17. EARLY SITE PERMIT QUALITY ASSURANCE MEASURES

17.1 Introduction

System Energy Resources, Inc. (SERI or the applicant), chose not to supply information on the quality assurance (QA) measures it employed for early site permit (ESP) activities in its application for locating an additional plant(s) at the existing Grand Gulf Nuclear Station (GGNS) site. During a preapplication meeting to discuss the ESP inspection process, the applicant submitted information on the QA measures applied by SERI and its principal subcontractors. The staff of the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection of the applicant's QA measures from February 9–13, 2004. Subsequently, the staff performed an in-office technical review to evaluate whether the applicant and its principal subcontractors had applied adequate QA measures. The staff also conducted a review to determine whether SERI adequately applied the guidance in Section 17.1.1 of Review Standard (RS)-002, "Processing Applications for Early Site Permits," to demonstrate the integrity and reliability of the data obtained during ESP activities.

Under Title 10, Section 52.18, "Standards 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, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," 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 site characteristics specified in the ESP. If the COL applicant references a certified design and an ESP and does not request a variance from the ESP in accordance with 10 CFR 52.39(b), the applicant must show that the site parameters postulated for the certified design fall within the characteristics 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 to the quality measures described in RS-002, 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

address the guidance in Section 17.1.1 of RS-002 for each relevant element (as determined by the applicant). The staff performed much of its evaluation during an inspection conducted in February 2004 and documented in Inspection Report 052000009/2004001 (ADAMS Accession No. ML040830045). For any element that the applicant determined not to be relevant, 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, Enercon. Inspection Report 052000009/2004001 includes details on additional subcontractors involved in ESP activities. Section 17.7 of this safety evaluation report (SER) discusses the adequacy of the QA measures applied by these subcontractors.

The staff reviewed the document developed by Enercon for SERI that provides general guidance for the quality measures applied to ESP activities. According to the document, Enercon would conduct activities related to the development of the application in accordance with the regulations and applicable portions of its QA program. Most of the subcontractors conducted ESP activities under Enercon's QA program.

17.1.1 Technical Information in the Application (Organization)

SERI did not supply information in its application about organization control. The "Quality Assurance Project Planning Document for Entergy Nuclear Potomac Early Site Permitting Project, Grand Gulf Nuclear Station Site," Project No. ENTO-002, Revision 5, dated October 6, 2003 (hereafter referred to as the QAPPD), describes the QA measures for ESP activities and identifies certain criteria in Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. Enercon applied elements from these criteria or verified that the controls used for ESP activities reflect the elements from these criteria, as outlined in the Enercon Services Quality Assurance Program Manual, Revision 8 (hereafter referred to as the QAPM). Enercon wrote the QAPM to comply with the requirements of Appendix B to 10 CFR Part 50; as such, it contains QA policies corresponding to each of the Appendix B criteria. The plan considers organization to be one of the criteria having elements associated with the control of ESP activities.

The QAPM describes the Enercon organization for establishing and executing the Enercon QA program. The QAPM specifies the primary responsibilities, authorities, and lines of communication for identifying, reporting, controlling, and resolving quality issues. An organizational chart identifies the Enercon structure responsible for implementing the Enercon QA program. This organizational structure ensures that personnel responsible for implementing the QA program report and/or have direct access to the highest levels of Enercon management and have sufficient independence of cost and schedule when related to safety and/or quality considerations. The QAPM describes the authorities and responsibilities for all management personnel, as well as the independence of personnel performing QA functions.

The QAPM states that any employee of Enercon who is aware of a nonconformance or has a quality concern is encouraged to express that concern to the project manager. If the concern is not resolved to their satisfaction, personnel have access to the company president through the project QA engineer or QA manager.

17.1.2 Regulatory Evaluation (Organization)

While the NRC does not require an organization to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the staff to use in evaluating the measures employed by an ESP applicant. In the QAPPD, the applicant's primary contractor states that its organization controls will ensure the development of the application in a quality manner and, where appropriate, in accordance with requirements of Appendix B to 10 CFR Part 50.

Paragraph 17.1.1.1 in Section 17.1.1 of RS-002 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 subcontractors, (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 Entergy

SERI, a subsidiary of Entergy Corporation, is the applicant for the ESP and authorized Entergy Nuclear Potomac Company to prepare the ESP application. Entergy Nuclear Potomac Company selected Enercon to perform the actual preparation of the ESP application and delegated ESP QA organizational responsibilities, including QA oversight, to Enercon. The Entergy supplier QA organization includes Enercon on its supplier list as a qualified vendor.

The staff noted that Entergy Nuclear Potomac Company assumed responsibility for the procurement of services for seismic and geotechnical ESP evaluations. The staff determined that this organizational structure is equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and meets the acceptance criteria contained in Section 17.1.1 of RS-002.

17.1.3.2 Enercon

The staff noted that Enercon's QAPM conforms to the requirements of Appendix B to 10 CFR Part 50. The staff's review of selected portions of Enercon's QAPM identifies several QA organization attributes.

The QAPM states that the QA manager is responsible for the execution of the Enercon QA program (including work performed by other organizations or companies) and that the QA manager has the authority to halt further processing, delivery, or installation of a nonconforming item, deficiency, or unsatisfactory condition until proper disposition has occurred. It also states that the QA manager reports directly to the Chief Operating Officer, Enercon Services, and has access to the President, Enercon Services.

The QAPM states that every Enercon employee has the responsibility to identify conditions adverse to quality and notify the QA manager/project QA engineer of the condition. It also

states that any employee may initiate a corrective action report (CAR) for conditions adverse to quality. If a reported condition adverse to quality is determined to be sufficiently significant, the President, Enercon Services, may be called upon to assist in obtaining timely corrective action.

The applicant indicated that the QAPPD was prepared by Enercon and reviewed by Entergy for the purpose of developing an ESP application. The QAPPD includes an organization chart depicting key organizational positions, such as project manager, QA program manager, and project technical/task leads. The QAPPD describes associated position responsibilities and qualification requirements. The staff noted that the Enercon QA manager fulfills the roles and responsibilities of that position. The staff also found that the individuals identified on the project organization chart appear to meet the guidance of Section 17.1.1 of RS-002.

17.1.4 Conclusions (Organization)

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 organization which meets the guidance in Section 17.1.1 of RS-002. This provides 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)

SERI did not supply information in its application about a QA program. The QAPPD describes the QA measures for ESP activities and identifies certain criteria in Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. Enercon applied elements from these criteria or verified that the controls applied to ESP activities reflect the elements from these criteria, as outlined in the Enercon QAPM. Enercon wrote the QAPM to comply with the requirements of Appendix B to 10 CFR Part 50; as such, it contains QA policies corresponding to each of the Appendix B criteria. The plan considers the QA program to be one of the criteria having elements associated with the control of ESP activities.

The QAPM states that the QA program is based on the requirements of Appendix B to 10 CFR Part 50. The QA program will be maintained to comply with the requirements of Appendix B to 10 CFR Part 50. The requirements of the American National Standards Institute (ANSI) N45.2-1977, “Quality Assurance Program Requirements for Nuclear Facilities,” applicable “daughter standards,” and ANSI NQA-1-1983, “Quality Assurance Program Requirements for Nuclear Power Plants,” will be used as guidelines for implementing the QA program and were considered during the preparation of this program.

The QAPM states that the QA program will provide for administrative control and verification of the performance of project activities that affect the quality of items supplied or services provided. The scope of work may not require the use of all sections of this program.

In addition, the QAPM states that the QA program will include control mechanisms for each activity depending on the type of activity and the importance of the activity to the achievement

and maintenance of quality. These control mechanisms are provided to ensure that (1) prerequisites are identified and met, (2) competent personnel are assigned, and (3) quality is verified by appropriate methods.

The QAPM provides additional guidance on QA program review and approval, distribution and control, periodic appraisal and reporting, and personnel indoctrination and training.

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 contains guidance for the staff to use in evaluating the measures employed by an ESP applicant. In the QAPPD, the applicant's primary contractor stated that its QA program controls will ensure the development of the application in a quality manner and, where appropriate, in accordance with the requirements of Appendix B to 10 CFR Part 50.

Paragraph 17.1.1.2 in Section 17.1.1 of RS-002 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 that relate 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 adequacy of personnel qualifications.

17.2.3 Technical Evaluation (QA Program)

This section of the SER evaluates the adequacy of the applicant and its primary contractor's overall QA program description. The SER provides a detailed review and evaluation of each applicable portion of the program under the appropriate sections.

The applicant determined that certain quality controls were not required to be fully implemented. The QAPPD identifies QA requirements only applicable to the ESP project. Specifically, of the 18 elements in the Enercon QAPM, the following elements do not apply to the ESP project:

- Section 8.0, "ID and Control of Material, Parts and Components"
- Section 9.0, "Control of Special Processes"
- Section 10.0, "Inspections"
- Section 11.0, "Test Control"
- Section 14.0, "Inspection, Test and Operating Status"
- Section 15.0, "Nonconforming Materials, Parts or Components"

For Section 12.0, "Control of Measuring and Test Equipment," the applicable ESP procedures address quality standards. The QAPPD includes attachments with specific project instructions tailored to the scope of work.

Enercon determined the applicability of QA policies in accordance with one of its corporate standard procedures (CSPs). The applicable sections of this SER will discuss whether these specific elements of the QAPM should have been applied to the ESP project.

17.2.3.1 Entergy

SERI authorized Entergy Nuclear Potomac Company, a subsidiary of Entergy Corporation, to prepare the ESP application. Entergy Nuclear Potomac Company selected Enercon as the lead contractor for development of the ESP application. The procurement documentation specifies that Enercon would implement a QA program in accordance with the criteria of Appendix B to 10 CFR Part 50 to address those ESP application activities that support the design input for future power plant design and construction. Specifically, this includes hydrological and meteorological site characterization activities. In addition, the procurement documentation specifies that Enercon would provide QA oversight of Entergy Nuclear Potomac Company's subcontractor, William Lettis & Associates (WLA), in developing the seismic and geologic input for the ESP application.

17.2.3.2 Enercon

The staff noted that the ESP agreement contract documents the selection of Enercon as the primary contractor responsible for developing the ESP application. The contract states that all services that could affect design input for safety-related SSCs in support of the ESP application must be performed under the auspices of the QAPM and the QAPPD developed by Enercon. It further states that, for work designated as safety related, the primary contractor must comply with the provisions of 10 CFR Part 21, "Reporting of Defects and Noncompliance."

Enercon wrote the QAPM to comply with the requirements of Appendix B to 10 CFR Part 50; as such, it contains QA policies corresponding to each of the Appendix B criteria. Enercon developed the QAPPD to provide guidance for implementing the QA program for the SERI application.

The staff reviewed the Enercon QAPPD, which Enercon developed to implement its QA program for specific activities related to the ESP application. Enercon intended the QAPPD to provide a detailed description of the total scope of work and tasks necessary to produce the ESP application. The QAPPD identifies hydrological and meteorological activities that fall within the Enercon QA program, as well as oversight of seismic and geotechnical work performed by WLA. The staff verified that calculations associated with the determination of atmospheric dispersion factors were performed with QA program controls within the scope of meteorological activities. In addition, the staff confirmed calculations to determine that population projections were developed with adequate quality measures.

