionally, the instruction states that the individuals performing audits of the plan have the experience, training, or background necessary to assess the quality of the product provided by the contractor. The staff reviewed the resumes and training records of Exelon individuals involved with QA plan oversight and audit and found their qualifications and training to be adequate.

The staff reviewed Exelon procedure that provided general guidance to its subcontractors about the quality measures to be applied to ESP activities. The instruction states that Exelon will conduct activities related to the development of the application in accordance with 10 CFR Part 52. The applicant determined that the Exelon Nuclear Quality Assurance Topical Report does not apply to ESP activities. However, the applicant did determine that elements of certain criteria of Appendix B to 10 CFR Part 50 are applicable. As detailed in Inspection Report 0520007/2004001, Exelon delegated the ESP activities. Exelon's subcontractors conducted their ESP activities in accordance with their own QA measures, by direction provided in procurement documents, or in accordance with the lead contractor's required QA measures. The staff found the guidance provided by the instruction to be adequate as an overall guide for the conduct of ESP activities.

17.2.3.2 CH2M HILL

CH2M HILL led the compilation of information for the SSAR. CH2M HILL conducted such tasks as seismic analysis, QA audit activities, environmental report preparation, and contract preparation. The staff reviewed the PQP developed by CH2M HILL for the Exelon ESP project. The PQP describes the quality program for the development of the ESP application. The PQP states that CH2M HILL will develop the application in accordance with the requirements of 10 CFR Part 52. The PQP describes the project organization, quality objectives and criteria, and project quality processes. The PQP organizes the project quality processes around the criteria found in Appendix B to 10 CFR Part 50 that were to be applied to the ESP activities conducted by CH2M HILL. In addition, CH2M HILL developed procedures that amplify Exelon guidance on the conduct of ESP activities. Inspection Report 0520007/2004001 provides additional information on the staff's review of these procedures.

The PQP states that, while Exelon retained the overall responsibility for the completeness and accuracy of the information provided in support of obtaining an ESP application, it delegated the initial gathering and analysis of this information to CH2M HILL. The document further states that the PQP provides adequate controls to ensure that the Exelon ESP application was prepared under quality practices commensurate with the intended use of the application and its content. To that end, the PQP only applied, as necessary, certain elements of the criteria set forth in Appendix B to 10 CFR Part 50, as well as other quality standards. As stated in RS-002, Attachment 2, Section 17.1.1, an applicant may determine the applicable quality measures. The staff reviewed the quality measures CH2M HILL considered to be applicable and determined that these measures are adequate for the activities conducted in support of the Exelon ESP activities.

17.2.4 Conclusion (QA Program)

As set forth above, the staff reviewed the applicant's QA measures and those of its primary contractor and concluded that these measures form an acceptable QA program which meets

the guidance in Section 17.1.1 of RS-002, Attachment 2, and helps provide reasonable assurance that any information derived from ESP activities that is used in the design and/or construction of SSCs important to safety will support satisfactory performance of such SSCs once they are in service.

17.3 Design Control

17.3.1 Technical Information in the Application (Design Control)

Exelon's application did not initially supply information on design controls, but it subsequently provided this information in response to an RAI. The applicant's instruction identifies certain criteria of Appendix B to 10 CFR Part 50 that contain the elements associated with the control of ESP activities. The instruction states that the applicant would apply elements from these criteria or verify that the controls applied to ESP activities reflect these elements. The applicant did not consider design controls to be a criterion having elements associated with the control of ESP activities.

The instruction states that the PQP will include controls for the development of and/or changes to ESP project products. However, the instruction also states that, since no activities associated with SSCs are to be conducted under this project, no QA measures are necessary for the control of design processes.

The PQP of the primary contractor describes the organizational, programmatic, and procedural requirements intended to result in a complete and accurate application and states that the contractor will use, where appropriate, the pertinent elements of Appendix B to 10 CFR Part 50.

The PQP describes application development inputs, outputs, development review, and control of development changes. The PQP states that development of the ESP application will be planned and controlled. Development planning will determine (1) stages of the development process, (2) required review and verification and validation (V&V) activities appropriate to each development state, and (3) responsibilities and authorities for development activities. The PQP states the controls for development of inputs and outputs.

According to the PQP, interfaces between different groups involved in development are managed to provide effective communication and clear assignment of responsibilities. The PQP also states that documents prepared for the ESP application will be reviewed and approved, development changes will be identified, and records of the changes will be maintained.

In RAI 17.1.1-2, the staff asked the applicant to describe the QA measures it used to authenticate and verify any data important to safety that were retrieved from Internet Web sites and which support information in the SSAR that could affect the design, construction, or operation of SSCs important to safety. In its response, the applicant stated that the measures it relied on to authenticate data retrieved from Internet Web sites include formal documentation of the Internet Web site used, peer review of the resulting application information, and independent examination of the source.

17.3.2 Regulatory Evaluation (Design Control)

While the NRC does not require design controls to comply with the criteria in Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002, Attachment 2, contains guidance for the staff to use in evaluating an ESP applicant's design controls. The applicant's instruction details the design controls applied to ESP activities.

Paragraph 17.1.1.3 in Section 17.1.1 of RS-002, Attachment 2, provides the QA measures that constitute an acceptable level of design control. Acceptable design controls should include (1) the scope of activities that could affect design and construction activities for SSCs important to safety that might be constructed on the site, (2) a definition of the organizational structure, activity, and responsibility of the positions or groups responsible for design activities important to safety (if any), (3) provisions to carry out design activities important to safety in a planned, controlled, and orderly manner, (4) provisions for interface control between functional units of the applicant's organization, (5) provisions to verify the technical adequacy of design documents applicable to ESP activities that could affect SSCs important to safety, and (6) provisions to control design changes applicable to ESP activities that could affect SSCs important to safety.

17.3.3 Technical Evaluation (Design Control)

17.3.3.1 Exelon

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, including Parsons Power Group, Inc., Geomatrix Consultants, and GRL Engineers, Inc. The staff reviewed and verified the adequacy of design control activities for each of these companies. Section 17.7 of this SER provides additional details on this topic.

The staff evaluated the applicant's response to RAI 17.1.1-2 concerning the QA measures it used to authenticate and verify data that were retrieved from Internet Web sites and which support information in the SSAR affecting the design, construction, or operation of SSCs important to safety. In its response to the RAI, the applicant described the method used to authenticate or verify the data. The staff found this method of authenticating Internet Web site data to be acceptable. The staff will verify completion of the applicant's method of authentication as part of its inspection program before developing the final SER. The staff identified this item as Confirmatory Item 17.3-1.

17.3.3.2 CH2M HILL

Exelon delineated the ESP work scope and quality requirements for CH2M HILL in a contract, as detailed in Inspection Report 0520007/2004001. The work scope identifies specific sections of the ESP application for which CH2M HILL was responsible for performing design control activities supporting analyses, evaluations, and procurement, as well as for ensuring that personnel involved with the project were trained and knowledgeable about the QA design control requirements. The staff reviewed CH2M HILL procedures and interviewed the responsible project and QA managers.

The staff reviewed the PQP, which describes the quality program for the development of an ESP application and outlines the ESP organizational, programmatic, and procedural requirements. The PQP also defines responsibilities regarding the traceability and appropriateness of information before its use in any design document.

The staff reviewed the PQP, as it relates to design control for ESP activities. The PQP describes 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. The PQP describes ESP design control elements related to Appendix B to 10 CFR Part 50. The PQP also provides for quality processes in the communication of the quality requirements of the PQP to the project leads and training of personnel used to perform activities affecting quality. The PQP describes development planning to determine required review and V&V activities related to the ESP project. It also provides for determination of functional and performance requirements and applicable statutory and regulatory requirements. Additionally, it establishes criteria for the approval of development inputs and outputs and the review and control of development changes, including computer software control.

The staff also reviewed several CH2M HILL ESP design control procedures, as detailed in Inspection Report 0520007/2004001. The staff concluded that the design control measures described in the CH2M HILL PQP and other reviewed procedures and documents are adequate.

17.3.4 Conclusion (Design Control)

As set forth above, the staff reviewed the CH2M HILL QA control measures and concluded that, with the exception of the confirmatory item for authenticating data retrieved from Internet Websites, the contractor implemented acceptable design controls which meet the guidance of Section 17.1.1 of RS-002, Attachment 2, and help provide reasonable assurance that any information derived from ESP activities that is used in the design and/or construction of SSCs important to safety will support satisfactory performance of such SSCs once they are in service.

17.4 Procurement Document Control

17.4.1 Technical Information in the Application (Procurement Document Control)

Exelon's application did not supply information about procurement document control, but the applicant subsequently provided this information in response to an RAI. The applicant's instruction identifies certain criteria of Appendix B to 10 CFR Part 50 that contain the elements associated with the control of ESP activities. The instruction states that the applicant would apply elements from these criteria or verify that the controls applied to the ESP activities reflected these elements. The applicant considered procurement document control to be a criterion having elements associated with the control of ESP activities.

