

17.0 EARLY SITE PERMIT QUALITY ASSURANCE MEASURES

17.0 Introduction

In Chapter 17 of the SSAR, SNC supplied information on QA measures applied to the development and maintenance of the ESP application. Chapter 17 of the SSAR includes the Nuclear Development Quality Assurance Manual, Revision 3 (hereafter referred to as the QA Manual). The QA Manual delineates the QA plan for the development of the ESP application. The applicant prepared this manual using guidance from the American Society of Mechanical Engineers (ASME) NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, except as specified in the QA Manual. The applicant's QA Manual provides details about the QA process for developing an ESP application and specifies the use of the processes in place that meet the requirements of the current SNC QA Program.

The NRC staff conducted an inspection from August 28–September 1, 2006, to verify the implementation of these QA measures. Subsequently, the NRC staff performed an in-office technical review to evaluate whether the applicant and its principal contractors had applied adequate QA measures. Specifically, the NRC staff sought to determine whether the applicant had adequately applied the guidance in Section 17.1.1 of RS-002, to demonstrate the integrity and reliability of data obtained to support its ESP application.

Under 10 CFR 52.18, "Standard for Review of Applications," the NRC staff evaluates ESP applications in accordance with the applicable regulations of 10 CFR Part 50, and its appendices, as well as 10 CFR Part 100, as they apply to CPs. 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 NRC does expect the applicant to implement QA measures equivalent in substance to the measures described in Appendix B to 10 CFR Part 50 to provide reasonable assurance that the information developed for the ESP application that could be used in the design and/or construction of SSCs important to safety would support satisfactory performance of such SSCs once in service. Therefore, the NRC staff evaluates quality measures for activities associated with the applicant's generation of site-related information that could be an input to the design of future SSCs. This evaluation ascertains that these measures provide reasonable assurance of the integrity and reliability of the information, and 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 COL references an ESP, it must contain information sufficient to demonstrate that the design of the facility falls within the site parameters specified in the ESP. Therefore, the ESP applicant must provide reasonable assurance of the reliability and integrity of data contained in or supporting the ESP application, which in turn supports any future COL or CP application.

Conformance with the QA 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 NRC staff focused its review on whether the applicant's QA measures adequately addressed the guidance in Section 17.1.1 of RS-002 for each applicable area, as determined by the applicant (e.g., organization and QA program). The NRC staff performed much of its evaluation in an inspection conducted in August 2006 and documented in Inspection

Report 05200011/2006001 (ADAMS Accession No. ML062830466). For any area that the applicant determined was not applicable, the NRC staff verified that the activities supporting the ESP application did not rely on QA measures associated with that area.

The applicant procured services from the following contractors for ESP engineering support and design activities:

- Bechtel—SSAR and design services
- William Lettis & Associates, Inc. (WLA)—geotechnical and geophysical analysis
- Risk Engineering, Inc. (REI)—seismic analysis
- MACTEC Engineering and Consulting, Inc. (MACTEC)—soil analysis and site borings
- Bay Geophysical, Inc. —seismic reflection and refraction maps
- Savannah River National Laboratory (SRNL)—soil analysis
- TtNUS—environmental report
- Third Rock—endangered species study (nonsafety related)
- New South Associates—archeological study (nonsafety related)

SNC contractors and subcontractors conducted their activities supporting the ESP application in accordance with their own QA measures, by direction provided in procurement documents, or in accordance with the primary contractor's required QA measures. The next sections document the NRC staff's evaluation of the applicant's and contractors' QA measures.

17.1 Organization

17.1.1 Introduction (Organization)

The applicant supplied information on the ESP organization in its QA Manual. The QA Manual describes the organization, programs, and procedural and administrative control requirements of the SNC QA Program. In the QA Manual, the applicant describes its Nuclear Development (ND) organization that is responsible for new nuclear plant licensing, engineering, procurement, construction, startup, and operations. The applicant states that the organizations that implement and support the QA Manual consist of, but are not limited to, Nuclear Development, Technical Support, Corporate Services, Nuclear Fleet Security and Emergency Planning, General Counsel, and QA.