Activities performed by WLA and other Enercon subcontractors, as well as WLA subcontractors, were governed by Enercon's QAPM through a purchase order or the QAPPD. Eustis Engineering Company, Inc. (Eustis), is one exception; the SER discusses this in Section 17.7.3.

17.2.3.3 William Lettis & Associates

WLA provided services for seismic and geotechnical evaluation of the site under a separate contract with Entergy Nuclear Potomac Company. WLA employees and its subcontractors were required to perform work in accordance with the Enercon QAPM. As detailed in Inspection Report 052000009/2004001, the staff reviewed selected project instructions

prepared by WLA and reviewed by Enercon to provide guidelines for conducting seismic and geotechnical activities. The staff verified that the project instructions require that work be performed under Enercon's QAPM.

The staff determined that WLA personnel appear to have extensive education and experience in seismic analyses. Furthermore, WLA adequately provided and documented training for its employees.

17.2.4 Conclusions (QA Program)

As set forth above, the staff reviewed the QA measures implemented by the applicant and its primary contractor. The staff concludes that they have implemented an acceptable QA program which meets the guidance in Section 17.1.1 of RS-002. This provides 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.

17.3 Design Control

17.3.1 Technical Information in the Application (Design Control)

SERI did not supply information in its application about design control. The QAPPD describes the QA measures for ESP activities and identifies certain criteria in Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. Enercon applied elements from these criteria or verified that the controls applied to ESP activities reflect the elements from these criteria, as outlined in its QAPM. Enercon wrote the QAPM to comply with the requirements of Appendix B to 10 CFR Part 50; as such, it contains QA policies corresponding to each of the Appendix B criteria. The plan considers design control to be one of the criteria having elements associated with the control of ESP activities.

The QAPM states that those applicable design inputs, such as design bases, regulatory requirements, codes, standards, and quality requirements, must be identified and documented in the QAPPD, individual calculations, or design reports, as appropriate. Changes to specified design inputs, as well as the reasons for these changes, must be identified, approved, documented, and controlled.

The QAPM states that design activities must be identified in the QAPPD and accomplished in accordance with procedures of a type sufficient to assure the achievement of the applicable design controls specified in this section. Design activities must be documented in sufficient detail to permit verification and auditing.

The QAPM notes that procedures must govern the preparation and control of drawings, specifications, and other design documents, such as installation instructions and test procedures. The QAPPD must specify the identification of design documents and the applicable procedures for their preparation and control.

The QAPM indicates that the project manager is responsible for all external or internal communications. Communications related to quality concerns of a design must be brought to the attention of the QA manager or project QA engineer.

In addition, the QAPM states that measures must be applied to verify the adequacy of design. A change in design requires that, when feasible, the same individual, group, or organization that reviewed and approved the original documents must also review and approve documents reflecting the change. When not feasible, the reviewing individual, group, or organization must have qualifications commensurate to those who prepared the original document.

In Request for Additional Information (RAI) 17.1-1, the staff asked the applicant to describe the QA measures it used to authenticate and verify any data important to safety retrieved from Internet Web sites that support information in the site safety analysis report (SSAR) that could affect the design, construction, or operation of SSCs important to safety. In its response, the applicant stated that Project Instruction (PI) ENTO-002-PI-02 describes the controls applied to the collection of data in support of the development of the SSAR for the ESP application. The applicant developed the PI for use during collection and review of data supporting those aspects of the SSAR dealing with the safety assessment of the ESP site, specifically hydrological and meteorological data. The PI also indicates the option of its use for other data collection and review, such as demographic data. The PI is applicable to published data and raw data (e.g., data collected from Internet Web site databases). Attachment 1 to the PI documents these sources, as required.

17.3.2 Regulatory Evaluation (Design Control)

While the NRC does not require design control to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the staff to use in evaluating the measures employed by an ESP applicant. In the QAPPD, the applicant's primary contractor stated that its design controls will ensure the development of the application in a quality manner and, where appropriate, in accordance with the requirements of Appendix B to 10 CFR Part 50.

Paragraph 17.1.1.3 in Section 17.1.1 of RS-002 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) 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)

Enercon is the primary contractor for the ESP project, providing personnel, systems, project management, and resources. Entergy Nuclear Potomac Company procured engineering services and support for specific design control activities from its subcontractor, WLA. WLA in turn subcontracted some of these activities to Eustis, GEOVision Physical Services,

Pacific Engineering, Inc., the University of Texas (UT), and Jack Benjamin & Associates. Subcontractors, with the exception of Eustis, were subject to Enercon's QA program and the QAPPD.

The staff evaluated the applicant's response to RAI 17.1-1 concerning the QA measures 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 it used to authenticate or verify the data. The staff found this method of authenticating Internet Web site data to be acceptable.

The staff determined, through review of the applicant's response to RAI 17.1-1, that it had provided adequate QA measures to authenticate and verify data retrieved from Internet Web sites that support information in the SSAR that could affect the design, construction, or operation of SSCs important to safety. Specifically, PI ENTO-002-PI-02, describes the administrative controls applied to the collection of data in support of the development of the SSAR for the ESP application. The PI states that data obtained from Internet Web site sources must be documented as to the source, date of receipt, date or revision level of the data, and title. The data must be retained in the project file. Finally, the data gatherer/user will ensure that data collected are appropriate for the task (based on the knowledge and experience of the individual), can be traced to their source, and support the intended use.

17.3.3.1 Enercon

Entergy Nuclear Potomac Company selected Enercon as the primary vendor to establish a QA program for the ESP. Enercon prepared the QAPPD that was used for applicable portions of the ESP application and established the overall quality framework for the ESP project. Enercon wrote its QAPM to comply with the requirements of Appendix B to 10 CFR Part 50.

The staff reviewed the ESP design control instructions attached to the QAPPD. Additionally, the staff reviewed the design control procedures referenced in the QAPPD. Inspection Report 052000009/2004001 details the staff's review of specific instructions and procedures.

The staff noted that the QAPM provides guidelines for QA controls in the areas of design input, verification, change control, and corrective actions. Additionally, the QAPM provides the guidelines for design process, interface control, and document control and references other Enercon QA procedures for document control and corrective actions. The staff found that the QA design control measures described in Enercon's QAPPD and other Enercon procedures and documents are equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and the guidance contained in Section 17.1.1 of RS-002 regarding ESP design control activities.

17.3.3.2 William Lettis & Associates

Entergy Nuclear Potomac Company contracted with WLA to perform various aspects of the work associated with the ESP permit project. WLA managed and directed field activities associated with the geological, geotechnical, and geophysical work involved with the ESP project. WLA and its subcontractors performed the work according to the guidance provided in

Enercon project instructions (noted previously in this section), portions of the Enercon QAPM, and American Society for Testing and Materials (ASTM) standards.

WLA compiled and evaluated the geosciences database and developed the seismic source model for input into the probabilistic seismic hazard assessment. Additionally, WLA performed the technical review of the data compilation and seismic source characterization activities. As discussed in Inspection Report 052000009/2004001, the staff reviewed documents related to the work performed, supervised, or reviewed by WLA, including (1) site boring summary sheets, (2) cone penetrometer test (CPT) summary logs, (3) static laboratory testing summaries for site borings, (4) borehole logging reports, and (5) WLA daily reports.

The staff noted that the documents independently verify the validity of stated assumptions, inputs, and references cited in engineering reports. The independent technical review determined that WLA and its subcontractors collected and analyzed the input data according to the standard-of-practice methodologies outlined in ASTM standards.

As detailed in Inspection Report 052000009/2004001, the staff also reviewed the engineering reports. These reports verify the validity of the assumptions, inputs, outputs, and references used for calculations. However, the staff noted that the independent reviews for these calculations, which conclude that no substantive discrepancies exist, were completed subsequent to the submission of the ESP application.

The staff concluded that the QA design control measures for the work performed by WLA in support of the ESP project are equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and the design control acceptance criteria contained in Section 17.1.1 of RS-002.

17.3.4 Conclusions (Design Control)

As set forth above, the staff reviewed the QA control measures employed by the primary contractor and its subcontractors and concluded that they implemented acceptable design controls which meet the guidance in Section 17.1.1 of RS-002. This provides 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.

17.4 <u>Procurement Document Control</u>

17.4.1 Technical Information in the Application (Procurement Document Control)

SERI did not supply information in its application about procurement document control. The QAPPD describes the QA measures for ESP activities and identifies certain criteria in Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. Enercon applied elements from these criteria or verified that the controls applied to ESP activities reflect the elements from these criteria, as outlined in the Enercon QAPM. Enercon wrote the QAPM to comply with the requirements of Appendix B to 10 CFR Part 50; as such, it contains QA policies corresponding to each of the Appendix B criteria. The plan

considers procurement document control to be one of the criteria having elements associated with the control of ESP activities.

The QAPM requires procurement document control for the purchase of all safety-related items and services. Procurement documents must be controlled to ensure that requirements, including the basis for acceptance of items or services, are fully and correctly specified. Either the procurement document or other referenced documents must detail technical and QA requirements.

The QAPM states that procurement documents must incorporate (1) inspections and tests to be performed by the subcontractor, including acceptance criteria, (2) source activities to be performed for Enercon (or the client), (3) designated hold points for Enercon or client personnel to perform QA functions, (4) access to records, and (5) QA programs to be documented and applied by the subcontractor that cover the relevant requirements of the Enercon QA program, including those mandated by 10 CFR Part 21, as applicable.

The QAPM notes that the project manager is responsible for all procurement documents. The QA manager must review procurement documents for safety-related items or services.

The QAPM also states that proposed revisions to safety-related procurement documents must be prepared and reviewed in the same manner as the original documents. Procurement documents developed as part of a project must be retained with the project files and must be controlled and maintained as specified in Section 17.0 of the QAPM.

17.4.2 Regulatory Evaluation (Procurement Document Control)

While the NRC does not require procurement document control to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the staff to use in evaluating the measures employed by an ESP applicant. In the QAPPD, the applicant's primary contractor stated that its procurement document controls will ensure development of the application in a quality manner and, where appropriate, in accordance with the requirements of Appendix B to 10 CFR Part 50.

Paragraph 17.1.1.4 in Section 17.1.1 of RS-002 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 the applicable technical requirements and QA controls, and (2) provisions for the review and approval of procurement documents for ESP activities that could affect SSCs important to safety.

17.4.3 Technical Evaluation (Procurement Document Control)

The contract between Entergy Operations, Inc., and Enercon assigns the primary responsibility for project control and preparation of the ESP application to Enercon. Under the contract, Enercon developed the QAPPD. The QAPPD identifies Entergy Nuclear Potomac Company as the client organization, Enercon as the primary contractor for preparation of the ESP application, and WLA as the primary subcontractor for ESP site characterization.

The contract with WLA assigns that organization the responsibility for regional and site investigations, geological hazards investigation, seismic source characterization, and updating the probabilistic seismic hazards analysis developed by the Electric Power Research Institute (EPRI). Entergy Nuclear Potomac Company issued a contract to EPRI, under the auspices of an existing service agreement, for control of information exchanged between EPRI and WLA.