The instruction states that the PQP will include controls for the procurement of ESP project products (including services). The instruction further states that Exelon will contract with vendors to provide services in connection with ESP activities in accordance with appropriate Exelon nuclear supply management procedures for nonsafety-related services.

The PQP of the primary contractor describes the organizational, programmatic, and procedural requirements intended to result in a complete and accurate application and states that the contractor will use, where appropriate, the pertinent elements of Appendix B to 10 CFR Part 50.

The PQP states that measures will be established to assure that the documents for procurement of material, equipment, and services (whether purchased by CH2M HILL, its contractors, or its subcontractors) suitably include or reference the applicable regulatory, design bases, and other requirements necessary to assure adequate quality. The PQP further states that, to the extent necessary, procurement documents will require contractors or subcontractors to provide a QA program that is at least consistent with the pertinent provisions of the PQP.

17.4.2 Regulatory Evaluation (Procurement Document Control)

While the NRC does not require procurement document controls to comply with the criteria in Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002, Attachment 2, contains guidance for the staff to use in evaluating an ESP applicant's procurement document controls. The applicant's instruction details the procurement document controls it applied to ESP activities.

Paragraph 17.1.1.4 in Section 17.1.1 of RS-002, Attachment 2, provides the QA measures that constitute an acceptable level of procurement document controls. Acceptable procurement document controls should include (1) provisions to ensure that procurement documents related to ESP activities that could affect SSCs important to safety include or reference applicable technical requirements and QA controls, and (2) provisions for review and approval of procurement documents for ESP activities that could affect SSCs important to safety.

17.4.3 Technical Evaluation (Procurement Document Control)

17.4.3.1 Exelon

The Exelon project manager served as the contract administrator in authorizing all services procured under the ESP application contract. During review of the Exelon contract file governing the ESP application, the NRC staff interacted with the project manager and the contract specialist and found them knowledgeable about contract administration.

The staff reviewed the Exelon agreement, which authorizes the primary contractor's scope of work. The contract defines the scope of work to be performed. Quality requirements incorporated as part of the contract stipulate that the scope of work should ensure that individual tasks are accomplished with the appropriate level of quality controls, such that the quality of the data would not be questioned during their subsequent use in the COL process, as set forth in 10 CFR Part 52. The contract requires a detailed written description of the quality control practices employed and the corresponding data or information to which these controls were applied.

17.4.3.2 CH2M HILL

Exelon selected CH2M HILL 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 used for the ESP task to the extent applicable.

The proposal also specified that CH2M HILL would review and approve all reports and records required by the application before forwarding them to Exelon.

The NRC staff interviewed the CH2M HILL project manager and QA manager regarding authorization of subcontract procurement. The CH2M HILL project manager authorizes CH2M HILL procurement in coordination with the CH2M HILL procurement officer located in the CH2M HILL Tucson, Arizona, office.

Based on its review of procurement purchase orders and interviews with authorizing contract personnel, the staff found the authorizing individuals knowledgeable about Exelon's QA requirements. Section 17.7 of this SER discusses specific details of the procurement controls applied to each subcontractor.

17.4.4 Conclusion (Procurement Document Control)

As set forth above, the staff reviewed the QA measures employed by the applicant and its primary contractor and concluded that they have implemented an acceptable level of procurement document control which meets the guidance of Section 17.1.1 of RS-002, Attachment 2, and helps provide reasonable assurance that any information derived from ESP activities that is used in the design and/or construction of SSCs important to safety will support satisfactory performance of such SSCs once they are in service.

17.5 Instructions, Procedures, and Drawings

17.5.1 Technical Information in the Application (Instructions, Procedures, and Drawings)

Exelon's application did not initially supply information about the control of instructions, procedures, and drawings, but the applicant subsequently provided this information in response to an RAI. The applicant's instruction identifies certain criteria of Appendix B to 10 CFR Part 50 that contain the elements associated with the control of ESP activities. The instruction states that the applicant would apply elements from these criteria or verify that the controls applied to ESP activities reflect these elements. The applicant considered control of instructions, procedures, and drawings to be a criterion having elements associated with the control of ESP activities.

The instruction states that the PQP will include controls for ESP project activities to be conducted in accordance with documented instructions, procedures, or drawings for which ESP project management deemed such written controls to be necessary. In addition, the instruction states that Exelon activities required by the PQP shall be controlled by documented instructions, procedures, or drawings. The primary contractor describes in its PQP the organizational, programmatic, and procedural requirements intended to result in a complete and accurate application and will use, where appropriate, the pertinent elements of Appendix B to 10 CFR Part 50.

The PQP states that activities affecting quality will be prescribed by documented instructions, procedures, or drawings of a type appropriate to the circumstances and will be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings will include appropriate quantitative or qualitative acceptance criteria for determining

that important activities have been satisfactorily accomplished. Work processes will be documented to the level required to complete the work in a consistent manner that meets applicable guidance.

17.5.2 Regulatory Evaluation (Instructions, Procedures, and Drawings)

While the NRC does not require instructions, procedures, and drawings to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002, Attachment 2, contains guidance for the staff to use in evaluating an ESP applicant's instructions, procedures, and drawings. The applicant's instruction lists the controls for instructions, procedures, and drawings it applied to ESP activities.

Paragraph 17.1.1.5 in Section 17.1.1 of RS-002, Attachment 2, provides the QA measures that constitute an acceptable level of control for instructions, procedures, and drawings. Acceptable controls for instructions, procedures, and drawings should include (1) provisions for ensuring that ESP activities that could affect SSCs important to safety are prescribed by and accomplished in accordance with instructions, procedures, or drawings, and (2) provisions for including quantitative and qualitative acceptance criteria in instructions, procedures, and drawings related to ESP activities that could affect SSCs important to safety.

17.5.3 Technical Evaluation (Instructions, Procedures, and Drawings)

17.5.3.1 Exelon

The applicant developed program procedures specific to ESP activities, as detailed in Inspection Report 0520007/2004001. The staff reviewed the program procedures and noted that the procedures meet the guidance in Section 17.1.1 of RS-002, Attachment 2. Additionally, the staff discusses the adequacy of instructions, procedures, and drawings in other technical evaluation sections of this SER.

17.5.3.2 CH2M HILL

The staff reviewed the PQP. According to the applicant, CH2M HILL prepared the PQP, and Exelon reviewed it, to provide quality controls to ensure that the Exelon ESP application was prepared under quality practices commensurate with the intended use of the application and its content. CH2M HILL prepared procedures for those quality functions described in the PQP. The staff reviewed several procedures, as detailed in Inspection Report 0520007/2004001, to determine the adequacy of the procedures to perform the stated procedure purpose. The staff found that the instructions, procedures, and drawings developed and used for ESP activities are adequate.

17.5.4 Conclusion (Instructions, Procedures, and Drawings)

As set forth above, the staff reviewed the QA measures employed by the applicant and its primary contractor and concluded that they have implemented an acceptable level of control for instructions, procedures, and drawings which meets the guidance of Section 17.1.1 of RS-002, Attachment 2, and helps provide reasonable assurance that any information derived from ESP

activities that is used in the design and/or construction of SSCs important to safety will support satisfactory performance of such SSCs once they are in service.

17.6 Document Control

17.6.1 Technical Information in the Application (Document Control)

Exelon's application did not supply information on document control, but the applicant subsequently provided this information in response to an RAI. The applicant's instruction identifies certain criteria of Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. The instruction states that the applicant would apply elements from these criteria or verify that the controls applied to ESP activities reflect these elements. The applicant considered document control to be a criterion having elements associated with the control of ESP activities.

The instruction states that the PQP will include controls for issuance of documents related to the ESP project. The instruction also states that Exelon will provide controls for review and acceptance of completed project documents and that the PQP will establish methods for the control of changes to project documents, including a means for notifying appropriate individuals of document changes.

The PQP of the primary contractor describes the organizational, programmatic, and procedural requirements intended to result in a complete and accurate application and states that the contractor will use, where appropriate, the pertinent elements of Appendix B to 10 CFR Part 50. The PQP states that measures will be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality. These measures will assure that authorized personnel review documents, including changes, for adequacy and approved for release, and that these documents are distributed to and used at the location where the prescribed activity is performed. The same organization(s) that performed the original review and approval will review and approve changes to those documents, unless Exelon designates another responsible organization.

17.6.2 Regulatory Evaluation (Document Control)

While the NRC does not require document control to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002, Attachment 2, contains guidance for the staff to use in evaluating an ESP applicant's document controls. In the instruction, the applicant provided the document controls it applied to ESP activities.