The QA Manual specifies the primary responsibilities, authorities, and lines of communication for identifying, reporting, controlling, and resolving quality issues. Organization charts in the QA Manual outline the overall structure and lines of authority. The QA Manual also sets forth each group's role and responsibilities, as well as the roles and responsibilities of first-line supervisors, management, and QA organizations. The QA Manual also says that it complies with ASME NQA-1-1994, Basic Requirement 1 and Supplement 1S-1, which pertain to QA organizations.

17.1.2 Regulatory Basis (Organization)

While the NRC does not require an ESP applicant to develop an organization compliant with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the NRC staff to use in evaluating an ESP applicant's organization. Paragraph 17.1.1.1 in Section 17.1.1 of RS-002 outlines the QA measures that constitute an acceptable organization,

including (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 those of its principal contractors; (2) the relative location of the QA organization, degree of independence from the organization performing the activities in support of the ESP application, 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 Southern Nuclear Operating Company

The NRC staff reviewed the description of the organizational structure contained in the SNC QA Manual. SNC developed the ND organization to manage the preparation of the ESP application and provide oversight of contractors. The NRC staff noted that the Senior Vice President of ND has the overall responsibility for implementing the QA Program for the ESP organization. In addition, the Executive Vice President—Nuclear supports ND activities through the Vice President—Vogtle, the Nuclear Fleet Security and Emergency Planning organization, and the QA organization.

The NRC staff noted that the Vogtle Licensing Manager and his staff are responsible for independently planning and performing activities to verify the development and effective implementation of nuclear management QA programs for activities associated with ESP application development. The NRC staff also noted that the QA Manager reports to the Executive President—Nuclear for the operations activities and to the Senior Vice President—Nuclear Development for the new reactor activities. The QA Manager is responsible for developing and maintaining the SNC QA programs, evaluating compliance with the programs, and managing the QA organization resources. The NRC staff also noted that the duties and activities of all the other organizations and persons assigned to activities affecting quality are clearly established and delineated.

The NRC staff observed that 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 NRC staff also noted that the organizational structure provides sufficient flexibility and freedom to allow for the resolution of disputes and/or conflicts involving quality. Moreover, organizations performing QA functions have direct access to any level of management necessary to perform these functions.

In RAI 17.1-1, the NRC staff asked the applicant to identify the organizations that perform QA activities under the QA Manual, under the existing operations QA Program, or under both QA programs.

In response to this RAI, the applicant stated that certain common program elements, procedures, and organizations described in the QA Manual also exist for currently operating SNC nuclear plants. The applicant also stated that these organizations perform common activities described in both QA Program documents and report to the same Chief Executive Officer. As a reference, the applicant provided Part II, Section 1, of the QA Manual, which

describes the reporting relationships, functional responsibilities, and authorities for organizations implementing and supporting the ND QA Program.

The NRC staff evaluated the applicant's response to RAI 17.1-1 and finds that Part II, Section 1, of the QA Manual describes the organizations that perform QA activities under the QA Manual and the existing operations of the QA Program in sufficient detail. On the basis of its evaluation, the NRC staff concludes that the applicant's response to RAI 17.1-1 is acceptable. Therefore, RAI 17.1-1 is resolved.