Enercon issued contracts to two principal subcontractors. One contract authorizes Omega to prepare calculations and analyses to determine radiological dose consequences. A second contract authorizes Black Diamond Consultants to update an evacuation time estimate (ETE).

WLA issued contracts in two general areas of activity. One area covers subsurface investigations and characterization of the site. The second area includes the preparation of seismic calculations and independent technical reviews under what are essentially personnel service contracts.

17.4.3.1 Enercon

Enercon is on the Entergy Nuclear Potomac Company's qualified supplier list to provide energy design, general engineering services, and computer software engineering services. The Nuclear Procurement Issues Committee (NUPIC) audited Enercon's QA program to ensure conformance with the technical requirements of Appendix B to 10 CFR Part 50 and the reporting requirements of 10 CFR Part 21. The Enercon QA program follows the guidelines of ANSI N45.2-1977 and ANSI/American Society of Mechanical Engineers (ASME) NQA-1.

Enercon accepted the primary contract from Entergy Nuclear Potomac Company for preparation of the ESP application. The contract sets forth the terms and conditions under which Enercon would provide consulting, professional, or technical services. The contract states that individual task orders would define specific work activities and schedules. The contract identifies the individuals responsible for technical administration, project performance, and contract management.

As detailed in Inspection Report 052000009/2004001, the staff reviewed the contract's QA and reporting requirements for the conduct of project-related activities. The contract states that Enercon would follow its QA program and the QAPPD, as approved by the Entergy Nuclear Potomac Company regulatory compliance/QA manager, in performing all services that are provided in preparation of the ESP application and that could affect the design input for the safety-related SSCs. Further, for work designated as safety related, the contractor would comply with the provisions of 10 CFR Part 21.

Under the contract, Enercon provides engineering, technical, and project management support to prepare an ESP application in accordance with 10 CFR Part 52. The key elements of an ESP application include (1) administrative information, (2) the SSAR, (3) the site environmental report, and (4) emergency planning information. As detailed in Inspection Report 052000009/2004001, the staff's review included contract-related letters issued by Enercon documenting acceptance of the contract, development of an infrastructure for the ESP, and other contract-related matters.

The staff found that the procurement document controls, with respect to Enercon, are equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and meet the guidance contained in Section 17.1.1 of RS-002.

17.4.3.2 William Lettis & Associates

An Entergy contract authorizes WLA to perform regional and site investigations. The contract's quality requirements state that all services provided which could affect the safety-related functions of SSCs associated with the ESP plant parameter envelope must be performed under the auspices of the Enercon QA program, supplemented by the Entergy QAPPD.

Enercon's QA program incorporates a mandate imposed on subcontractors to implement the reporting requirements of 10 CFR Part 21. Therefore, a subcontractor's acceptance of a task under the Enercon QA program also imposes the requirements of 10 CFR Part 21.

The contract provides for access rights by representatives of Entergy to observe contract-related activities and review for acceptance all services provided under the contract. The work orders generally invoke the quality requirements of the service agreement described above.

The staff found that the procurement document controls, with respect to WLA, are equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and meet the guidance contained in Section 17.1.1 of RS-002.

17.4.4 Conclusions (Procurement Document Control)

As set forth above, the staff reviewed the QA measures employed by the primary contractor and its subcontractors and concluded that they have implemented an acceptable level of procurement document control which meets the guidance in Section 17.1.1 of RS-002. This provides 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 the 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)

SERI did not supply information in its application about the control of instructions, procedures, and drawings. The QAPPD describes the QA measures for ESP activities and identifies certain criteria in Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. Enercon applied elements from these criteria or verified that the controls applied to ESP activities reflect the elements from these criteria, as outlined in the Enercon QAPM. Enercon wrote the QAPM to comply with the requirements of Appendix B to 10 CFR Part 50; as such, it contains QA policies corresponding to each of the Appendix B criteria. The plan considers the control of instructions, procedures, and drawings to be one of the criteria having elements associated with the control of ESP activities.

The QAPM states that documented procedures, instructions, and drawings that include appropriate quantitative and qualitative criteria for determining satisfactory work performance and quality compliance must prescribe activities affecting quality. An appropriate level of

management must review the instructions, procedures, and drawings for adequacy and approve them for use.

According to the QAPM, the QAPPD identifies applicable QA requirements for an individual project. The QAPPD may be used to provide and/or identify project-specific instructions in cases in which the issuance or revision of a CSP would be inappropriate or unnecessary.

17.5.2 Regulatory Evaluation (Instructions, Procedures, and Drawings)

While the NRC does not require control of instructions, procedures, and drawings to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the staff to use in evaluating the measures employed by an ESP applicant. In the QAPPD, the applicant's primary contractor stated that its control of instructions, procedures, and drawings will ensure the development of the application in a quality manner and, where appropriate, in accordance with the requirements of Appendix B to 10 CFR Part 50.

Paragraph 17.1.1.5 in Section 17.1.1 of RS-002 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, and drawings, and (2) provisions for incorporating 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)

Section 17.3.3 of this SER provides a detailed discussion of instructions, procedures, and drawings implemented by the primary subcontractor. The staff considered the scope of controls for instructions, procedures, and drawings to be adequate for ensuring that the primary subcontractor properly conducted ESP activities for the applicant and primary contractor. The staff also reviewed the adequacy of activities conducted by additional subcontractors. The following discusses the staff's review of the ESP activities conducted by the additional subcontractors to ensure that controls for instructions, procedures, and drawings are adequate for their scopes of work.

17.5.3.1 University of Texas

WLA subcontracted with the UT Soil Dynamics Laboratory to perform boring sample dynamic laboratory analyses for the ESP project. The QA program policies contained in the UT report comply with the Soil Dynamics Laboratory QA program, which the U.S. Department of Energy previously approved for the Yucca Mountain project dynamic soil and rock tests. Documentation from UT describes technical and test procedures for the resonant column and torsional shear testing performed in the Soil Dynamics Laboratory.

As discussed in Inspection Report 052000009/2004001, the staff noted that UT designed the dynamic test results, reports, and validation procedures to meet the standards of ASTM D3740, "Standard Practice for Minimum Requirements for Agencies Engaged in Testing and/or Inspection of Soil and Rock as Used in Engineering Design and Construction." The staff also

found that the UT engineering personnel involved in performing the tests and writing the reports appear to be adequately trained for the work they performed on the ESP project.

The staff concluded that the instruction, procedure, and drawing controls applied to the work performed by UT in support of the ESP project are equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and meet the guidance contained in Section 17.1.1 of RS-002 regarding ESP design control activities.

17.5.3.2 Eustis

WLA subcontracted with Eustis to perform CPTs and laboratory analysis in support of seismic studies for the ESP project. Eustis carried out the CPT sounding under the requirements of a QAPPD instruction, as specified in its subcontract with WLA. Eustis performed the laboratory analysis in accordance with the Eustis QA procedure, which was reviewed and approved by the Enercon QA manager.

The staff determined that the Eustis QA manual specifies that qualified, trained individuals use approved procedures in accordance with ASTM or other industry standards to complete the laboratory analysis.

The staff concluded that the instruction, procedure, and drawing controls applied to the work performed by Eustis in support of the ESP project are equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and the guidance contained in Section 17.1.1 of RS-002 regarding ESP design control activities.

17.5.3.3 GEOVision

WLA subcontracted with GEOVision to perform geophysical surveying for the ESP project. GEOVision performed its work in accordance with Enercon's QAPM, as specified in Entergy Nuclear Potomac Company's contract with WLA.

The staff noted that GEOVision implemented procedures for the validation of the software output calculations and similar calculations performed by hand.

The staff concluded that the instruction, procedure, and drawing controls applied to the work performed by GEOVision in support of the ESP project are equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and meet the guidance contained in Section 17.1.1 of RS-002 regarding ESP design control activities.

17.5.3.4 Pacific Engineering

WLA subcontracted with Pacific Engineering to complete work for the ESP project under the guidance contained in the Enercon QAPM. Pacific Engineering (1) provided technical advice for the detailed site investigation and laboratory testing program, (2) evaluated preliminary and final analysis of safe-shutdown earthquake (SSE) site response effects, and (3) developed SSE site amplification factors and a calculation package to document the results.

Pacific Engineering worked with Jack Benjamin & Associates to conduct SSE ground motion analyses for the proposed ESP site. All calculations and software used in the development of SSE ground motions were certified for use in accordance with applicable Enercon CSPs.

The staff concluded that the instruction, procedure, and drawing controls applied to the work performed by Pacific Engineering in support of the ESP project are equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and meet the guidance contained in Section 17.1.1 of RS-002 regarding ESP design control activities.

17.5.3.5 Jack Benjamin & Associates

WLA subcontracted with Jack Benjamin & Associates to perform work for the ESP project in accordance with Enercon's QAPM. Jack Benjamin & Associates (1) developed SSE ground motion based on site response amplification factors, (2) provided an updated EPRI probabilistic seismic hazard assessment for the proposed site, (3) updated seismicity parameters for EPRI source zones, as required, and (4) prepared a calculation package documenting any analysis.

The staff concluded that the instruction, procedure, and drawing controls applied to the work performed by Jack Benjamin & Associates in support of the ESP project are equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and meet the guidance contained in Section 17.1.1 of RS-002 regarding ESP design control activities.

17.5.3.6 Omega Technical Services

Omega performed the assessment for radiological dose consequences in support of the ESP project. The scope of work performed by Omega includes both nuclear and nonnuclear safety-related activities. The activities that Omega and Enercon determined to be nuclear safety related were subject to the requirements of Enercon's QAPM and CSPs. The staff noted that Omega personnel involved in the ESP project (1) drafted calculations used to develop the normal dose calculation estimates for radiological consequence evaluations, (2) performed dose calculations for various accidents associated with the advanced boiling-water reactor, Westinghouse Advanced Plant 1000 (AP1000), and Advanced CANDU Reactor-700 plants, (3) performed calculations for normal atmospheric dispersion factors required to determine maximum offsite dose, and (4) evaluated the proposed methodology for the preparation of calculations and analyses.

The staff found that the instruction, procedure, and drawing controls applied to the work performed by Omega in support of the ESP project are equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and the guidance contained in Section 17.1.1 of RS-002 regarding ESP design control activities.

17.5.4 Conclusions (Instructions, Procedures, and Drawings)

As set forth above, the staff reviewed the QA measures employed by the primary subcontractors and concluded that they have implemented an acceptable level of control for instructions, procedures, and drawings which meets the guidance in Section 17.1.1 of RS-002. This provides 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 the satisfactory performance of such SSCs once they are in service.

17.6 Document Control

17.6.1 Technical Information in the Application (Document Control)

SERI did not supply information in its application about document control. The QAPPD describes the QA measures for ESP activities and identifies certain criteria of Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. Enercon applied elements from these criteria or verified that the controls applied to ESP activities reflect these elements, as outlined in the Enercon QAPM. Enercon wrote the QAPM to comply with the requirements of Appendix B to 10 CFR Part 50; as such, it contains QA policies corresponding to each of the Appendix B criteria. The plan considers document control to be one of the criteria having elements associated with the control of ESP activities.