Paragraph 17.1.1.6 in Section 17.1.1 of RS-002, Attachment 2, provides the QA measures that constitute an acceptable level of document control. Acceptable document controls should include provisions to ensure that documents related to ESP activities that would affect SSCs important to safety, including changes, were reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity was performed.

17.6.3 Technical Evaluation (Document Control)

A detailed discussion of the document controls applied by the applicant is given in Section 17.5 of this SER. In addition, each section of this SER details the specific documents reviewed and any relevant discussions of their adequacy. The staff considers the scope of the documents reviewed to be adequate for the ESP activities that were conducted. The staff reviewed documents that were reviewed and approved for issuance to ensure the document control process was followed. The staff confirmed that the applicant and its primary subcontractor had adequate controls in place to ensure the proper revision of a document.

17.6.3.1 Exelon

Inspection Report 0520007/2004001 discusses the staff's review of the applicant's document controls. The staff noted that procedures required that the Exelon ESP project management establish the necessary project documentation to control project activities consistent with regulatory requirements. The staff found that the procedures provide adequate guidance for document control, and the applicant had adequately implemented the procedural requirements.

17.6.3.2 CH2M HILL

Exelon selected CH2M HILL as its primary contractor for preparing the ESP application. In its proposal, CH2M HILL specified that it would apply the existing CH2M HILL QA program, which implements its QMS, for the ESP task to the extent applicable. CH2M HILL would also review and approve all reports and records required by the application before sending them to Exelon.

The CH2M HILL proposal specified that the company would develop and approve special procedures for controlling processes used in data collection and report generation in accordance with the CH2M HILL controlled document program. These special procedures, together with existing procedures from CH2M HILL, would be assembled 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. CH2M HILL applied the document control program 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. Inspection Report 0520007/2004001 details the staff's review of the adequacy of the primary contractor's procedures. The staff found the primary contractor's document controls to be adequate.

17.6.4 Conclusion (Document Control)

As set forth above, the staff reviewed the QA measures employed by the applicant and its primary contractor and concluded that they have implemented acceptable document controls, which meet the guidance of Section 17.1.1 of RS-002, Attachment 2, and help provide reasonable assurance that any information derived from ESP activities that could be used in the design and/or construction of SSCs important to safety will support satisfactory performance of such SSCs once they are in service.

17.7 Control of Purchased Material, Equipment, and Services

17.7.1 Technical Information in the Application (Control of Purchased Material, Equipment, and Services)

Exelon's application did not initially supply information about control of purchased material, equipment, and services, but the applicant subsequently provided this information in response to an RAI. The applicant's instruction identifies certain criteria of Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. The instruction states that the applicant would apply elements from these criteria or verify that the controls applied to ESP activities reflect these elements. The applicant considered control of purchased material, equipment, and services to be a criterion having elements associated with the control of ESP activities.

The instruction states that the PQP will include controls for products, equipment, and services purchased for the ESP project commensurate with the intended use of the products or services. The instruction also states that any material, equipment, or services purchased directly by Exelon in connection with the development of an ESP application will be in accordance with Exelon procedures.

In its PQP, the primary contractor described the organizational, programmatic, and procedural requirements intended to result in a complete and accurate application. Where appropriate, the contractor will use the pertinent elements of Appendix B to 10 CFR Part 50. The PQP states that measures will be established to assure that purchased material, equipment, and services (whether purchased directly or through contractors and subcontractors) conform to the procurement documents. These measures will include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. CH2M HILL will assess the effectiveness of the contractor and subcontractor quality control at intervals consistent with the importance, complexity, and quantity of the product or services provided.

17.7.2 Regulatory Evaluation (Control of Purchased Material, Equipment, and Services)

While the NRC does not require the control of purchased material, equipment, and services to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002, Attachment 2, contains guidance for the staff to use in evaluating an ESP applicant's control of purchased material, equipment, and services. In the instruction, the applicant described the control of purchased material, equipment, and services it applied to ESP activities.

Paragraph 17.1.1.7 in Section 17.1.1 of RS-002, Attachment 2, provides the QA measures that constitute an acceptable level of control of purchased material, equipment, and services. Acceptable controls of purchased material, equipment, and services should include (1) provisions for the control of purchased material, equipment, and services related to ESP activities that could affect SSCs important to safety that apply to selecting suppliers, as well as to assessing the adequacy of quality, and (2) provisions to ensure onsite availability of documented evidence of the conformance to procurement specifications of material and

equipment related to ESP activities that could affect SSCs important to safety before their installation or use.

17.7.3 Technical Evaluation (Control of Purchased Material, Equipment, and Services)

Section 17.4 of this SER details the controls of purchased material, equipment, and services applied by Exelon to its primary subcontractor. This section of the SER focuses on the additional subcontractors that were engaged in ESP activities. The following discussion addresses the scope of activities and the QA measures applied to those activities.

17.7.3.1 Parsons Energy & Chemicals Group

The overall scope of work conducted by Parsons Energy & Chemicals Group (Parsons) includes 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 of 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.

Inspection Report 0520007/2004001 details the staff's review of Parsons' preparation of the SSAR in support of the ESP application. The Parsons QA manual states that the requirements of Appendix B to 10 CFR Part 50, American National Standards Institute N45.2, and American Society of Mechanical Engineers NQA-1 will be met. Parsons conducted work under this document and supplementary procedures.

The staff reviewed the adequacy of the guidance for the accumulation, control, and maintenance of QA records relating to the project. The staff also reviewed the organizational responsibilities and lines of communication between the different engineering disciplines that were established in each of the reviewed procedures. This included designation of personnel who originated the initial design or input and the associated reviewers. A Parsons procedure delineates guidelines for the review of specifications to produce design criteria and documentation used for the design of the project. The staff evaluated procedures for the review of calculations, including spreadsheet/database utilities and computer analyses.

The staff noted that the QA manual provides administrative directives to project personnel and includes the quality plan implemented for the project. The manual identifies organizational structure and interfaces, outlines project personnel responsibilities, and defines design control, interface control, and client-specific requirements. The manual recognizes the need for controls and procedures for the work performed under this task based on the use of the data generated. The manual states that it should be used for those portions of the work, such as calculations, where the requirements of Appendix B to 10 CFR Part 50 apply. The manual also details the specific areas that are applicable.

The staff found the QA manual and procedures to be adequate to cover the areas of ESP activities that were the responsibility of Parsons.

17.7.3.2 Testing Services Corporation

Testing Services Corporation (TSC) provided engineering, technical, and laboratory services associated with geotechnical activities. Geotechnical activities include site borings, sample collection, testing, and inspection of soil and rock as used in engineering design and construction. The staff reviewed the QA manual prepared by TSC for ESP activities. The TSC manual includes a description of the TSC organization, the resumes of personnel who conducted geotechnical activities, data reports and records, calibration records and procedures, and procedures related to sample testing and onsite inspections. TSC performed site borings and sample collections in accordance with the TSC manual. CH2M HILL reviewed and approved the manual and found it to be prepared in accordance with the criteria required in the PQP and in 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." Inspection Report 0520007/2004001 details the staff's review of additional procedures related to the work conducted by TSC.

TSC designated a licensed professional engineer as responsible for ensuring internal quality reviews of work activities. The TSC QA manual includes a copy of the internal quality review check sheet.

Other subcontractors, including Stratigraphics and GEOVision, were involved in similar work. These subcontractors were also required to follow the same ASTM standards and CH2M HILL procedures.

The staff's review of the procedures and the TSC QA manual found that the documents provide a thorough description of the work processes and adequate QA measures.

17.7.3.3 Geomatrix

Geomatrix performed seismic and geologic data collection, site response studies, and the determination of the safe-shutdown earthquake (SSE) for the ESP application. The staff reviewed documentation related to calculations and analyses, software validation, verification and control, and the Geomatrix purchase order. The staff also reviewed company personnel resumes and QA training records. 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 used software developed or modified by the company to perform calculations related to the seismic analysis in the ESP application. The staff reviewed Geomatrix documentation, which provides additional information regarding the verification and validation (V&V) performed on the modified software. The documentation explains procedures for software V&V performed by Geomatrix. The documentation also includes a summary description of the V&V presentation provided by Geomatrix personnel to the NRC staff. During the presentation, Geomatrix personnel described the V&V procedures for two of the software codes used to perform the seismic hazard analysis and explained the software modifications necessary to perform the ESP calculations.

As further described in Inspection Report 0520007/2004001, Geomatrix performed verification activities for its software before 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 for the Seismic Owners Group is considered acceptable to characterize the seismic hazard for nuclear power plants, as stated in Regulatory Guide (RG) 1.165, "Identification and Characterization of Seismic Sources and Determination of Safe-Shutdown Earthquake Ground Motion." Appendix B, Section 3.2.1, to the ESP SSAR documents the results, which the staff reviewed.