17.1.3.2 Bechtel Power Corporation

The applicant selected Bechtel as its primary contractor for ESP application activities. Bechtel describes its QA controls in the firm's "Nuclear Quality Assurance Manual" (NQAM), Revision 4, dated November 1, 2002. Bechtel designed its NQAM to meet the requirements of Appendix B to 10 CFR Part 50. Bechtel used the NQAM to develop the "Quality Assurance Program Plan" (QAPP), Revision 0, dated April 22, 2005, specifically for the VEGP application effort. The NQAM contains detailed organization charts and describes personnel responsibilities. Bechtel's Project Quality Assurance Manager (PQAM) directs and controls the project QA Program. Bechtel developed the PQAM position to ensure that the QA actions throughout the project organization are performed in accordance with the QA Program criteria. The NRC staff noted that the PQAM has organizational independence, as the position reports directly to the President of Bechtel's Nuclear Global Business Unit (GBU). The GBU President has overall responsibility for the adequacy and implementation of the Bechtel nuclear QA Program. The NRC staff noted that Bechtel's organizational structure provides sufficient flexibility and freedom to allow for the identification of problems affecting quality and for the resolution of conflicts involving quality. As a result, the NRC staff finds Bechtel's guidance for organizational roles and responsibilities adequate for conducting ESP application development and maintenance activities.

Bechtel subcontracted with WLA for support in performing the seismic and geotechnical evaluation of the proposed ESP site. Because WLA does not have a QA Program that meets the requirements of Appendix B to 10 CFR Part 50, WLA performs work in accordance with Bechtel's QA Program. As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed selected project instructions prepared by WLA and reviewed by Bechtel to provide guidelines for conducting seismic and geotechnical activities. The NRC staff verified that the project instructions required that work be performed under the Bechtel QA Program.

Bechtel also subcontracted with REI for support in the performance of probabilistic seismic hazard and sensitivity analyses for the Vogtle site. REI is a small company with no standalone QA organization. However, REI had established QA guidance in its QA manual which described organizational responsibilities and procedure controls. The NRC staff noted that REI had appropriately delineated the functional personnel titles necessary to define the QA program, authority, and responsibility for QA controls.

17.1.3.3 MACTEC Engineering and Consulting, Inc.

SNC subcontracted with MACTEC for geological testing support. MACTEC describes its QA controls in its QA Manual, Revision 1, dated June 17, 2005. In addition, MACTEC developed

the Quality Assurance Project Document (QAPD) to provide guidance for organizational responsibilities, QA oversight, and training. As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed both the QA Manual and the QAPD prepared by MACTEC to ascertain the adequacy of the QA measures. The NRC staff noted that, as denoted in MACTEC's QA Project Document, the MACTEC's Project Manager retains overall authority and responsibility for implementing the MACTEC QA Manual onsite. The NRC staff noted that MACTEC considers the client quality, technical, and contractual requirements to be the governing documents for the project. The MACTEC QA organization is independent of the organizations performing field or lab work. In addition, the QAPD includes provisions to stop work in instances where violations of policies, procedures, or likelihood of inferior work are occurring. The NRC staff finds the MACTEC organizational QA measures acceptable.

17.1.4 Conclusion (Organization)

As described above, the NRC staff concludes that the applicant and its primary contractors have implemented an acceptable organization which meets the guidance in Section 17.1.1 of RS-002. This provides reasonable assurance that any information developed for the ESP application 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 Introduction (QA Program)

The applicant supplied information on the QA Program in its QA Manual, which states that the objective of the Nuclear Development Quality Assurance Program for the ESP application is to assure that SNC nuclear generating plants are designed and constructed in accordance with governing regulations and license requirements. The applicant also ensures, through QA Program implementation, that suppliers of SSCs or services meet the criteria in Appendix B to 10 CFR Part 50.

The QA Manual states that activities governed by the QA Program follow documented instructions, procedures, and drawings that exhibit a level of detail appropriate for the activity's complexity and effect on safety. The manual also states that positions identified in the organization section of the QA Manual may delegate all or part of the activities of planning, establishing, and implementing the program for which they are responsible to others, but the applicant retains the responsibility for the program's effectiveness.

The QA Manual identifies the quality-related activities that are covered by the QA Program and associated with the design, licensing, and construction of new nuclear power plants as described in the ESP SSAR and COL FSAR. Examples of ESP/COL program safety-related activities provided by the applicant include, but are not limited to, site-specific engineering related to safety-related SSCs, site geotechnical investigations, site engineering analysis, seismic analysis, and meteorological analysis.