The QAPM states that all safety-related documents associated with a specific project are subject to the following three procedural requirements:

(1) responsibility and methodology are established for preparing, reviewing, approving, and issuing documents and their revisions

(2) unique identification is provided by assignment of document numbers

(3) distribution is controlled by recording document number, date of issue, and all document recipients

The QAPM states that, before approval, the new or revised document will be reviewed to ensure that regulatory, technical, and QA requirements have been appropriately and adequately addressed. A designated person will approve the document after review comments have been resolved. A copy of the latest approved revision will be retained as a QA record.

The QAPM states that revision of any document associated with a quality-related activity will receive the same level of review and approval as the original document. Unless provided for by contractual agreement, only the latest revision of a document will be used.

The QAPM states that transmittal of revised documents will normally be in accordance with the revised document's current distribution list.

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 contains guidance for the staff to use in evaluating the measures employed by an ESP applicant. In the QAPPD, Enercon stated that its document controls will ensure the development of the application in a quality manner and, where appropriate, in accordance with the requirements of Appendix B to 10 CFR Part 50.

Paragraph 17.1.1.6 in Section 17.1.1 of RS-002 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 could affect SSCs important to safety, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed.

17.6.3 Technical Evaluation (Document Control)

Section 17.5 of this SER discusses the document controls applied by the subcontractors. In addition, Inspection Report 052000009/2004001 details the specific documents reviewed and any relevant discussions of their adequacy. The staff considers the scope of document control to be adequate for the ESP activities that were conducted. The staff evaluated documents that were reviewed and approved for issuance to ensure that the document control process was followed. The staff determined that the applicant and its primary contractor had adequate document controls in place for ESP activities.

17.6.3.1 Enercon

The staff found that the primary contractor adequately controlled the distribution of the copies of the QAPM and CSPs. Enercon identified controlled copies of the QAPM and CSPs. The QA manager maintained a record of distribution and properly incorporated revisions into applicable documents. Enercon identified authorized users of the procedures. The staff determined that Enercon adequately controlled documents used for ESP activities.

17.6.4 Conclusions (Document Control)

As set forth above, the staff reviewed the QA measures employed by the primary contractor and concluded that it implemented acceptable document controls which meet the guidance in Section 17.1.1 of RS-002. This provides 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 the satisfactory performance of such SSCs once they are in service.

17.7 <u>Control of Purchased Material, Equipment, and Services</u>

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

SERI did not supply information in its application about the control of purchased material, equipment, and services. The QAPPD describes the QA measures for ESP activities and identifies certain criteria in Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. Enercon applied elements from these criteria or verified that the controls applied to ESP activities reflect the elements from these criteria, as outlined in the Enercon QAPM. Enercon wrote the QAPM to comply with the requirements of Appendix B to 10 CFR Part 50; as such, it contains QA policies corresponding to each of the Appendix B criteria. The plan considers control of purchased material, equipment, and services to be one of the criteria having elements associated with the control of ESP activities.

The QAPM notes that the project manager is responsible for incorporating the technical and QA requirements in procurement documents. The project manager must control communication with subcontractors, assuring that changes and other contractual matters are referred to the manager of projects or division manager for action. The QA manager or designee is responsible for review and concurrence of specified QA requirements in the procurement documents, as well as scheduling and performance of source QA activities. The project manager or QA engineer is responsible for quality verification of items or services received.

The QAPM states that procurement activity controls must ensure that procured items and services affecting the quality of safety-related items conform to the requirements of the procurement documents.

The QAPM states that, if the procured item or service is to be delivered under a QA program that is not Enercon's or the client's, a review and source audit(s) of the subcontractor's QA program must be completed and documented. Enercon or the client may conduct this review and audit, as contractually agreed upon. If the subcontractor is on the client's approved vendor list, this review and audit(s) is not required, provided that client approval is obtained.

The QAPM states that Enercon will verify that procured items and services conform to the requirements of procurement documents. For these items, Enercon must verify that all characteristics required by the procurement document have been completed and documented, that the results of tests and examinations are in accordance with the acceptance criteria specified in the procurement document, and that the qualifications and certifications of personnel are in accordance with the procurement document requirements. For services procured by Enercon, acceptance will be accomplished by the review of documents produced and may require verification of conformance to specifications by surveillance or audit of the activity. The importance to safety, complexity, and the subcontractor's quality performance will determine, at least in part, the methods selected for verification. Verification activities, including data and results, will be documented. Provisions will be made so that the supplier, the client, or Enercon maintain documentary evidence of conformance to procurement documents for purchased material before and during the use of such material and equipment at the client's facility. Enercon's verification will not relieve the subcontractor of its responsibility for quality or quality verification.

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

While the NRC does not require 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 contains guidance for the staff to use in evaluating the measures employed by an ESP applicant. In the QAPPD, Enercon stated that its control of purchased material, equipment, and services will ensure the development of the application in a quality manner and, where appropriate, in accordance with the requirements of Appendix B to 10 CFR Part 50.

Paragraph 17.1.1.7 in Section 17.1.1 of RS-002 provides the QA measures that constitute an acceptable level of control of purchased material, equipment, and services. Acceptable controls 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 that documented evidence of the conformance to procurement specifications of material and equipment related to ESP activities that could affect SSCs important to safety are available at the site before installation or use.

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

Section 17.4.3 of the SER discusses the controls of purchased material, equipment, and services applied by SERI to the primary contractor. This section of the SER focuses on the

additional subcontractors that were engaged in activities for the ESP project. The following sections discuss the scope of activities and the QA measures applied to those activities.

17.7.3.1 Omega

Enercon's service agreement authorizes Omega to conduct an assessment of a radiological dose consequence approach in support of the ESP application. The associated work order authorized calculation of the accident atmospheric dispersion factors for the exclusion boundary and low-population zone. For these safety-related activities, the contract specified that Omega complete calculations under the applicable CSPs. Inspection Report 052000009/2004001 further discusses the staff's review of the procurement controls.

The staff found that the procurement controls, with respect to Omega, are equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and meet the guidance contained in Section 17.1.1 of RS-002.

17.7.3.2 Black Diamond Consultants

Enercon's contract authorizes Black Diamond Consultants to review the ESP project's site emergency plan and update the associated ETE. The scope of work entails a field evaluation of roadway conditions and relevant changes (since the original update estimate was completed in 1986) and interviews with appropriate State and local officials. Enercon specified the work to be performed in accordance with NUREG-0654, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants" (NUREG-0654 FEMA-REP-1, Revision 1 Addenda), Section II, and the requirements of 10 CFR 52.17(b)(2)(i). The contract specified that the documentation of the analyses should include methods, contacts, assumptions, and results, as appropriate, to support conclusions reached. The contract authorized a specific individual to perform the work.

The staff found that the procurement controls, with respect to Black Diamond Consultants, are equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and meet the guidance contained in Section 17.1.1 of RS-002.

17.7.3.3 Eustis

Under a work order, WLA subcontracted with Eustis to provide CPTs and laboratory test services in support of WLA seismic investigations at the ESP site. The ESP site work involved the completion of four CPT soundings at the ESP site, estimated to require borings approximately 80 to 120 feet deep. Eustis carried out the CPT soundings under Enercon's QA program and in accordance with applicable project requirements, specified in the QAPPD instructions. The contract reserved the right of access for Enercon representatives to observe and inspect CPT operations for compliance with the company's QA requirements. Additionally, the contract required that all Eustis personnel involved in data acquisition processing receive training in the Enercon QA program.

The work order specified that Eustis carry out laboratory analysis in accordance with its quality procedures. Enercon conducted a qualification audit of the Eustis laboratory, which concluded that, although Eustis did not have a QA program that met the requirements of Enercon's QA

program, adequate controls were in place to support adding Eustis to the Enercon qualified supplier list for material testing in support of the ESP project.

Eustis contract deliverables included maintenance of a scientific notebook and daily field reports for the CPT investigations. Upon project completion, Eustis must provide copies of the scientific notebook, calibration records, or documentation of CPT logs or laboratory results. Eustis must provide a report documenting the scope of work, methodology, data, and results of investigations. The staff reviewed a summary of the results in the ESP application.

The staff found that the procurement document controls, with respect to Eustis, are equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and meet the guidance contained in Section 17.1.1 of RS-002. However, the contract did not impose the reporting requirements of 10 CFR Part 21. Additionally, SERI did not require the work performed by this subcontractor to meet the criteria of 10 CFR Part 21. Since the results of the laboratory testing may be used for support of load-bearing structures and equipment, an RAI focused on the lack of documentation regarding 10 CFR Part 21 requirements. Inspection Report Open Item 052000009/2004001-02 discusses this omission.

Subsequently, in RAI 17.1-4, the staff asked the applicant to describe the actions it took to ensure the work performed by Eustis for the ESP project complied with the requirements of 10 CFR Part 21. In its response, the applicant stated that the Enercon QA program qualified, by source audit, the Eustis QA program to perform static soil testing. Eustis does not maintain a 10 CFR Part 21 reporting process. Project records document the adequacy of the work that Eustis provided. Eustis completed all testing in accordance with the applicable ASTM standards, as prescribed in the Enercon QA procedures. In addition, before performing ESP work, the U.S. Army Corps of Engineers (USACE) certified Eustis for similar work.

The applicant noted that, during the ESP phase, static soil data provided by Eustis will be used in a qualitative, rather than quantitative manner for soil classification, general evaluation of geologic hazards and comparative evaluation with the data in the updated final safety analysis report. During the second phase (i.e., the COL phase), the data may be used to supplement additional information required to be collected during this phase (additional boreholes and testing will be required at the COL phase). This COL data will be used to evaluate liquefaction potential, foundation-bearing capacities, foundation settlements, and excavation design. The work performed for the COL phase, which will serve to further validate the original Eustis work, will require 10 CFR Part 21 requirements to be applied.

The staff found that the procurement controls, with respect to Eustis, are equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and meet the guidance contained in Section 17.1.1 of RS-002. In addition, the staff found the alternative method that the applicant proposed to address a lack of 10 CFR Part 21 requirements, specifically as applied to Eustis, to be acceptable.

17.7.3.4 GEOVision

WLA contracted with GEOVision to conduct ESP site activities related to geophysical surveys and pressure and shear wave suspension logging. GEOVision performed its work in accordance with Enercon's QAPM and applicable project requirements, as specified in the QAPPD.

GEOVision identified the pressure and shear wave surveys that were conducted within the scope of the contract as safety related and, as such, required calibration of equipment and documentation of all work in a scientific notebook. The staff reviewed the GEOVision activities associated with this contract in the applicable site-boring logs and classification logs. The staff found that GEOVision appropriately documented the required calibrations and work.

The staff found that the procurement controls, with respect to GEOVision, are equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and meet the guidance contained in Section 17.1.1 of RS-002.

17.7.3.5 University of Texas

WLA contracted with Dr. Ken Stokey of UT to conduct laboratory testing services in support of the WLA seismic investigations. Testing included six dynamic triaxial tests and resonant column and torsional shear tests. Dr. Stokey and UT performed the work in accordance with Enercon's QA program and the applicable project requirements, as specified in Enercon's QAPPD. The contract specified that the work be carried out under existing UT procedures, which the Enercon QA manager reviewed and approved for the project. The applicant included the approved procedure as an attachment in the QAPPD (PI ENTO-002-PI-05).