The staff concluded that Geomatrix complied with the CH2M HILL PQP and that the design control measures used by Geomatrix for seismic studies incorporated into the ESP application are adequate.

CH2M HILL developed a procedure to outline the quality measures to be employed by Geomatrix to conduct ESP activities. The procedure details the specific work to be conducted, such as seismic hazard and geotechnical studies. The procedure states that Geomatrix will conduct the work in accordance with the PQP. Additionally, the scope of work covered by the procedure was intended to be consistent with the guidance provided in RGs 1.70, "Standard Format and Content of Safety Analysis Reports," and 1.165. The staff determined that the procedure provides adequate guidance for the scope of work conducted.

17.7.3.4 GRL Engineers, Inc.

The staff reviewed the GRL Engineers Incorporated (GRL) QA manual. GRL conducted standard penetration test (SPT) measurement work. The staff reviewed documentation that provides the extent of QA measures applied to ESP activities. GRL performed its measurements in accordance with ASTM D4945, "Standard Test Method for High-Strain Dynamic Testing of Piles," concerning dynamic measurements. Measurement gages and signal processing equipment complied with the standard for dynamic measurements. In addition, GRL prepared and reviewed engineering calculations in accordance with the GRL QA plan. The staff reviewed the GRL QA plan and found the plan to be adequate for GRL's ESP activities.

GRL performed SPTs in accordance with the GRL QA plan and Section 6.1 of ASTM D4945 for dynamic measurements. A CH2M HILL field supervisor monitored the work performed and verified that it was performed in accordance with the seismic field work plan. CH2M HILL reviewed the GRL quality manual following completion of GRL's work and found that the manual meets the requirements of the PQP. The staff found the primary contractor's controls adequate for the scope of work GRL conducted.

17.7.3.5 Stratigraphics

Stratigraphics performed cone penetrometer measurements and testing used for the geotechnical aspects of the ESP application. CH2M HILL monitored the work, which was performed in accordance with the CH2M HILL PQP and ESP project quality field work plans. The staff found the primary contractor's controls adequate for the scope of work conducted by Stratigraphics.

17.7.3.6 University of Texas

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

The UT QA program policies contained in the report are 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 UT. Documentation presented by UT describes technical and test procedures for the RCTS testing performed in its soil dynamics laboratory. The staff also reviewed an overview of the test program, theoretical background of RCTS tests, discussion of the dynamic test results and reports, and validation procedures. No deficiencies were found.

17.7.3.7 10 CFR Part 21 Applicability

During the QA inspection, the staff identified one open item regarding an issue that was not addressed during the inspection, but which required followup action by the NRC staff. The open item, discussed in detail in Inspection Report 05200007/2004001, involved the applicability of 10 CFR Part 21, "Reporting of Defects and Noncompliance," to the Exelon ESP project (Open Item 52-007/2004-01-02, "Applicability of 10 CFR Part 21 to ESP Applicants").

Subsequently, in RAI 17.1.1-5, the staff asked the applicant to describe the actions taken to ensure that the Exelon ESP project complies with the requirements of 10 CFR Part 21. In its response, the applicant stated that 10 CFR Part 21 applies to safety-related SSCs and to the activities and services that are associated with the SSCs. However, Exelon stated that its application does not identify or request approval of any SSCs, and it does not designate any SSCs or activities as safety-related. The applicant stated that it believes that, even if an error associated with a site characteristic is subsequently identified by the applicant or its contractors, there can be no means of evaluating the error in the context of 10 CFR Part 21.

The applicant also stated that, under the provisions in 10 CFR 52.37, compliance with 10 CFR Part 21 is not required until an ESP is issued. Thus, the applicant stated that it would not impose 10 CFR Part 21 reporting requirements on contractors until the ESP is issued.

The staff does not agree with Exelon's position that none of its ESP activities could affect safety-related SSCs. 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) document the NRC position regarding the applicability of 10 CFR Part 21 to ESP applicants and holders. The staff considers Exelon's failure to address the applicability of 10 CFR Part 21 to its ESP activities as Open Item 17.1-1.

17.7.4 Conclusion (Control of Purchased Material, Equipment, and Services)

As set forth above, the staff reviewed the QA measures employed by the applicant and its contractors and concluded that they have implemented acceptable controls for purchased

material, equipment, and services which meet the guidance of Section 17.1.1 of RS-002, Attachment 2, and help provide reasonable assurance that any information derived from ESP activities that is used in the design and/or construction of SSCs important to safety will support satisfactory performance of such SSCs once they are in service, with the exception of the issue identified in Open Item 17.1-1.

17.8 Identification and Control of Materials, Parts, and Components

17.8.1 Technical Information in the Application (Identification and Control of Materials, Parts, and Components)

Exelon's application did not initially supply information about the identification and control of materials, parts, and components, but the applicant subsequently provided this information in response to an RAI. The applicant's instruction identifies certain criteria of Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. The instruction stated that the applicant would apply elements from these criteria or verify that the controls applied to the ESP activities reflect these elements. The applicant did not consider identification and control of materials, parts, and components to be a criterion having elements associated with the control of ESP activities.

The instruction states that identification and control of materials, parts, and components did not apply to ESP activities because these activities do not involve fabrication, erection, installation, and use of materials, parts, or components.

The PQP of the primary contractor describes the organizational, programmatic, and procedural requirements intended to result in a complete and accurate application and states that the contractor will use, where appropriate, the pertinent elements of Appendix B to 10 CFR Part 50. The PQP states that this quality criterion does not apply to ESP activities.

In RAI 17.1.1-3, the staff asked the applicant to explain why identification and control of materials, parts, and components does not apply to the development of the ESP application. Alternatively, if this QA measure were to apply, the staff asked the applicant to describe the QA measures it and its primary contractor used for the ESP application. In its response, the applicant stated that the development of the ESP application does not involve the fabrication, erection, installation, and use of materials, parts, or components. Thus, no QA measures are necessary to prevent the use of incorrect or defective fabricated, erected, or installed materials, parts, or components.

17.8.2 Regulatory Evaluation (Identification and Control of Materials, Parts, and Components)

While the NRC does not require the identification and control of materials, parts, and components to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002, Attachment 2, contains guidance for the staff to use in evaluating an ESP applicant's identification and control of materials, parts, and components. The applicant's instruction states that the identification and control of materials, parts, or components does not apply to ESP activities.

Paragraph 17.1.1.8 in Section 17.1.1 of RS-002, Attachment 2, provides the QA measures that constitute an acceptable level of identification and control of materials, parts, and components. Acceptable identification and control of materials, parts, and components should include (1) provisions to identify and control materials, parts, and components related to ESP activities that could affect SSCs important to safety, and (2) provisions to ensure that incorrect or defective items are not used in ESP activities that could affect SSCs important to safety.

17.8.3 Technical Evaluation (Identification and Control of Materials, Parts, and Components)

Neither the applicant nor its primary contractor invoked QA measures for the identification and control of materials, parts, and components. The staff concluded, based on its review of the applicant's response to RAI 17.1.1-3 and its observations during the inspection, that the applicant and CH2M HILL did not conduct activities important to safety requiring identification and control of materials, parts, and components.

17.8.4 Conclusion (Identification and Control of Materials, Parts, and Components)

As set forth above, the staff reviewed the need for QA measures by the applicant and its primary contractor and concluded that, based on the scope of work for the ESP project, the identification and control of materials, parts, and components is not required.

17.9 Control of Special Processes

17.9.1 Technical Information in the Application (Control of Special Processes)

Exelon's application did not initially supply information about the control of special processes, but the applicant subsequently provided this information in response to an RAI. The applicant's instruction identifies certain criteria of Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. The instruction states that the applicant would apply elements from these criteria or verify that the controls applied to ESP activities reflect these elements. The applicant did not consider control of special processes to be a criterion having elements associated with the control of ESP activities.

The instruction states that control of special processes does not apply to ESP activities. In accordance with the instruction, because no special processes such as welding, heat treating, and nondestructive testing are involved in ESP activities, no measures are necessary for the control of special processes.

The PQP of the primary contractor describes the organizational, programmatic, and procedural requirements intended to result in a complete and accurate application and states that the contractor will use, where appropriate, the pertinent elements of Appendix B to 10 CFR Part 50. The PQP states that this quality criterion does not apply to ESP activities.

In RAI 17.1.1-3, the staff asked the applicant to explain why control of special processes does not apply to the development of the ESP application. Alternatively, if this QA measure were to apply, the staff asked the applicant to describe the QA measures it and its primary contractor used for the ESP application. In its response, the applicant stated that the development of the

ESP application does not involve special processes, such as welding, heat treating, and nondestructive testing. Thus, no QA measures are necessary for the control of special processes.