The QA Manual states that SNC will conduct ongoing reviews of the status and adequacy of the QA Program and its implementation via senior management review of QA audit reports. Additionally, the QA Manual assigns responsibilities for revisions and issuance of the QA

Program to incorporate additional QA commitments that may be established during the ESP and COL application development process.

The QA Manual specifies the indoctrination and training programs for personnel performing, verifying, or managing activities within the scope of the QA Program. This training program includes the use of code, regulation, or standard requirements and the retention of personnel training and qualification records.

The QA Manual also says that it complies with ASME NQA-1-1994, Basic Requirement 2 and Supplements 2S-1, 2S-2, 2S-3, and 2S-4, pertaining to QA programs.

17.2.2 Regulatory Basis (QA Program)

While the NRC does not require an ESP applicant to have a QA Program compliant with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the NRC staff to use in evaluating an ESP applicant's QA Program. Paragraph 17.1.1.2 of RS-002 outlines the QA measures that constitute an acceptable level of control for activities supporting the ESP application. The QA Program should include (1) a scope of QA measures adequate to ensure that appropriate quality controls are applied to all site characterization data related to the design and analysis of SSCs important to safety that might be constructed on the proposed site, (2) provisions to ensure proper implementation of QA measures, and (3) provisions to ensure the adequacy of personnel qualifications.

17.2.3 Technical Evaluation (QA Program)

17.2.3.1 Southern Nuclear Operating Company

The NRC staff reviewed the SNC QA Manual, which delineates its QA Program for the development of an ESP application. The applicant states that the QA Manual outlines the programs, procedural requirements, and responsibilities for the applicant's QA Program. The applicant also states that it developed the QA Manual using guidance from ASME NQA-1-1994.

The NRC staff noted that the applicant identifies types or classes of SSCs and activities covered by the QA Program and provides examples of such activities. In addition, the applicant states that the ND organization is the entity responsible for the identification of the ESP safety-related design-basis activities. The NRC staff also noted that the QA Program includes provisions to ensure that activities affecting quality implement QA measures as directed by documented instructions, procedures, or drawings. The QA Manager is the individual responsible for verifying the overall effectiveness of the QA Manual. The QA Manual also identifies responsibilities for the establishment and execution of the QA Program by others, such as contractors or consultants. The NRC staff noted that SNC management retains overall responsibility for the project, including the responsibility for attaining quality objectives. The QA Manual further states that persons and organizations with QA functions have the organizational freedom to identify problems in quality.

The NRC staff observed that SNC developed procedures specific to activities supporting the ESP application and also utilized existing QA procedures from Vogtle Units 1 and 2 where appropriate. As described in Inspection Report 05200011/2006001, the NRC staff reviewed

specific procedures developed for activities supporting the ESP application and noted that the procedures meet the guidance in Section 17.1.1 of RS-002. The NRC staff finds no deficiencies.

The NRC staff noted that the QA Program includes provisions to ensure that individuals assigned to implement elements of the QA Program have the experience, training, or background necessary to assess the quality of the product. As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed the training and qualification program documents for all involved QA personnel. The NRC staff verified a sample of training records of key QA personnel involved with the project and found no deficiencies. Additionally, the NRC staff interviewed with key applicant personnel involved in activities supporting the ESP application. From the interviews, the NRC staff concludes that these personnel are knowledgeable about their roles and responsibilities. In addition, instructions and procedures used by contractors in activities supporting the ESP application need not be reviewed by the applicant. The applicant delegates the establishment and implementation of QA measures to contractors, as described in procurement documents reviewed by the NRC staff.

The NRC staff noted that the applicant describes in its QA Manual the controls implemented for the periodic reviews of the QA Program. As detailed in Section 2.5 of SNC's Nuclear Quality Assurance Manual (NQAM), changes to the NQAM are evaluated by the ND QA Project Engineer to ensure that such changes do not degrade previously approved QA controls specified in the NDQA Program. The SNC Nuclear Development Quality Assurance Committee, in conjunction with senior management, is responsible for the status and adequacy of the QA Program through evaluation of audit results.