The staff found that the procurement controls, with respect to UT, are equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and meet the guidance contained in Section 17.1.1 of RS-002.

17.7.3.6 Jack Benjamin & Associates

WLA subcontracted with Jack Benjamin & Associates for a designated individual to provide technical services, including a technical review of ground motion sensitivity analysis and development of rock ground motions. A subsequent work order authorized (1) additional technical reviews to update the seismicity parameters for EPRI source zones and the EPRI probabilistic seismic hazard assessment and median ground rock ground motion for site response analysis, (2) preparation of calculation packages documenting these reviews, and (3) preparation of ESP SSAR Sections 2.5.2.3 and 2.5.2.5. Although the contract did not impose any specific QA requirements, on the basis of a discussion between the NRC staff and the project managers, such contracts are common within the industry, functioning like a staff augmentation program with the independent subcontractor working under the QA program of the contracting organization. In this case, Jack Benjamin & Associates performed subcontractor work under Enercon's QA program, as stipulated in the Entergy contract with WLA. The calculations performed under this subcontract were not available for review.

The staff found that the procurement controls, with respect to Jack Benjamin & Associates, are equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and meet the guidance contained in Section 17.1.1 of RS-002.

17.7.3.7 Pacific Engineering

Pacific Engineering personnel performed technical services under this contract. Pacific Engineering provided technical advice for detailed site investigation and laboratory testing. The individual designated in the above Jack Benjamin & Associates contract was responsible for

ground motion sensitivity analysis. The contract also authorized work for the performance of the final site response analysis, development of SSE site amplification factors, and preparation of a calculation package in SSAR Section 2.5.2.4. The same QA requirements as noted in the Jack Benjamin & Associates contract applied to the work performed by Pacific Engineering.

The staff found that the procurement document controls, with respect to Pacific Engineering, are equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and meet the guidance contained in Section 17.1.1 of RS-002.

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

As set forth above, the staff reviewed the QA measures employed by the primary subcontractors and concluded that they have implemented acceptable controls for purchased material, equipment, and services which meet the guidance in Section 17.1.1 of RS-002. This provides 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 the satisfactory performance of such SSCs once they are in service.

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)

SERI did not supply information in its application about the identification and control of materials, parts, and components. The QAPPD describes the QA measures for ESP activities and identifies certain criteria in Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. Enercon applied elements from these criteria or verified that the controls applied to ESP activities reflect the elements from these criteria, as outlined in the Enercon QAPM. Enercon wrote the QAPM to comply with the requirements of Appendix B to 10 CFR Part 50; as such, it contains QA policies corresponding to each of the Appendix B criteria. The plan does not consider identification and control of materials, parts, and components to be one of the criteria having elements associated with the control of ESP activities.

The QAPPD does not provide justification as to why the identification and control of materials, parts, and components does not apply to ESP activities. However, in its QAPM, the primary contractor describes the requirements for identifying safety-related items.

The QAPM states that item specification or procurement documents will state identification requirements for items. Identification will be keyed to some unique feature, such as lot, heat, part, or serial number.

The QAPM states that, when direct identification is impractical or insufficient, physical separation or procedural controls will be added or substituted to ensure that each item can be positively identified. Markings on tags and labels, when required, will be applied in a manner that is not detrimental to the item or its use. Markings on items, tags, and labels will be legible, unambiguous, and durable. Coding may be used, provided that the code is explained in records traceable to the items. All documents intended to provide a record of the necessary characteristics (quality) or performance of required processes or activities on an item will

include the identification of the item. The catalog number or standard identification marked on the container may identify standard shelf or catalog items, which are procured in quantity and which do not have specific material, test, or inspection requirements.

The QAPM states that the identification of items will be maintained at all times. Item and item record identification will be verified before installation of the material, part, or component.

In RAI 17.1-3, the staff asked the applicant to explain why the 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 used for the ESP application. In its response, SERI stated that the development of the ESP application does not require procurement, fabrication, receipt, or erection of safety-related materials, parts, components, or partially fabricated assemblies for installation into a nuclear power plant. A QAPPD instruction specifies the applicable quality controls, governing codes, and national consensus standards for control of all equipment used in the laboratory testing of samples. This criterion is therefore not applicable to the ESP project.

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 contains guidance for the staff to use in evaluating the measures employed by an ESP applicant. In the QAPPD, the applicant's primary contractor states that its identification and control of materials, parts, and components does not apply to ESP activities. However, the QAPM does have the requisite controls.

Paragraph 17.1.1.8 in Section 17.1.1 of RS-002 provides the QA measures that constitute an acceptable level of identification and control of materials, parts, and components. An acceptable level 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 17.1-3 and its observations during the inspection, that the applicant and Enercon did not conduct activities important to safety that require the identification and control of materials, parts, and components.

17.8.4 Conclusions (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 the scope of work for the ESP project does not require the identification and control of materials, parts, and components.

17.9 Control of Special Processes

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

SERI did not supply information in its application about control of special processes. The QAPPD describes the QA measures for ESP activities and identifies certain criteria of Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. Enercon applied elements from these criteria or verified that the controls applied to ESP activities reflect the elements from these criteria, as outlined in the Enercon QAPM. Enercon wrote the QAPM to comply with the requirements of Appendix B to 10 CFR Part 50; as such, it contains QA policies corresponding to each of the Appendix B criteria. The plan does not consider control of special processes to be one of the criteria having elements associated with the control of ESP activities.

The QAPPD does not provide justification as to why the identification and control of special processes does not apply to ESP activities. However, in its QAPM, Enercon describes that this criterion of Appendix B to 10 CFR Part 50 addresses the necessity of establishing controls to assure that those special processes, such as welding and heat treating, are correctly performed by properly qualified and certified personnel.

The QAPM states this criterion is not within the scope of services currently provided by Enercon. Should events dictate, Enercon would add this criterion to the program and obtain separate client approval before beginning any activity that requires it to control special processes.

In RAI 17.1-3, the staff asked the applicant to explain why the 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 used for the ESP application. In its response, the applicant stated that the development of the ESP application does not involve any special processes, including welding, heat treating, or nondestructive examination. No requirements are in place for use of personnel qualified in accordance with specific codes and standards governing nondestructive examination activities. Therefore, this criterion does not apply to the ESP project.

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 17.1.1of RS-002 contains guidance for the staff to use in evaluating an ESP applicant's control of special processes. In the Enercon QAPM, the primary contractor stated that the development of the ESP application will not involve the use of special processes.

Paragraph 17.1.1.9 in Section 17.1.1 of RS-002 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 special processes related to ESP activities that could affect SSCs important to safety are performed by qualified personnel using qualified procedures and equipment.

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 17.1-3 and its observations during the inspection, that the applicant and Enercon did not conduct activities important to safety that require control of special processes.

17.9.4 Conclusions (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)

SERI did not supply information in its application about controls for inspection. The QAPPD describes the QA measures for ESP activities and identifies certain criteria in Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. Enercon applied elements from these criteria or verified that the controls used for ESP activities reflect the elements from these criteria, as outlined in the Enercon QAPM. Enercon wrote the QAPM to comply with the requirements of Appendix B to 10 CFR Part 50; as such, it contains QA policies corresponding to each of the Appendix B criteria. The plan does not consider controls for inspection to be one of the criteria having elements associated with the control of ESP activities.

The QAPPD does not provide justification as to why inspection controls do not apply to ESP activities. However, in its QAPM, Enercon describes that this criterion addresses the establishment of a program for performing inspections for work activities important to safety.

The QAPM states that this criterion is not within the scope of services currently provided by Enercon. However, Enercon or its subsidiaries provide qualified personnel for certification to client inspection programs. Enercon's involvement is limited to providing personnel who, by virtue of review of resumes, certificates, and other such documentation, provide reasonable assurance of meeting the minimum qualification requirements of ANSI N45.2.6, "Qualifications of Inspection, Examination, and Testing Personnel for Nuclear Power Plants," or American Society for Nondestructive Testing (ASNT)-TC-1A, "Recommended Practice, Personnel Qualification and Certification in Nondestructive Testing," where applicable. In cases in which such evidence is weak or questionable, Enercon will verify the individual's qualifications with previous employers. Enercon will provide personnel certified in specific disciplines in accordance with the client's certification program.

In RAI 17.1-3, 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 used for the ESP application. In its response, the applicant stated that the development of the ESP application does not involve inspection process monitoring activities. In addition, no hold or witness points were required to

be established for any of the activities performed under the ESP project. The applicant and its primary contractor performed quality surveillances and audits under the QAPPD. Therefore, this criterion does not apply to the ESP project.

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 contains guidance for the staff to use in evaluating an ESP applicant's control for inspections. In its QAPM, the primary contractor states that development of the ESP application will not involve the use of controls for inspection.

Paragraph 17.1.1.10 in Section 17.1.1 of RS-002 provides the QA measures that constitute an acceptable level of inspection control, including (1) provisions for the inspection of activities affecting the quality of ESP activities that could affect SSCs important to safety, in addition to the items and activities to be covered, (2) establishment of 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 17.1-3 and its observations during the inspection, that the applicant and Enercon did not conduct activities important to safety that require inspection.

17.10.4 Conclusions (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 is not required.

17.11 Test Control

17.11.1 Technical Information in the Application (Test Control)

SERI did not supply information in its application about test control. The QAPPD describes the QA measures for ESP activities and identifies certain criteria in Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. Enercon applied elements from these criteria or verified that the controls used for ESP activities reflect the elements from these criteria, as outlined in the Enercon QAPM. Enercon wrote the QAPM to comply with the requirements of Appendix B to 10 CFR Part 50; as such, it contains QA policies corresponding to each of the Appendix B criteria. The plan considers test control to be one of the criteria having elements associated with the control of ESP activities.

The QAPPD does not provide justification as to why test control does not apply to ESP activities. However, in its QAPM, Enercon describes requirements for test control.

The QAPM provides the roles and responsibilities of Enercon personnel for test control. It also states that independent tests or a test program will be planned, as required by the contract, and documented to identify the testing required and the test schedule for the ESP project. Enercon will submit test planning documents to the client for review and approval, as required by the contract. The QAPPD addresses the specific requirements for test planning. For each test or system of tests, the test planning documents will include the schedule for the development of test procedures, performance of the tests, and qualification of test personnel, when applicable.

The QAPM states that test procedures will identify the item to be tested and the purpose of the test. Test procedures will specify, as applicable, (1) preparations and inspections that must be accomplished before testing, (2) special environments, (3) prerequisites, (4) calibrated instrumentation, (5) instructions, (6) hold points, (7) acceptance criteria based on applicable design documents, and (8) methods for documenting or recording test data and results.

The QAPM notes that, when test results or an evaluation reveals a nonconformance, the test documentation will clearly state the degree, cause, and disposition of nonacceptability.

In RAI 17.1-3, the staff asked the applicant to explain why test control 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 used for the ESP application. In its response, the applicant stated that the development of the ESP application does not require a test program to demonstrate that the SSCs would perform satisfactorily in service. The applicant and its primary contractor did not perform any testing under the ESP project that relates to proof testing, preoperational testing, or operational testing.