17.9.2 Regulatory Evaluation (Control of Special Processes)

While the NRC does not require the control of special processes to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002, Attachment 2, contains guidance for the staff to use in evaluating an ESP applicant's control of special processes. In Section 4.2.9 of the instruction, the applicant stated that the use of special processes does not apply to ESP activities.

Paragraph 17.1.1.9 in Section 17.1.1 of RS-002, Attachment 2, provides the QA measures that constitute an acceptable level of control of special processes. Acceptable control of special processes should include (1) provisions to ensure the acceptability of special processes used for ESP activities that could affect SSCs important to safety, and (2) provisions to ensure that qualified personnel using qualified procedures and equipment perform special processes related to ESP activities that could affect SSCs important to safety.

17.9.3 Technical Evaluation (Control of Special Processes)

Neither the applicant nor its primary contractor invoked QA measures for the control of special processes. The staff concluded, based on its review of the applicant's response to RAI 17.1.1-3 and its observations during the inspection, that the applicant and CH2M HILL did not conduct activities important to safety that required control of special processes.

17.9.4 Conclusion (Control of Special Processes)

As set forth above, the staff reviewed the need for QA measures by the applicant and its primary contractor and concluded that, based on the scope of work for the ESP project, control of special processes is not required.

17.10 Inspection

17.10.1 Technical Information in the Application (Inspection)

Exelon's application did not initially supply information about the control of inspection, but the applicant subsequently provided this information in response to an RAI. The applicant's instruction identifies certain criteria of Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. The instruction stated that the applicant would apply elements from these criteria or verify that the controls applied to ESP activities reflect these elements. The applicant did not consider the control of inspection to be a criterion having elements associated with the control of ESP activities.

The instruction states that the control of inspection does not apply to ESP activities; therefore, since no safety-related material or product processing is involved in the ESP activities, no inspection activities (by the applicant) are expected or planned.

The PQP of the primary contractor describes the organizational, programmatic, and procedural requirements intended to result in a complete and accurate application and states that the contractor will use, where appropriate, the elements of Appendix B to 10 CFR Part 50. The PQP states that this quality criterion does not apply to ESP activities.

In RAI 17.1.1-3, the staff asked the applicant to explain why inspection does not apply to the development of the ESP application. Alternatively, if this QA measure were to apply, the staff asked the applicant to describe the QA measures it and its primary contractor used for the ESP application. In its response, the applicant stated that the development of the ESP application does not involve safety-related material or product processing. Thus, the applicant does not expect or plan to conduct any QA inspections.

17.10.2 Regulatory Evaluation (Inspection)

While the NRC does not require inspection controls to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002, Attachment 2, contains guidance for the staff to use in evaluating an ESP applicant's controls for inspection. In Section 4.2.10 of the instruction, the applicant stated that inspection did not apply to ESP activities.

Paragraph 17.1.1.10 in Section 17.1.1 of RS-002, Attachment 2, provides the QA measures that constitute an acceptable level of inspection control. Acceptable inspection controls should include (1) provisions for the inspection of activities affecting the quality of ESP activities that could affect SSCs important to safety, including the items and activities to be covered, (2) organizational responsibilities and qualifications for individuals or groups performing inspection of ESP activities that could affect SSCs important to safety, and (3) provisions for inspection personnel to be independent of the performance of the activity being inspected.

17.10.3 Technical Evaluation (Inspection)

Neither the applicant nor its primary contractor invoked QA measures for inspection. The staff concluded, based on its review of the applicant's response to RAI 17.1.1-3 and its observations during the inspection, that the applicant and CH2M HILL did not conduct activities important to safety that required control of inspection.

17.10.4 Conclusion (Inspection)

As set forth above, the staff reviewed the need for QA measures by the applicant and its primary contractor and concluded that, based on the scope of work for the ESP project, inspection by the applicant is not required.

17.11 Test Control

17.11.1 Technical Information in the Application (Test Control)

Exelon's application did not initially supply information on test control, but the applicant subsequently provided this information in response to an RAI. The applicant's instruction identified certain criteria of Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. The instruction states that the applicant would apply elements

from these criteria or verify that the controls applied to ESP activities reflect these elements. The applicant considered test control to be a criterion having elements associated with the control of ESP activities.

The instruction states that the PQP will include controls for testing accomplished in connection with the development of an ESP application.

The PQP of the primary contractor describes the organizational, programmatic, and procedural requirements intended to result in a complete and accurate application and states that the contractor will use, where appropriate, the pertinent elements of Appendix B to 10 CFR Part 50. The PQP states that testing will be conducted in accordance with controlled procedures established after consideration of the applicable industry standards. Test procedures will include provisions for verifying that the prerequisites for a given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. Test results will be documented and evaluated to verify that the test requirements have been satisfied.

17.11.2 Regulatory Evaluation (Test Control)

While the NRC does not require test controls to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002, Attachment 2, contains guidance for the staff to use in evaluating an ESP applicant's test controls. The applicant's instruction details the test controls it applied to the ESP activities.

Paragraph 17.1.1.11 in Section 17.1.1 of RS-002, Attachment 2, provides the QA measures that constitute an acceptable level of test control. Acceptable test controls should include (1) provisions to ensure that tests performed related to ESP activities that could affect SSCs important to safety are appropriately controlled to provide confidence that these SSCs will perform adequately once they are in service, and (2) provisions to ensure that prerequisites are provided in written test procedures and that test results are documented and evaluated for ESP activities that could affect SSCs important to safety.

17.11.3 Technical Evaluation (Test Control)

17.11.3.1 Exelon

ESP quality project personnel observed activities performed at the proposed ESP site. The following field activities were performed:

- 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 (performed by TSC).
- Three groundwater piezometers were installed (performed by TSC).
- Four cone penetrometer test (CPT) soundings were advanced. Two of these included seismic wave CPTs for the measurement of the 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 (performed by Stratigraphics).

- One suspension logging test was conducted to log the shear wave velocity of the subsurface profile (performed by GEOVision).
- Each of the boring and sounding locations was surveyed for horizontal coordinates. Elevations of each location were measured by differential leveling (performed by Chastain).

The “ESP Project Activity Matrix,” which Exelon provided to the staff, identified the contractors performing ESP-related activities. Contractors on site during the field activities included (1) TSC, responsible for site borings, sample collection, and piezometer tests, (2) GRL Engineers, Inc., responsible for SPT measurements, (3) GEOVision Geographical Services, responsible for suspension logging tests to determine shear and compressional wave velocities, and (4) Homer Chastain and Associates, responsible for collection, review, and preparation of the data for inclusion in the ESP application.

The staff considered test control to be adequate based on its field observations and review of ESP quality project personnel logs.

17.11.3.2 CH2M HILL

The staff reviewed the CH2M HILL purchase orders for each of the contractors. With the exception of TSC and GRL Engineers, Inc., the contractors worked in accordance with the CH2M HILL PQP. TSC and GRL Engineers, Inc., conducted activities in accordance with their own internal quality plans. The staff reviewed all quality plans.

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, and was reviewed and 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 Ph.D. in civil engineering, as attested on his resume.

During the period of field activities, the CH2M HILL auditor was on site full time and observed activities in progress on a daily basis. The staff reviewed his field log for each of the days on which the subsurface investigations were conducted. The log documented work by TSC from the time the drill rig arrived at the site through the time of its departure when the auditor secured the site.

In addition to the surveillance activities that occurred during the performance of subsurface investigations, CH2M HILL conducted an audit while boring was in progress. The CH2M HILL project QA manager conducted the audit, with the CH2M HILL senior geotechnical engineer providing technical assistance. 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 UT representative. This individual was responsible for the

resonant column/cyclic testing performed; the ESP application documents the results of this testing. The staff documented its observations for this visit in a September 9, 2002, memorandum (ADAMS Accession No. ML022530396).

17.11.4 Conclusion (Test Control)

As set forth above, the staff reviewed the QA measures employed by the applicant and its primary contractor. The staff concluded that these measures implement acceptable test controls which meet the guidance of Section 17.1.1 of RS-002, Attachment 2, and help provide reasonable assurance that any information derived from ESP activities that is used in the design and/or construction of SSCs important to safety will support satisfactory performance of such SSCs once they are in service.

17.12 Control of Measuring and Test Equipment

17.12.1 Technical Information in the Application (Control of M&TE)

Exelon's application did not initially supply information about the control of measuring and test equipment (M&TE), but the applicant subsequently provided this information in response to an RAI. The applicant's instruction identified certain criteria of Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. The instruction stated that the applicant would apply elements from these criteria or verify that the controls applied to ESP activities reflect these elements. The applicant considered control of M&TE to be a criterion having elements associated with the control of ESP activities.

The instruction states that the PQP will include controls for the accuracy of M&TE used in connection with the development of an ESP application, as well as guidance that addresses actions to be taken when said equipment is unacceptable for use.