In addition, the NRC staff noted that the applicant ensures supplier compliance with approved program and implementing procedures through periodic audits of supplier QA programs and routine interfaces with project personnel. Section 17.18 of this document discusses additional details of the NRC staff's review of the audit process. The NRC staff finds the applicant's methodology for a QA Program, which is based on the implementation of ASME NQA-1-1994, to be adequate for conducting activities supporting the ESP application.

17.2.3.2 Bechtel Power Corporation

Bechtel's NQAM identifies requirements for the development of quality program projects, such as the VEGP application. The Bechtel NQAM provides organizational information and guidance for preparation, review, approval, and control of instructions, procedures, and drawings associated with the ESP. The QA Program policies in the NQAM are designed to meet the requirements of Appendix B to 10 CFR Part 50 and contain QA policies corresponding to all of the Appendix B criteria.

The NQAM was used to develop the task-specific QAPP. A stated purpose of the QAPP is to establish the quality program interface between the Bechtel NQAM and SNC specific requirements applicable to the ESP application development activities. The QAPP specifically identifies the QA policies that apply to the development of the ESP application. Bechtel developed the NQAM for the full scope of the company's services, while the QAPP specifically identifies QA policies that apply to Bechtel's work on the development of the ESP application. The QA Program established in the QAPP applies to the quality-related activities associated

with the preparation of the VEGP application. The NRC staff noted that Bechtel applies the requirements of the QA Program established in the QAPP in a graded manner, commensurate with the importance to safety of the activities being performed. The NRC staff reviewed the QAPP and finds that organizational responsibilities, QA activities, and QA responsibilities are clearly documented and defined. Modifications to the QA policies, as appropriate, reflect unique project or applicant requirements.

As described in Section 18 of the NQAM, Bechtel conducts audits to determine the adequacy of supplier and contractor QA programs. Overall program implementation is reviewed as part of the implementation of the audit process.

As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed Bechtel's procedures governing the training requirements for key supervisors and personnel. This requirement also applied to personnel with WLA, a Bechtel subcontractor, because this subcontractor was working under Bechtel's QA Program. As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed a sample of training and qualification records for Bechtel and WLA personnel and verified that the firms had met the training requirements delineated by the QA Programs.

17.2.3.3 MACTEC Engineering and Consulting, Inc.

The general format of the MACTEC QA Manual follows the criteria outlined in Appendix B to 10 CFR Part 50 and ASME NQA-1-1994. The QA Manual includes provisions for project-specific requirements. These requirements are incorporated through the MACTEC QAPD. SNC required MACTEC to develop a project-specific QAPD to ensure that it met applicable requirements in Appendix B to 10 CFR Part 50. MACTEC developed the QAPD to incorporate project-specific quality requirements that included organizational responsibilities, QA oversight, and training. The NRC staff reviewed these documents for the adequacy of the QA measures. The NRC staff noted that the MACTEC QA organization is independent of the organizations performing field or lab work. Additionally, all reports, proposals, and test data are required to have secondary QA review. Qualified personnel must perform the review for all services requiring engineering or scientific evaluation, interpretation, or judgment. The NRC staff finds that the MACTEC organizational QA measures are adequate.

The MACTEC QA Manual states that personnel acquire and maintain a working knowledge of QA requirements that apply to their tasks. To this end, MACTEC conducted QA-related training sessions specific to the ESP application development for personnel involved with work at the Vogtle site. The NRC staff reviewed a sample of records for this training and finds that MACTEC has met the training requirements.

17.2.4 Conclusion (QA Program)

As described above, the NRC staff reviewed the QA measures implemented by the applicant and its primary contractors and concludes that these measures form an acceptable QA Program which meets the guidance in Section 17.1.1 of RS-002. This provides reasonable assurance that information developed for the ESP application that could be used in the design and/or construction of SSCs important to safety would support satisfactory performance of such SSCs once in service.