This criterion addresses testing differently than the laboratory testing performed on samples taken for seismological data collection activities and field geophysical testing. This criterion specifies and implements the appropriate quality controls for laboratory and geophysical testing and analysis in accordance with the requirements of design control. A QAPPD instruction specifies the applicable quality controls, governing codes, and national consensus standards for testing of these samples. Therefore, this criterion does not apply to the ESP project.

17.11.2 Regulatory Evaluation (Test Control)

While the NRC does not require test control to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the staff to use in evaluating the measures employed by an ESP applicant. In the QAPPD, the applicant's primary contractor stated that its test controls do not apply to ESP activities. However, the QAPM does have the requisite controls.

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

17.11.3 Technical Evaluation (Test Control)

The staff indicated that observations made by QA personnel meet quality measures for test control. This section uses the term "surveillance" as a set of observations of limited scope performed by an individual. The staff considered the surveillances that QA personnel conducted an appropriate indicator of acceptable test controls in place for ESP activities. A surveillance would cover such areas as properly completed tests, completed prerequisites in the test procedure, and properly documented results.

The staff reviewed the Enercon QA manager's performance of two surveillances at the ESP site and one surveillance at UT, where Enercon conducted dynamic material testing. Instead of Enercon overseeing surveillances, an independent subcontractor with QA experience performed surveillances at the WLA offices in San Rafael and Walnut Creek, California. The following discusses the staff's review of these surveillance results.

17.11.3.1 Site Evaluation Activities

The Enercon QA manager conducted two surveillances while site activities were in progress. In the first surveillance, the QA manager observed mud rotary drilling at Borehole No. 1. This surveillance verified that SERI recorded the core barrel dimension and condition of bits and steel, as required. Based on this observation, the QA manager concluded that the equipment complies with ASTM D1586-84, "Standard Test Method for Penetration Test and Split-barrel Sampling of Soils." The QA manager also checked equipment for thin-wall sampling, determining that it complies with ASTM D1587-94, "Standard Practice for Thin-walled Geotechnical Sampling of Soils." Two deficiencies, involving handling of soil samples, were dispositioned and closed during the surveillance.

The second surveillance verified that observed attributes met the requirements of ASTM D5778-95, "Standard Test Method for Performing Electronic Friction Cone and Piezocone Penetration Testing of Soils." One deficiency, involving field calibration of equipment, was dispositioned and closed during the surveillance.

The staff found that the test controls for the ESP site evaluation activities are equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and meet the guidance contained in Section 17.1.1 of RS-002.

17.11.3.2 Material Testing Laboratories

The Enercon QA manager conducted a surveillance of activities associated with resonant column and torsional shear testing at UT. The surveillance examined test apparatus and configuration and calibration documentation. Based on observation of equipment setup and testing activities, the QA manager concluded that SERI performed the testing in accordance with the applicable QAPPD instruction. The QA manager identified three deficiencies associated with calibration dates on test equipment. Two were attributed to typographical errors; the third was attributed to an out-of-date calibration sticker. All deficiencies were dispositioned and closed during the surveillance.

The staff found that the test controls for material testing activities are performed and controlled in a manner equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and meet the guidance contained in Section 17.1.1 of RS-002.

17.11.3.3 William Lettis & Associates

The staff reviewed three internal surveillance reports documenting surveillances conducted at the WLA offices in San Rafael and Walnut Creek, California.

WLA conducted the first surveillance before any calculations had been performed. The WLA staff used a checklist to verify that project requirements, such as a project file, resumes for project personnel, and project instructions, were in place.

WLA conducted a second surveillance to verify that the records required by QAPPD instructions were complete. This surveillance followed the completion of site activities, and the report identified a number of needed actions.

WLA conducted the third surveillance to verify completeness of project deliverables, the preparation of which was controlled by QAPPD instructions. In addition, the surveillance reviewed project documentation for compliance with the applicable Enercon CSP for issuance of project deliverables.

With the exception of six findings and two recommendations identified in the three surveillances, the staff concluded that WLA satisfied the applicable requirements of the QAPPD instructions. The staff documented the actions taken to close the findings and recommendations in an email to the primary contractor. The primary contractor documented closure of the findings and recommendations in a letter.

The staff found that the test controls for activities conducted by WLA are equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and meet the guidance contained in Section 17.1.1of RS-002.

17.11.4 Conclusions (Test Control)

As set forth above, the staff reviewed the QA measures employed by the applicant and the primary contractor and its subcontractors, concluding that they have implemented acceptable test controls which meet the guidance in Section 17.1.1 of RS-002. This provides 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.

17.12 <u>Control of Measuring and Test Equipment (M&TE)</u>

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

SERI did not supply information in its application about the control of M&TE. The QAPPD describes the QA measures for ESP activities and identifies certain criteria in Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. Enercon

applied elements from these criteria or verified that the controls applied to ESP activities reflect the elements from these criteria, as outlined in the Enercon QAPM. Enercon wrote the QAPM to comply with the requirements of Appendix B to 10 CFR Part 50; as such, it contains QA policies corresponding to each of the Appendix B criteria. The plan considers the control of M&TE to be one of the criteria having elements associated with the control of ESP activities.

The QAPM states that, to ensure accuracy, M&TE will be controlled, calibrated, adjusted, and maintained at prescribed intervals or before use against certified equipment having known valid relationships to nationally recognized standards. If no national standards exist, the basis for calibration will be documented. Special calibration will be performed when the accuracy of the equipment is suspect. When M&TE is found to be out of calibration, an evaluation will document the validity of previous inspection or test results and the acceptability of the items previously inspected or tested. If any M&TE is consistently found to be out of calibration, it will be repaired or replaced.

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 contains guidance for the staff to use in evaluating the measures employed by an ESP applicant. In the QAPPD, the applicant's primary contractor stated that its control of M&TE will ensure the development of the application in a quality manner and, where appropriate, in accordance with the requirements of Appendix B to 10 CFR Part 50.

Paragraph 17.1.1.12 in Section 17.1.1 of RS-002 provides the QA measures constituting an acceptable level of control of M&TE. Acceptable control of M&TE should include (1) provisions to ensure that tools, gauges, instruments, and other measuring and testing devices are properly identified and controlled, and (2) provisions to ensure that those tools and devices are calibrated and adjusted at specified intervals.

17.12.3 Technical Evaluation (Control of M&TE)

17.12.3.1 William Lettis & Associates

WLA managed and directed the field activities. WLA used various specialty subcontractors for exploratory drilling and sampling, geophysical surveying, and laboratory testing. The WLA project manager provided overall direction for the work and supervised a staff of senior and staff geologists. WLA conducted its work in accordance with a QAPPD instruction for geologic and geophysical field exploration and laboratory testing. The QAPPD instruction provided guidelines to ensure that WLA performed the field and laboratory studies in a manner consistent with applicable regulations and nuclear industry standards. WLA conducted testing in accordance with ASTM standards. The staff reviewed the completed M&TE calibration data sheets attached to the instruction and found no deficiencies. WLA also enclosed pertinent calibration methodology procedures, which meet ASTM standards.

17.12.3.2 University of Texas

The UT performed boring sample dynamic laboratory analysis. The staff reviewed the testing report, which details procedures that UT designed for the control of M&TE to meet ASTM D3740. The staff considered the procedures adequate for the scope of work conducted by UT.

The UT conducted linear and nonlinear dynamic soil property measurements determined by combined resonant and torsional shear tests. The staff reviewed engineering report results that document the work conducted at UT. The report contains all documentation associated with (1) the testing and calibration procedures, (2) the QA program, and (3) the overall system checks conducted before and after UT performed dynamic testing. The staff also ensured that the calibration standards used are traceable to the National Institute of Standards and Technology (NIST).

17.12.3.3 Eustis

Eustis conducted four CPTs at the site using an electronic piezocone penetrometer. The sleeve friction is measured directly using a subtraction load cell. Eustis completed the testing in accordance with methods and procedures outlined in ASTM D5778-95. During the CPTs, Eustis recorded CPT parameters (tip resistance and friction resistance) and pore pressure measurements. Eustis made pore pressure measurements using a pore pressure element located behind the tip. The staff reviewed the instrumentation calibration report and found that it is traceable to NIST.

17.12.3.4 GEOVision

GEOVision conducted suspension soil velocity measurements. The staff noted that GEOVision performed the velocity measurements using industry-standard or better methods for both measurements and analyses. GEOVision completed all work under its QA procedures, which include (1) use of before and after NIST-traceable calibrations, where applicable, for field and laboratory instrumentation, (2) use of standard field data logs, (3) use of independent verification of data by comparison of receiver-to-receiver and source-to-receiver velocities, and (4) independent review of calculations and results by a registered professional engineer, geologist, or geophysicist. The staff found that the GEOVision controls for M&TE appear adequate for the work performed.

17.12.4 Conclusions (Control of M&TE)

As set forth above, the staff reviewed the QA measures employed by the primary subcontractors and concluded that they implemented acceptable controls for M&TE that meet the guidance in Section 17.1.1 of RS-002. This provides 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.

17.13 Handling, Storage, and Shipping

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

SERI did not supply information in its application on handling, storage, and shipping controls. The QAPPD describes the QA measures for ESP activities and identifies certain criteria in Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. Enercon applied elements from these criteria or verified that the controls applied to ESP activities reflect the elements from these criteria, as outlined in the Enercon QAPM. Enercon wrote the QAPM to comply with the requirements of Appendix B to 10 CFR Part 50; as such, it contains QA policies corresponding to each of the Appendix B criteria. The plan considers the handling, storage, and shipping controls to be one of the criteria having elements associated with the control of ESP activities.

The QAPM states that, when necessary, particular items, special coverings, special equipment, and special protective environments (i.e., inert gas, temperature levels, and moisture content) will be specified, provided, and their existence verified. For critical, sensitive, perishable, or high-valued articles, specific written procedures for handling, storage, packaging, shipping, and preservation will be used. Special handling tools and equipment will be provided, as necessary, to ensure safe and adequate handling. Markings will be adequate to identify, maintain, and preserve the shipment, including indication of the presence of a special environment or the need for special control.

17.13.2 Regulatory Evaluation (Handling, Storage, and Shipping)

While the NRC does not require handling, storage, and shipping controls to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the staff to use in evaluating the measures employed by an ESP applicant. In the QAPPD, the applicant's primary subcontractor states that its handling, storage, and shipping controls will ensure the development of the application in a quality manner and, where appropriate, in accordance with the requirements of Appendix B to 10 CFR Part 50.

Paragraph 17.1.1.13 in Section 17.1.1 of RS-002 provides the QA measures that constitute an acceptable level of handling, storage, and shipping control. Acceptable controls should include provisions to control the 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 Enercon

The staff did observe a specific example of Enercon's controls for handling, storage, and shipping, which it details in a site visit report (ADAMS Accession No. ML022320222). Enercon conducted exploratory borings and CPTs during the staff visit. This enabled the staff to observe the performance of two CPTs and the partial drilling of a test hole with the collection of soil samples. The exploratory boring characterized subsurface geologic conditions, performed

in-situ testing, conducted borehole geophysical surveys, and obtained soil samples for laboratory testing. The staff saw several wood boxes of soil samples from a boring that were stored in a shaded area, awaiting shipment to UT for dynamic soil testing. Each box contained several plastic tubes of soil samples. Enercon marked and sealed each tube with wax at both ends to prevent the escape of moisture from the soil. The soil samples appeared to be properly sealed and packed.