The PQP of the primary contractor describes the organizational, programmatic, and procedural requirements intended to result in a complete and accurate application and states that the contractor will use, where appropriate, the pertinent elements of Appendix B to 10 CFR Part 50. The PQP states that measures will be established to assure that tools, gages, instruments, and other measuring devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

17.12.2 Regulatory Evaluation (Control of M&TE)

While the NRC does not require the control of M&TE to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002, Attachment 2, contains guidance for the staff to use in evaluating an ESP applicant's control of M&TE. The applicant's instruction details the control of M&TE it applied to ESP activities.

Paragraph 17.1.1.12 in Section 17.1.1 of RS-002, Attachment 2, provides the QA measures that constitute an acceptable level of control of M&TE. Acceptable control of M&TE should include provisions to ensure that tools, gauges, instruments, and other measuring and testing devices are properly identified and controlled, and are calibrated and adjusted at specified intervals.

17.12.3 Technical Evaluation (Control of M&TE)

The instruction states that Exelon is responsible for the establishment and execution of a project QA plan for the ESP project, but that Exelon would typically delegate to others, such as contractors, the work of establishing and executing the QA plan. For control of M&TE, most of the subcontractors implemented their own controls. These controls are detailed below.

17.12.3.1 GRL Engineers, Inc.

GRL Engineers, Inc., conducted SPT measurement work. The staff reviewed the controls GRL Engineers, Inc., applied to M&TE. GRL performed its measurements in accordance with ASTM D-4945 for dynamic measurements. Measurement gages and signal processing equipment were in compliance with the standard for dynamic measurements. The staff found that GRL Engineers, Inc., complied with the ASTM standard.

17.12.3.2 Testing Services Corporation

CH2M HILL subcontracted to TSC to obtain geological testing support, such as site borings, sample collection, and piezometer installation. The staff reviewed the adequacy of the TSC work plan and QA manual for control of M&TE. The manual indicates that reviews of test results were conducted. Furthermore, the staff noted that the QA manual states that TSC performs calibration and verification of required equipment at specified intervals. Additionally, TSC keeps a calibration and verification file for each piece of equipment. The staff found TSC's control of M&TE to be adequate for the scope of work conducted.

17.12.3.3 University of Texas

The UT performed soil sample RCTS. The staff reviewed the testing report, which detailed procedures for the control of M&TE. The procedures were designed to meet ASTM D-3740. The staff considered the procedures adequate for the control of M&TE for the scope of work conducted by UT.

17.12.4 Conclusion (Control of M&TE)

As set forth above, the staff reviewed the QA measures employed by the applicant and its contractors, concluding that control of M&TE which meets the guidance of Section 17.1.1 of RS-002, Attachment 2, and helps provide reasonable assurance that any information derived from ESP activities that is used in the design and/or construction of SSCs important to safety will support satisfactory performance of such SSCs once they are in service.

17.13 Handling, Storage, and Shipping

17.13.1 Technical Information in the Application (Handling, Storage, and Shipping)

Exelon's application did not initially supply information about handling, storage, and shipping, but the applicant subsequently provided information in response to an RAI. The applicant's instruction identified certain criteria of Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. The instruction stated that the applicant would

apply elements from these criteria or verify that the controls applied to ESP activities reflect these elements. The applicant considered handling, storage, and shipping to be a criterion having elements associated with the control of ESP activities.

The instruction states that the PQP will include controls for the handling, storage, and shipping of ESP project material and equipment.

The PQP of the primary contractor describes the organizational, programmatic, and procedural requirements intended to result in a complete and accurate application and states that the contractor will use, where appropriate, the pertinent elements of Appendix B to 10 CFR Part 50.

The PQP states that measures will be established to control the handling, storage, shipping, cleaning, and preservation of material and equipment, in accordance with work and inspection instructions as necessary, to prevent damage or deterioration. When necessary for particular products, the PQP will specify and provide, if appropriate, special protective environments such as inert gas atmosphere, specific moisture content levels, and temperature levels.

17.13.2 Regulatory Evaluation (Handling, Storage, and Shipping)

While the NRC does not require controls for handling, storage, and shipping to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002, Attachment 2, contains guidance for the staff to use in evaluating an ESP applicant's controls for handling, storage, and shipping. The applicant's instruction details the handling, storage, and shipping controls it applied to ESP activities.

Paragraph 17.1.1.13 in Section 17.1.1 of RS-002, Attachment 2, provides the QA measures that constitute an acceptable level of handling, storage, and shipping control. Acceptable controls for handling, storage, and shipping should include provisions to control handling, storage, shipping, cleaning, and preservation of items related to ESP activities that could affect SSCs important to safety, in accordance with work and inspection instructions, to prevent damage, loss, and deterioration by environmental conditions, such as temperature or humidity.

17.13.3 Technical Evaluation (Handling, Storage, and Shipping)

17.13.3.1 CH2M HILL

With the exception of TSC and GRL Engineers, Inc., the contractors conducted their work in accordance with the CH2M HILL PQP. TSC and GRL Engineers, Inc., conducted handling, storage, and shipping activities in accordance with their own internal quality plans. In conjunction with the governing quality plans, site activities were controlled by a task-specific geotechnical field workplan, prepared by CH2M HILL. The staff reviewed all quality plans and the workplan and found them to be adequate for handling, storage, and shipping controls. The staff also reviewed field notes and logs and noted no deficiencies related to handling, storage, and shipping controls.

17.13.4 Conclusion (Handling, Storage, and Shipping)

As set forth above, the staff reviewed the QA measures the primary contractor and its subcontractors used, concluding that there were acceptable controls for handling, storage, and shipping which meet the guidance of Section 17.1.1 of RS-002, Attachment 2, and help provide reasonable assurance that any information derived from ESP activities that is used in the design and/or construction of SSCs important to safety will support satisfactory performance of such SSCs once they are in service.

17.14 Inspection, Test, and Operating Status

17.14.1 Technical Information in the Application (Inspection, Test, and Operating Status)

Exelon's application did not initially supply information about the control of inspection, test, and operating status, but the applicant subsequently provided information in response to an RAI. The applicant's instruction identifies certain criteria of Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. The instruction states that the applicant would apply elements from these criteria or verify that the controls applied to ESP activities reflect these elements. The applicant did not consider the control of inspection, test, and operating status to be a criterion having elements associated with the control of ESP activities.

The instruction states that control of inspection, test, and operating status does not apply to ESP activities. Because ESP activities do not involve inspection, testing, or operation of SSCs of a nuclear power plant, the instruction does not require measures relating to the inspection, testing, or operation of such SSCs.

The PQP of the primary contractor describes the organizational, programmatic, and procedural requirements intended to result in a complete and accurate application and states that the contractor will use, where appropriate, the pertinent elements of Appendix B to 10 CFR Part 50. The PQP states that this quality criterion does not apply to ESP activities.

In RAI 17.1.1-3, the staff asked the applicant to explain why the control of inspection, test, and operating status does not apply to the development of the ESP application. Alternatively, if this QA measure were to apply, the staff asked the applicant to describe the QA measures it and its primary contractor used for the ESP application. In its response, the applicant stated that the development of the ESP application does not involve inspection, testing, or operation of SSCs of a nuclear power plant, therefore, QA measures relating to the inspection, testing, or operation of such SSCs are not necessary.

17.14.2 Regulatory Evaluation (Inspection, Test, and Operating Status)

While the NRC does not require controls for inspection, test, and operating status to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002, Attachment 2, contains guidance for the staff to use in evaluating an ESP applicant's controls for inspection, test, and operating status. In Section 4.2.14 of the instruction, the applicant stated that controls for inspection, test, and operating status do not apply to ESP activities.

Paragraph 17.1.1.14 in Section 17.1.1 of RS-002, Attachment 2, provides the QA measures that constitute an acceptable level of controls for inspection, test, and operating status. Acceptable controls for inspection, test, and operating status should include provisions to indicate the inspection, test, and operating status of items related to ESP activities that could affect SSCs important to safety. These provisions will prevent inadvertent use or bypassing of inspection and tests.

17.14.3 Technical Evaluation (Inspection, Test, and Operating Status)

Neither the applicant nor its primary contractor invoked QA measures for inspection, test, and operating status. The staff concluded, based on its review of the applicant's response to RAI 17.1.1-3 and its observations during the inspection, that the applicant and CH2M HILL did not conduct activities important to safety requiring inspection, test, and operating status.

17.14.4 Conclusion (Inspection, Test, and Operating Status)

As set forth above, the staff reviewed the need for QA measures by the applicant and its primary contractor and concluded that, based on the scope of work for the ESP project, inspection, test, and operating status measures are not required.