17.3 Design Control

17.3.1 Introduction (Design Control)

The applicant supplied information on design control in its QA Manual, which states that its design control program includes interface controls necessary to control the development, verification, approval, release, status, distribution, and revision of design inputs and outputs. The QA Manual states that SNC and supplier procedures detail the division of responsibilities for design-related activities.

The QA Manual states that controls are in place to ensure that design inputs (such as design bases and the performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions) so that the final design output can be related to the design input in sufficient detail to permit verification. In addition, the QA Manual provides controls to ensure that changes to specified design inputs, as well as the reasons for these changes, are identified, reviewed, approved, documented, and controlled. Further, design changes, including field changes, are subject to design control measures commensurate with those applied to the original design and the applicable, specified design requirements.

The QA Manual establishes measures for review of the selection and suitability of the application of materials, parts, equipment, and processes essential to safety-related or safety-significant functions. The QA Manual also provides controls for verifying or checking the adequacy of design through the performance of design reviews, alternative calculations, and qualification testing. The QA Manual states that design verifications are performed by competent individuals or groups other than those who devised the original design but who may be from the same organization.

According to the QA Manual, the QA Program governs the development, procurement, testing, maintenance, and use of computer application and digital equipment software when used in safety-related applications and designated nonsafety-related applications. Further, procedures require that application software be assigned a proper quality classification, that designated SNC and supplier management approve revisions to application software, and that maintenance and security of computer hardware are appropriately controlled and documented.

The QA Manual also says that it complies with ASME NQA-1-1994, Basic Requirement 3 and Supplement 3S-1, pertaining to design control.

17.3.2 Regulatory Basis (Design Control)

While the NRC does not require an ESP applicant to implement design controls compliant with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the NRC staff to use in evaluating an ESP applicant's design controls. Paragraph 17.1.1.3 of RS-002 describes the QA measures that constitute an acceptable level of design control. Acceptable design controls should include (1) the scope of activities that could affect design and construction activities for SSCs important to safety that might be constructed on the site; (2) a definition of the organizational structure, activity, and responsibility of the positions or groups responsible for design activities important to safety (if any); (3) provisions to carry out

design activities important to safety in a planned, controlled, and orderly manner; (4) provisions for interface control between functional units of the applicant's organization; (5) provisions to verify the technical adequacy of design documents applicable to activities supporting the ESP application that could affect SSCs important to safety; and (6) provisions to control design changes applicable to activities supporting the ESP application that could affect SSCs important to safety (if any).

17.3.3 Technical Evaluation (Design Control)

17.3.3.1 Southern Nuclear Operating Company

The NRC staff reviewed the SNC QA Manual and procedures describing design control measures in the areas of design verification, computer software control, engineering drawings, design calculations, personnel training, design deviations, internal and external design control communications, design documentation, organizational responsibilities, and field changes and revisions. The QA Manual describes the processes for design control, design changes, design verification, design records, and computer applications and digital equipment software.

The QA Manual delineates the QA plan for developing an ESP application and describes personnel roles and responsibilities for those involved in the design control process. The NRC staff noted that the design control process includes procedures to ensure that design bases, regulatory requirements, codes, and standards are correctly translated into specifications, drawings, procedures, or instructions.

For design verification, the QA Manual requires that procedures be established and implemented to ensure that appropriate verification methods are used, appropriate design parameters to be verified are chosen, acceptance criteria are identified, and verification is satisfactorily accomplished and documented. As discussed in Inspection Report 05200011/2006001, the NRC staff verified the adequacy of the SNC design control process by reviewing applicable procedures. The procedures describe (1) organizational functions and responsibilities; (2) the process for handling engineering and licensing records; (3) applicable design criteria and QA requirements for supporting analysis, calculations, evaluation, and engineering activities in support of activities supporting the ESP application; and (4) the process and instructions used for preparing or revising specifications to be utilized for the development, review, approval, and control of design, purchase, installation, and maintenance of SSCs at SNC nuclear plants.