A QAPPD instruction describes field techniques for controlling field samples. The instruction states that control-numbered field notebooks will be used to record data and field observations and measurements. The recording geologist will number and sign notebook pages. In addition, samples collected will be numbered and labeled in a manner consistent with the outcrops identified in the field notebooks. The QAPPD instruction also covers (1) field techniques for controlling field samples, (2) sample storage, (3) labeling and identification of samples, (4) recording samples, (5) sample storage, and (6) the sample retention period.

Another QAPPD instruction describes the handling and storage of various soil and rock samples. Specific instructions apply to various types of samples from different sampling methods, such as mud rotary drilling, diamond wireline rock coring, rock sampling, and borehole logging. The ASTM Standards D4220-95, “Standard Practices for Preserving and Transporting Soil Samples,” and D5079-90, “Standard Practices for Preserving and Transporting Rock Core Samples,” outline the guidelines for collecting and transporting samples for lab testing or future analysis.

17.13.4 Conclusions (Handling, Storage, and Shipping)

As set forth above, the staff reviewed the QA measures employed by the primary contractor and concluded that it implemented acceptable controls for handling, storage, and shipping which meet the guidance in Section 17.1.1 of RS-002. This provides 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.

17.14 Inspection, Test, and Operating Status

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

SERI did not supply information in its application about controls for inspection, test, and operating status. The QAPPD describes the QA measures for ESP activities and identifies certain criteria in Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. Enercon applied elements from these criteria or verified that the controls applied to ESP activities reflect the elements from these criteria, as outlined in the Enercon QAPM. Enercon wrote the QAPM to comply with the requirements of Appendix B to 10 CFR Part 50; as such, it contains QA policies corresponding to each of the Appendix B criteria. The plan does not consider controls for inspection, test, and operating status to be one of the criteria having elements associated with the control of ESP activities.

The QAPPD does not provide justification as to why identification and controls inspection, test, and operating status do not apply to ESP activities. However, in its QAPM, the primary

contractor states that this criterion addresses the necessity of identifying the status of inspections, tests, and/or operability of safety-related SSCs. The QAPM further states that this criterion is not within the scope of services currently provided by Enercon. Should events dictate, Enercon will add this criterion to the program and obtain separate client approval.

In RAI 17.1-3, the staff asked the applicant to explain why inspection, test, and operating status do 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 used for the ESP application. In its response, the applicant stated that the development of the ESP application does not entail the design, fabrication, or installation of any safety-related SSCs. No measures were required to indicate whether components have passed inspections or tests. Similarly, no SSCs are presumed to operate where tagging or operational controls would be required to indicate status. A QAPPD instruction specifies the applicable quality controls and the governing codes and standards for control of all equipment used in laboratory testing of samples. Therefore, this criterion does not apply to the ESP project.

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 contains guidance for the staff to use in evaluating an ESP applicant's control of special processes. In its QAPM, Enercon states that controls for inspection, test, and operating status are not within the scope of services it currently provides. Should events dictate, Enercon will add this criterion to the program and obtain separate client approval.

Paragraph 17.1.1.14 in Section 17.1.1 of RS-002 provides the QA measures that constitute an acceptable level of controls for inspection, test, and operating status. Acceptable controls should include provisions to indicate the inspection, test, and operating status of items related to ESP activities that could affect SSCs important to safety in order to 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 17.1-3 and its observations during the inspection, that the applicant and Enercon did not conduct activities important to safety that require control of inspection, test, and operating status.

17.14.4 Conclusions (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 is not required.

17.15 Nonconforming Materials, Parts, or Components

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

SERI did not supply information in its application about control of nonconforming materials, parts, or components. The QAPPD describes the QA measures for ESP activities and identifies certain criteria in Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. Enercon applied elements from these criteria or verified that the controls applied to ESP activities reflect the elements from these criteria, as outlined in the Enercon QAPM. Enercon wrote the QAPM to comply with the requirements of Appendix B to 10 CFR Part 50; as such, it contains QA policies corresponding to each of the Appendix B criteria. The plan does not consider control of nonconforming materials, parts, or components to be one of the criteria having elements associated with the control of ESP activities.

The QAPPD does not provide justification as to why control of nonconforming materials, parts, or components does not apply to ESP activities. However, in its QAPM, Enercon describes requirements for the control of nonconforming materials, parts, or components. According to the QAPM, the QAPPD will include, if applicable to the project scope, requirements in procedures for identification, documentation, segregation, disposition, and notification to affected organizations of nonconforming items.

The QAPM states that nonconforming items will be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures. Repaired or reworked items will be reinspected based on applicable procedures. Measures that control further processing, delivery, or installation of a nonconforming or defective item pending a decision on its disposition will be established and maintained. Nonconforming items may be disposed of by acceptance as is, by scrapping or repairing the defective item, or by reworking to complete or correct to a drawing or specification. The measures will require documentation verifying the acceptability of nonconforming items that have the disposition of “repair” or “use as is.” As a guideline, control of nonconforming items by tagging, marking, or other means of identification is acceptable when physical segregation is not practical, although physical segregation and markings are preferred.

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 contains guidance for the staff to use in evaluating the measures employed by an ESP applicant. In the QAPPD, the applicant’s primary subcontractor states that its control of nonconforming materials, parts, or components will ensure the development of the application in a quality manner and, where appropriate, in accordance with the requirements of Appendix B to 10 CFR Part 50.

Paragraph 17.1.1.15 in Section 17.1.1 of RS-002 provides the QA measures that constitute an acceptable level of nonconforming materials, parts, or components control. Acceptable controls 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 control of nonconforming materials, parts, or components. The staff concluded, based on its review of the applicant's response to RAI 17.1-3 and its observations during the inspection, that the applicant and Enercon did not conduct activities important to safety that require identification and control of nonconforming materials, parts, or components.

17.15.4 Conclusions (Nonconforming Materials, Parts, or Components)

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

17.16 Corrective Action

17.16.1 Technical Information in the Application (Corrective Action)

SERI did not supply information in its application about corrective action. The QAPPD describes the QA measures for ESP activities and identifies certain criteria in Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. Enercon applied elements from these criteria or verified that the controls applied to ESP activities reflect the elements from these criteria, as outlined in the Enercon QAPM. Enercon wrote the QAPM to comply with the requirements of Appendix B to 10 CFR Part 50; as such, it contains QA policies corresponding to each of the Appendix B criteria. The plan considers corrective action to be one of the criteria having elements associated with the control of ESP activities.

In the QAPM, the scope of corrective action includes provisions for response to significant conditions adverse to quality or that require action by Enercon to comply with the requirements of 10 CFR Part 21. The QAPM also provides for the initiation of "stop work" action.

The QAPM states that every Enercon employee must identify conditions adverse to quality and notify the QA manager or designee of the condition. This responsibility for notification is not limited to known conditions but may also include conditions suspected to be adverse to quality. The QA manager and project manager are both responsible for identifying any CARs that could represent a condition requiring evaluation and reporting based on the requirements of 10 CFR Part 21. For project problems, the project manager is responsible for resolving the corrective action request and for initiating actions to correct the condition. The project manager will describe these actions on a corrective action resolution form, which will be sent to the QA manager for acceptance.

According to the QAPM, the QA manager, project QA engineer, or lead auditor is responsible for verifying the adequacy and completion of corrective action and, upon such verification, for closeout and documentation of the CARs. Documentation of corrective action includes (1) a description of the identified problem, (2) a root cause analysis of the problem, (3) immediate actions taken to correct a specific problem, and (4) the actions taken to prevent recurrence of the problem (if evaluated as necessary).

According to the QAPM, the project manager will notify subcontractors of conditions adverse to quality within the subcontractor's facility or of conditions adverse to quality that could impact work being performed by the subcontractor.

The QAPM states that, once a verification that immediate actions and actions taken to prevent recurrence is complete, the CAR will be closed out. An original of the closeout report, including any correspondence related to the report, will be retained in the project files as quality records. The QA manager will retain a copy of the report and associated correspondence.

17.16.2 Regulatory Evaluation (Corrective Action)

While the NRC does not require corrective action to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the staff to use in evaluating the measures employed by an ESP applicant. In the QAPPD, the applicant's primary contractor states that its corrective action will ensure the development of the application in a quality manner and, where appropriate, in accordance with the requirements of Appendix B to 10 CFR Part 50.

Paragraph 17.1.1.16 in Section 17.1.1 of RS-002 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, such provisions should preclude recurrence.

17.16.3 Technical Evaluation (Corrective Action)

17.16.3.1 Enercon

Enercon's QAPM provides for controls on the identification and correction of conditions adverse to quality. The primary contractor used a CAR to document conditions adverse to quality. The staff determined that the applicable CSP on corrective action provides adequate guidance for the conduct of a corrective action program. However, the staff identified that neither the QAPM nor the CSP define a condition adverse to quality. As discussed below, the staff found that the threshold at which the primary contractor documented CARs and took corrective action was appropriate for ESP activities. The Enercon QA manager generated a CAR to document the staff's finding. Inspection Report 052000009/2004001 further details the staff's review of the corrective action program.

The staff reviewed a CAR which documents that Enercon did not use a reference summary form for population data sources, as required by the QAPPD instructions. Initially, the population data were not considered safety related. The applicant used the population data in at least one safety-related calculation for the projected dose to the public resulting from normal plant releases via the liquid or gaseous pathways, based on a worst-case release. The staff found that the corrective actions resulted in the addition of appropriate information to the reference summary form.

The staff reviewed a CAR that documents that Omega prepared the design verification checklists' reviewer and verification sheets for calculations that were not properly numbered, in

accordance with the applicable CSP. The staff considered this CAR to be administrative in nature.

The staff reviewed a CAR that documents that the project manager did not review a purchase order for a Eustis laboratory analysis, as required by Enercon's QAPM. Resolution of the CAR determined that the project manager was aware of the purchase order. However, this purchase order had unique arrangements for completion of the work by WLA. Entergy Nuclear Potomac Company contracted with WLA directly to perform the seismic and geotechnical work required for the ESP application. The staff determined that, although Eustis worked under the Enercon QAPM, the subcontractor was contractually obligated to WLA, who was actually responsible for the work.

The staff noted the low number of CARs generated during the ESP project and that only the Enercon QA manager had documented deficiencies, which the QA manager noted in a CAR.

The staff found that the Enercon corrective action program is equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and meets the guidance contained in Section 17.1.1 of RS-002.

17.16.3.2 William Lettis & Associates

WLA conducted an internal surveillance to ensure its compliance with applicable QA requirements contained in the relevant QAPPD instructions. The individual who conducted the surveillance identified 15 items and did not include those items in the Enercon corrective action process. The same individual conducted a followup surveillance, which reviewed these items. From this surveillance, six items remained. WLA responded in an email to the individual who conducted the surveillance that it had addressed the items. The staff conducted a followup of some items to ensure that WLA had adequately addressed and closed the items. Three of the items pertained to revising procedures. Two items involved WLA needing verification that the subcontractors completed the tasks. One item involved WLA documenting review of field logs. Although WLA did not formally place the items in Enercon's corrective action program, the items had been adequately addressed. The Enercon QA manager documented the staff's observation that the discrepancies noted in the surveillances were not entered into Enercon's corrective action process on a CAR.