17.15 Nonconforming Materials, Parts, or Components

17.15.1 Technical Information in the Application (Nonconforming Materials, Parts, or Components)

Exelon's application did not initially supply information about control of nonconforming materials, parts, or components, but the applicant subsequently provided this information in response to an RAI. The applicant's instruction identifies certain criteria of Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. The instruction states that the applicant would apply elements from these criteria or verify that the controls applied to ESP activities reflect these elements. The applicant did not consider the control of nonconforming materials, parts, or components to be a criterion having elements associated with control of ESP activities.

The instruction states that control of nonconforming materials, parts, or components does not apply to ESP activities. Since ESP activities do not involve the fabrication, erection, installation, and use of materials, parts, or components, no measures are necessary to prevent the use or installation of nonconforming materials, parts, or components.

The PQP of the primary contractor describes the organizational, programmatic, and procedural requirements intended to result in a complete and accurate application and states that the contractor will use, where appropriate, the pertinent elements of Appendix B to 10 CFR Part 50. The PQP states that this criterion does not apply to ESP activities.

In RAI 17.1.1-3, the staff asked the applicant to explain why control of nonconforming materials, parts, and components does not apply to the development of the ESP application. Alternatively, if this QA measure were to apply, the staff asked the applicant to describe the QA measures it and its primary contractor used for the ESP application. In its response, the

applicant stated that the development of the ESP application does not involve fabrication, erection, installation, and use of materials, parts, or components. Thus, no QA measures are necessary to prevent the use or installation of nonconforming materials, parts, or components.

17.15.2 Regulatory Evaluation (Nonconforming Materials, Parts, or Components)

While the NRC does not require control of nonconforming materials, parts, or components to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002, Attachment 2, contains guidance for the staff to use in evaluating an ESP applicant's control of nonconforming materials, parts, or components. The applicant's instruction states that the control of nonconforming materials, parts or components does not apply to ESP activities.

Paragraph 17.1.1.15 in Section 17.1.1 of RS-002, Attachment 2, provides the QA measures that constitute an acceptable level of nonconforming materials, parts, or components control. Acceptable controls for nonconforming materials, parts, or components should include provisions to control the use or disposition of nonconforming materials, parts, or components related to ESP activities that could affect SSCs important to safety.

17.15.3 Technical Evaluation (Nonconforming Materials, Parts, or Components)

Neither the applicant nor its primary contractor invoked QA measures for the control of nonconforming materials, parts, or components. The staff concluded, based on its review of the applicant's response to RAI 17.1.1-3 and its observations during the inspection, that the applicant and CH2M HILL did not conduct activities important to safety that required control of nonconforming materials, parts, or components.

17.15.4 Conclusion (Nonconforming Materials, Parts, or Components)

As set forth above, the staff reviewed the need for QA measures by the applicant and its contractors and concluded that, based on the scope of work for the ESP project, control of nonconforming materials, parts, or components is not required.

17.16 Corrective Action

17.16.1 Technical Information in the Application (Corrective Action)

Exelon's application did not initially supply information about corrective action, but the applicant subsequently provided this information in response to an RAI. The applicant's instruction identifies certain criteria of Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. The instruction states that the applicant would apply elements from these criteria or verify that the controls applied to ESP activities reflect these elements. The applicant considered corrective action to be a criterion having elements associated with control of ESP activities.

The instruction states that the PQP will include controls for the identification and correction of ESP project conditions adverse to quality. In addition, any conditions adverse to quality pertaining to the actions or functions of the Exelon-specific segment of the ESP project will be

addressed either in accordance with the corrective action program identified in the PQP, or in accordance with the Exelon corrective action program.

The PQP of the primary contractor describes the organizational, programmatic, and procedural requirements intended to result in a complete and accurate application and states that the contractor will use, where appropriate, the pertinent elements of Appendix B to 10 CFR Part 50. The PQP states that measures will be established to promptly identify and correct conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances. In the case of significant conditions adverse to quality, the measures will determine the cause of the conditions and cause corrective action to be taken to correct the condition and to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken will be documented and reported to the appropriate level of management. The QA Manager is responsible for the corrective action program and its implementing procedures, as well as for processing corrective actions. Project personnel may address quality issues directly to the QA Manager or project manager when it is apparent that normal processes are not timely or capable of resolving the issue.

17.16.2 Regulatory Evaluation (Corrective Action)

While the NRC does not require a corrective action program to comply with Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002, Attachment 2, contains guidance for the staff to use in evaluating an ESP applicant's corrective action program. The applicant's instruction states that corrective action does apply to ESP activities.

Paragraph 17.1.1.16 in Section 17.1.1 of RS-002, Attachment 2, provides the QA measures that constitute an acceptable level of control of corrective action. An acceptable corrective action program should include provisions to ensure that conditions adverse to quality are promptly identified and corrected. For significant conditions adverse to quality, those provisions should preclude recurrence.

17.16.3 Technical Evaluation (Corrective Action)

17.16.3.1 Exelon

The instruction provides controls for the identification and correction of ESP project conditions adverse to quality. The instruction specifies that 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 Exelon's own corrective action program.

The PQP provides for the identification and correction of conditions adverse to quality. The PQP states that for the identification of a significant condition adverse to quality the cause of the condition, and the corrective action taken, will be documented and reported to the appropriate level of management. The CH2M HILL QA Manager is responsible for the corrective action program and its implementing procedures, and for processing corrective actions. The staff determined through interviews with the QA Manager and review of relevant

documentation that he possesses adequate training and qualification, including knowledge of the corrective action process and the resolution of condition reports.

17.16.3.2 CH2M HILL

The staff reviewed the CH2M HILL project procedure for the corrective action program, as detailed in Inspection Report 0520007/2004001. The procedure provides instructions for establishing and operating a corrective action program and establishes processes and methods to be used to resolve issues. Documentation is 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 is effective to resolve the issue. The staff determined the guidance in the procedure to be adequate for the conduct of a corrective action program.

The staff reviewed all of the corrective action reports (CARs) that were generated during Exelon's ESP activities, including subsequent actions to obtain resolution of identified issues. Inspection Report 0520007/2004001 provides further information. The staff also discussed some of its observations with the CH2M HILL QA Manager. For the majority of the CARs, the staff found the proposed corrective action and subsequent resolution to be adequate in addressing the identified problem. The staff did note that the auditor performing the audit had generated all of the CARs. The personnel conducting the ESP activities did not generate any CARs. The staff also noted an instance in which CH2M HILL did not initially document the root cause of an adverse condition. The applicant identified this deficiency to CH2M HILL, which subsequently corrected it. Finally, an Exelon audit identified many adverse findings related to procedural deficiencies revealed during the early stages of ESP activities. Exelon ensured the findings were corrected. The staff determined that the findings identified above did not have a significant impact on ESP activities and were adequately resolved.

17.16.4 Conclusion (Corrective Action)

As set forth above, the staff reviewed the QA measures employed by the applicant and its primary contractor and concluded that they have implemented an acceptable corrective action program which meets the guidance of Section 17.1.1 of RS-002, Attachment 2, and helps provide reasonable assurance that any information derived from ESP activities that could be used in the design and/or construction of SSCs important to safety will support satisfactory performance of such SSCs once they are in service.

17.17 Quality Assurance Records

17.17.1 Technical Information in the Application (Quality Assurance Records)

Exelon's application did not initially supply information about the control of QA records, but the applicant subsequently provided information in response to an RAI. The applicant's instruction identifies certain criteria of Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. The instruction states that the applicant would apply elements from these criteria or verify that the controls applied to ESP activities reflect these elements. The applicant considered QA records to be a criterion having elements associated with the control of ESP activities.

The instruction states that the PQP will include controls for the identification, retention, and maintenance of ESP project records. In addition, Exelon records of audits and reviews are maintained in project files until the completion of the project. If the ESP application were to be used to obtain a COL, the project records would become records associated with the requirements of 10 CFR Part 52, Subpart C, for a licensed facility. Exelon will, at ESP project completion, take possession of and retain from the lead contractor all applicable ESP project documentation in accordance with its records retention and storage processes.

The PQP of the primary contractor describes the organizational, programmatic, and procedural requirements intended to result in a complete and accurate application and states that the contractor will use, where appropriate, the pertinent elements of Appendix B to 10 CFR Part 50. The PQP states that records required for the quality program will be controlled. Controls will be implemented to ensure that the records are legible, readily identifiable, and retrievable. Consistent with applicable regulatory requirements, specific requirements concerning record retention, such as duration, location, and assigned responsibility, will be determined. Records may be in any format consistent with these storage requirements, including hard copy, electronic, or other media. Sufficient records will be maintained to furnish evidence of activities affecting quality. The records will include, at a minimum, operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records will also include closely-related data, such as qualifications of personnel, procedures, and equipment. Inspection and test records will also identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted.

17.17.2 Regulatory Evaluation (Quality Assurance Records)

While the NRC does not require control of QA records to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002, Attachment 2, contains guidance for the staff to use in evaluating an ESP applicant's QA records. In its instruction, the applicant stated that control of QA records applies to ESP activities.

Paragraph 17.1.1.17 in Section 17.1.1 of RS-002, Attachment 2, provides the QA measures that constitute an acceptable level of QA records control. Acceptable control of QA records should include provisions for the identification, retention, retrieval, and maintenance of quality records.

17.17.3 Technical Evaluation (Quality Assurance Records)

17.17.3.1 Exelon

The instruction states that the PQP will include controls for the identification, retention, and maintenance of ESP project records. The staff reviewed the Exelon procedures associated with records retention. Inspection Report 0520007/2004001 details this review. An Exelon procedure 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 has not yet occurred for ESP records. Exelon stated that it intends to retain ESP-related QA records until it decides whether to use the ESP in support of a 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 staff reviewed the Exelon requirements imposed on contractors for turning over ESP quality records. The instruction requires that Exelon, at ESP project completion, take possession from the lead contractor of all applicable ESP project documentation in accordance with Exelon 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, Exelon, through a service agreement, required CH2M HILL to provide it with all information and documentation within the contractor's scope of services and which Exelon requires for the design, construction, licensing, QA, operation, or maintenance of the services or of the facility for which the services are intended.

17.17.3.2 CH2M HILL

The PQP states that records required for the quality program will be controlled and that sufficient records will be maintained to furnish evidence of activities affecting quality. The PQP also lists the types of records required to be controlled as quality records.

The staff reviewed several of the primary contractor's QA records procedures, which are discussed in Inspection Report 0520007/2004001. A CH2M HILL project procedure establishes instructions for identifying, storing, retrieving, protecting, retaining, and disposing of project QA records. This procedure outlines responsibility for QA records for project managers, the document control manager, and recordkeepers. It also provides a listing of categories of QA records and requirements for storage and protection, retrieval, and disposition of these records. For example, the procedure requires that recordkeepers consider security, fire, and environment (heat and humidity) prior to storing records.

The staff also reviewed the CH2M HILL record retention requirements. The record retention procedure states that the retention time of all quality records will be defined. It referred to the CH2M HILL online records management retention schedule, which contains 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 staff 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 that are associated with the clients' projects. Several line entries in the online retention schedule related to project records contain language consistent with these statements. As detailed in Inspection Report 0520007/2004001, the staff also reviewed procedures for document control and creation, as well as for peer and technical review.

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 secure computer server in the CH2M HILL offices in Idaho Falls, Idaho. The CH2M HILL

Document Control Manager (DCM) stated that she controlled access to and storage of the records. She stated that the server containing the documents was housed in a secure room, which 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. Inspection Report 0520007/2004001 discusses these issues.

Finally, the staff 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. Inspection Report 0520007/2004001 provides further detail.

17.17.4 Conclusion (Quality Assurance Records)

As set forth above, the staff reviewed the QA measures the applicant and its primary contractor used and concluded that they have implemented an acceptable level of control for QA records which meets the guidance of Section 17.1.1 of RS-002, Attachment 2, and helps provide reasonable assurance that any information derived from ESP activities that is used in the design and/or construction of SSCs important to safety will support satisfactory performance of such SSCs once they are in service.

17.18 Audits

17.18.1 Technical Information in the Application (Audits)

Exelon's application did not initially supply information about the control of audits, but the applicant subsequently provided this information in response to an RAI. The applicant's instruction identifies certain criteria of Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. The instruction states that the applicant would apply elements from these criteria or verify that the controls applied to ESP activities reflect these elements. The applicant considered control of audits to be a criterion having elements associated with the control of ESP activities.

The instruction states that the PQP will include controls for the verification of compliance with its requirements. In addition, Exelon may, from time to time, perform audits of the primary contractor's implementation of the PQP.

The PQP of the primary contractor describes the organizational, programmatic, and procedural requirements intended to result in a complete and accurate application and states that the contractor will use, where appropriate, the pertinent elements of Appendix B to 10 CFR Part 50.

The PQP states that planned audits will be carried out to verify compliance with the QA program and to determine the effectiveness of the program. The audits will be performed in accordance with written procedures by trained personnel who do not have direct responsibility for the area being audited. The task lead having responsibility for the area being audited will review the audit results. Followup action, including reaudit of deficient areas, will be taken where indicated. The QA Manager will coordinate the conduct of internal audits of project processes and procedures. Findings of nonconformance will be recorded in the corrective action/preventive action spreadsheet or other similar tacking mechanism.

17.18.2 Regulatory Evaluation (Audits)

While NRC does not require the control of audits to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002, Attachment 2, contains guidance for the staff to use in evaluating an ESP applicant's control of audits. In its instruction, the applicant stated that audits did apply to ESP activities.

Paragraph 17.1.1.18 in Section 17.1.1 of RS-002, Attachment 2, provides the QA measures that constitute an acceptable level of control of audits. Acceptable audits should include (1) provisions for audits to verify compliance with all aspects of QA controls and to determine the effectiveness of these controls, and (2) responsibilities and procedures for conducting, documenting, and reviewing the results of audits (including designating management levels to review and assess audit results).

17.18.3 Technical Evaluation (Audits)

The staff reviewed all audits and the requisite audit reports that covered Exelon's ESP activities. Inspection Report 0520007/2004001 provides the details of the audit reports. The staff also addressed the adequacy of the audit process related to ESP activities.

17.18.3.1 Exelon

The ESP project team consisted of representatives from Exelon, CH2M HILL, Parsons, and Geomatrix. All of these organizations were audited during preparation of the ESP application.

Tasks performed by organizations not represented on the ESP project team were performed in conjunction with field investigations at the ESP site. 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 staff concluded that oversight of contract activities for the preparation of the ESP application was adequate.

The instruction states 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 staff reviewed the qualifications of the Exelon personnel that conducted the audit. All audit personnel appeared to have adequate qualifications.

As discussed in Inspection Report 0520007/2004001, procedures were in place for the conduct of audits of internal CH2M HILL activities, including project subcontractors. Audit deficiencies were documented in the applicant's corrective action process. 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 staff reviewed the results of the audits and assessments the applicant conducted. Inspection Report 0520007/2004001 discusses the review of the audits and assessments and the resultant findings. The audit was performed using the process developed by the Nuclear Utilities Procurement Issues Committee. The staff found the audit process adequate.

The staff 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 based on existing NOS procedures. The staff concluded that the applicant had adequately implemented an assessment process of the project quality controls which provided reasonable assurance of ESP application quality.

17.18.3.1.1 Board of Review

An independent board of review assisted the project staff during the seismic work. The board of review evaluated the implementation plan for the seismic hazard work, the interim results of the work, and the conclusions reached during the work.

The staff reviewed the board of review's product. The review involved checking Sections 2.5 and 3.4 of the SSAR and providing feedback. The staff reviewed the qualifications of the members of the board of review and found their qualifications to be adequate.

17.18.3.1.2 Independent Review of the SSAR

In addition to the routine audits and performance assessments detailed in Inspection Report 0520007/2004001, Exelon had Sargent & Lundy (S&L) and Idaho National Engineering and Environmental Laboratory (INEEL) perform an independent review of draft SSAR sections. 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. The staff found the review to be adequate in scope.

17.18.3.2 CH2M HILL

Exelon's 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. CH2M HILL integrated the audit program with its 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 nonconforming steps or outputs through the corrective action program.

The PQP provides that planned audits will be conducted to verify compliance with the QA program to determine the effectiveness of the program. An audit program procedure outlined the administration and implementation of the audit program. Procedure guidance covered personnel responsibility, internal auditor training requirements, development of an audit schedule, audit documentation, and processing audit findings.

The staff reviewed the qualifications of the CH2M HILL personnel who conducted audits, concluding that all audit personnel appeared to have adequate qualifications.

Based on its review of the audits and assessments conducted by CH2M HILL, the staff concluded that CH2M HILL adequately implemented its audit program.

17.18.3.2.1 Peer Review

Before 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.

17.18.4 Conclusion (Audits)

As set forth above, the staff reviewed the QA measures the applicant and its primary contractor used and concluded that they have implemented acceptable audit controls which meet the guidance of Section 17.1.1 of RS-002, Attachment 2, and help provide reasonable assurance that any information derived from ESP activities that is used in the design and/or construction of SSCs important to safety will support satisfactory performance of such SSCs once they are in service.

17.19 Conclusions

Based on its review and evaluation of the QA measures contained in the applicant's ESP program as set forth above, the staff concludes that, with the exception of the open item in Section 17.7.3.7, the applicant's QA measures conform to the guidance in RS-002, Attachment 2, as well as appropriate industry standards, and that they were implemented for the ESP application activities.