17.16.4 Conclusions (Corrective Action)

As set forth above, the staff reviewed the QA measures employed by the primary contractor and its subcontractors and concluded that they have implemented an acceptable corrective action program that meets the guidance in Section 17.1.1 of RS-002. This provides 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)

SERI did not supply information in its application about QA records. The QAPPD describes the QA measures for ESP activities and identifies certain criteria in Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. Enercon applied elements from these criteria or verified that the controls applied to ESP activities reflect the elements from these criteria, as outlined in the Enercon QAPM. Enercon wrote the QAPM to comply with the requirements of Appendix B to 10 CFR Part 50; as such, it contains QA policies corresponding to each of the Appendix B criteria. The plan considers QA records to be one of the criteria having elements associated with the control of ESP activities.

The QAPM states that Enercon and the client, as agreed upon, will determine and dispose of requirements for project-specific QA records. The QAPPD will document these requirements. The project manager or QA engineer will establish the QA record files specified before beginning work on a project.

The QAPM states that QA records will be legible, accurate, and complete, as appropriate. QA records generated on a project will be controlled to ensure retrievability, prevent loss, and provide for accountability upon project completion. The project manager will transmit all project records involving lifetime storage retention, as specified in ANSI N45.2.9-1979, “Requirements for Collection, Storage, and Maintenance of Quality Assurance Records for Nuclear Power Plants,” to the client at the completion of a project. Records specified as corporate QA records, and any project record not transmitted to the client as stated above, will be maintained for a period consistent with the recommendations of ANSI N45.2.9-1979. QA records will be stored neatly, maintained in files, logbook, or otherwise organized to protect the records from damage or deterioration.

The QAPM states that the QA manager must establish and maintain files for (1) copies of superceded sections of the Enercon QAPM and CSPs, (2) distribution logs for the Enercon QAPM and CSPs, (3) annual and periodic reports to management on QAPM effectiveness, (4) notification records of 10 CFR Part 21 problems, (5) reports of internal and client audits and associated documentation of corrective actions, (6) records of auditor training and qualification and lead auditor certifications, (7) CARs and logs, and (8) reports of project audits, subcontractor audits, and preaward surveys.

The QAPM states that the project manager or designee must establish and maintain a QA document file consisting of applicable project-related documents, including (1) controlled copies of current and superceded revisions of the QAPPD, (2) records of training administered, (3) reports of project audits, (4) CARs related to the project and documentation of actions taken, (5) quality records related to design, (6) procurement documents, (7) instructions, procedures, and drawings which prescribe quality activities, (8) document control logs or resisters, (9) evidence of verification of procured items or services, (10) records of qualifications of project personnel, and (11) other records specified in the QAPPD or CSPs.

17.17.2 Regulatory Evaluation (Quality Assurance Records)

While the NRC does not require QA records to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the staff to use in evaluating the measures employed by an ESP applicant. In the QAPPD, the applicant's primary contractor states that its QA records will ensure the development of the application in a quality manner and, where appropriate, in accordance with the requirements of Appendix B to 10 CFR Part 50.

Paragraph 17.1.1.17 in Section 17.1.1 of RS-002 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 Enercon

According to Enercon's QAPM, the elements of the QA program (as identified above) must be used to ensure the quality of the ESP project. The QAPM states that the CSP documents the requirements and responsibilities for records transmittal, retention, and maintenance.

In its review of test records produced by WLA and Eustis, audits and surveillances of the Enercon subcontractors, and surveillances performed at WLA, the staff noted that the subcontractors maintained all of the records in accordance with the QAPM.

17.17.4 Conclusions (Quality Assurance Records)

As set forth above, the staff reviewed the QA measures employed by the primary contractors and concluded that they have implemented an acceptable level of control for QA records which meets the guidance in Section 17.1.1 of RS-002. This provides 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.

17.18 <u>Audits</u>

17.18.1 Technical Information in the Application (Audits)

SERI did not supply information in its application about audits. The QAPPD describes the QA measures for ESP activities and identifies certain criteria in Appendix B to 10 CFR Part 50 that contain elements associated with the control of ESP activities. Enercon applied elements from these criteria or verified that the controls applied to ESP activities reflect the elements from these criteria, as outlined in the Enercon QAPM. Enercon wrote the QAPM to comply with the requirements of Appendix B to 10 CFR Part 50; as such, it contains QA policies corresponding to each of the Appendix B criteria. The plan considers audits to be one of the criteria having elements associated with the control of ESP activities.

According to the QAPM, the QA manager must schedule audits; select, train, and certify audit personnel; verify completed corrective actions resulting from audits; and maintain audit files.

The lead auditor must plan audits, perform audits, report findings and recommendations, notify appropriate personnel of conditions noted that are adverse to quality, and follow up and close out audit reports.

The QAPM states that the QA manager will determine the required frequency of audits for a specific project and assign personnel to perform the audit. When scheduling audits, consideration will be given to the nature and complexity of the activity. The QAPPD will identify the audit schedule. At its discretion, the QA manager may supplement the regularly scheduled audits with additional ones.

According to the QAPM, personnel selected to perform as auditors will have a working knowledge of the Enercon QA program and will have experience or training commensurate with the scope, complexity, or any special attributes of the activity to be audited. Audit personnel should be familiar with the requirements of ANSI N45.2.12, "Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants." The qualifications will be certified and documentation will be placed in the individual's audit records maintained by the QA manager.

The QAPM states that personnel selected for auditing will not have any direct responsibility for performance of the activity they will audit. Before the audit, audit personnel will prepare an audit plan describing the audit to be performed, including appropriate checklists.

According to the QAPM, an audit report will be prepared upon completion of the audit detailing those results. The audit report will include any CARs written as a result of the audit. The audited organization will respond to CARs within 30 days following receipt of the audit report, unless an alternate schedule has been established.

17.18.2 Regulatory Evaluation (Audits)

While the NRC does not require audits to comply with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the staff to use in evaluating the measures employed by an ESP applicant. In the QAPPD, the applicant's primary contractor stated that its audits will ensure the development of the application in a quality manner and, where appropriate, in accordance with the requirements of Appendix B to 10 CFR Part 50.

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

17.18.3 Technical Evaluation (Audits)

17.18.3.1 Enercon

The Enercon QAPM outlines the conduct of audits, but includes no specific procedures. The QAPM describes auditor qualifications, audit planning, performance, reporting, and followup action. Enercon conducted the audits using applicable portions of its QA checklist, which was

modeled on the NUPIC audit checklist. The same Enercon individual conducted two audits that were related to ESP activities. The staff reviewed the resume, qualifications, and training records of the individual. The individual appeared to be adequately qualified and trained to conduct audits.

The first audit verified the implementation of applicable QA controls at Eustis for the ESP project work. Eustis conducted the retrieval of soil samples for testing and then tested the soil samples at its materials testing laboratory. The audit established a basis for placing Eustis on the Enercon qualified supplier list. Eustis was conditionally approved for ESP geotechnical testing. The audit determined that, although Eustis did not implement a QA program that meets all the requirements of Appendix B to 10 CFR Part 50, the company did have sufficient controls in place to warrant its conditional approval as a supplier of materials testing for the ESP project. This conclusion was primarily based on the evidence of existing controls, as reviewed by the staff in the Enercon QA checklist document, that Enercon judged to be adequate for the work Eustis conducted. The results of recent accreditation evaluations conducted by the USACE and the American Association of State Highway and Transportation Officials supplemented Enercon's conclusion. The evaluations measured compliance by Eustis to applicable ASTM standards.

No audit findings or CARs were issued as a result of the audit. The staff found that the audit provided evidence that Eustis implemented adequate controls for work conducted on the ESP project.

The second audit verified the implementation of applicable QA controls by the Enercon Atlanta and Oklahoma City offices, as applicable to the ESP project. The auditor applied portions of the Enercon QA checklist. The audit determined that, with the exception of three CARs issued for minor infractions, Enercon completed all work performed on the ESP project in accordance with its QA requirements.

The three CARs detailed (1) a failure to use reference forms for demographic data determined by the auditor to be safety related, (2) a failure to properly number the pages for calculation design verification checklists, and (3) a failure to obtain explicit approval by the project manager for a purchase order issued by a subcontractor. Section 17.16 of this SER details the staff's determination of adequate corrective actions for the CARs.

In the QAPPD, the staff noted that Enercon will conduct audits and inspections of project activities as directed by the Enercon QA manager. This may include surveillance of field activities that are done in accordance with the QAPPD, surveillance of laboratory testing activities and activities conducted at the various offices, and detailed audits of project activities at the Enercon and WLA offices. Instead of, or in addition to, scheduled audits, a lead auditor may inspect project output documents requiring the implementation of a QA program to comply with the QAPPD requirements. An inspection report will document audits and inspections.

The staff noted that Enercon did not conduct an audit or an inspection of WLA. A representative of Entergy Nuclear Potomac Company stated that it would conduct an audit of WLA in the future.

The staff reviewed a recent NUPIC audit conducted to requalify Enercon on the Entergy Nuclear Potomac Company's qualified supplier list as a provider of safety-related design engineering services. Enercon performed and reported the audit in accordance with applicable Entergy Nuclear Potomac Company procedures using the NUPIC audit checklist. Enercon did not identify any findings during the audit, and no followup actions were required. The scope of the NUPIC audit was not specific to the ESP project. However, the NUPIC audit satisfactorily covered the general scope of technical services provided by Enercon to the ESP project.

The staff found that Enercon performed audits that are equivalent in substance to the requirements of Appendix B to 10 CFR Part 50 and meet the guidance contained in Section 17.1.1 of RS-002.

17.18.4 Conclusions (Audits)

As set forth above, the staff reviewed the QA measures employed by the primary contractor and concluded that it implemented acceptable audit controls that meet the guidance in Section 17.1.1 of RS-002. This provides 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.

17.19 Conclusions

Based on its review and evaluation of the QA measures contained or referenced in the SSAR, as set forth above, the staff concludes the following:

- The organizations and persons performing QA functions have the independence and authority necessary to effectively carry out QA measures without undue influence from those directly responsible for costs and schedules.

- The QA procedures and measures, when properly implemented, are equivalent in substance to the criteria of Appendix B to 10 CFR Part 50 and conform to the guidance in RS-002, Section 17.1.1.

- The applicant applied QA measures to all ESP activities that established information regarding (1) the design and construction of SSCs important to safety which might be constructed on the proposed site, or (2) the establishment of site characteristics for comparison to the values of site parameters postulated in a certified design or to serve as design inputs for a custom design. The measures provide adequate confidence that information provided in the ESP application and accepted by the NRC is reliable and, when used as input for the design or construction of SSCs important to safety, would not adversely impact their ability to perform satisfactorily in service. Therefore, the staff concludes that the applicant implement acceptable QA measures fore the ESP activities.