The NRC staff noted that the QA Manual provides for verification and/or independent review of the adequacy of design through design reviews, use of alternate calculational methods, or testing. Additionally, the NRC staff finds that the QA Manual adequately addresses control of design changes and organizational interfaces. As described in Section 3 of the NQAM, SNC provides controls for changes in design documents. Additionally, Section 16 of the NQAM states that activities affecting quality are to be documented and actions are to be taken to ensure that errors and deficiencies are identified and corrected. For these reasons, the NRC staff finds that the guidance of the QA Manual and procedures outline the necessary QA measures for an adequate design control process.

17.3.3.2 Bechtel Power Corporation

Bechtel's QAPP establishes the QA Program interface between the Bechtel NQAM and the SNC specific requirements and commitments. Bechtel states in the QAPP that, for design control, it performs quality-related activities associated with the preparation of the ESP application in accordance with its NQAM, with no modifications.

As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed the Bechtel NQAM and procedures describing design control measures in the areas of design criteria, design interface control, design review and verification, computer software control, engineering drawings, design calculations, design deviations, and organizational responsibilities. Bechtel's NQAM describes the scope of the design control program and provides controls for design activities associated with the preparation and review of design documents. Specifically, it describes the requirements for the generation of design criteria, control of design interfaces, design verification, design change control, and computer programs. As described in Section Q-3.4 of the Bechtel's NQAM, Bechtel provides controls for changes in design documents. Additionally, Section Q-16.1 of the Bechtel's NQAM states that activities affecting quality are to be documented and actions are to be taken to ensure that errors and deficiencies are identified and corrected.

The NRC staff finds that the design controls outlined in Bechtel's NQAM and procedures for preparation, review, approval, and control of design criteria are clearly stated and in accordance with ANSI N45.2.11 or ASME NQA-1-1994, as applicable. The NRC staff verified that the procedure provided the means to coordinate and communicate design criteria changes (including revision control) throughout any affected project discipline group. The procedure also specifies internal document management requirements including revision control and record retention.

As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed the design interface controls in Bechtel's NQAM and implementing procedures. The NQAM and procedures clearly outline the responsibilities of internal and external organization personnel including communication, documentation, distribution of design control criteria, and interdisciplinary coordination. This includes control of design input and development, special analysis, and approvals. The NRC staff noted that procedural requirements adequately establish the applicability of 10 CFR Part 21 for nuclear safety-related work assigned to an off-project entity (non-Bechtel organization).

The NRC staff reviewed the NQAM and procedures that describe responsibilities and requirements for the verification of design work performed internally by Bechtel. Requirements are defined for the performance and documentation of design verification on SSCs important to safety for the development of the ESP application. As discussed in Inspection Report 05200011/2006001, procedural controls and descriptions exist for design verification either by interdisciplinary design review, independent off-project design review by technical staff personnel, or individual critical design review. The procedures require documentation of design reviews. Once a verification method is selected, the procedure specifies that the verification method is documented with the cognizant chief engineer's concurrence and that deviations are justified and documented. Controls are in place to ensure that the verifier is qualified and not responsible for the design and that all the design review elements applicable to the component

are identified. Where design verification is performed by qualification tests, controls are in place to (1) identify the test or tests to be performed; (2) document test configuration(s), operating modes, and environmental conditions; and (3) consider conditions that simulate the most adverse design conditions.

As discussed in Inspection Report 05200011/2006001, Bechtel's NQAM and procedures describe design change controls. The NRC staff noted that the procedures specify requirements to control changes to the design of SSCs important to safety after the initial design is complete. Also, procedures include requirements for review and independent verification of those changes. The procedures have controls in place to review proposed design changes from project engineering, suppliers, field engineering, and others, using the same design control measures that were applied to the original design. Additionally, the NRC staff reviewed procedures for the control of design calculations and engineering drawings that specify engineering responsibilities and requirements for initial as well as revised or changed documents and drawings affecting the ESP application. The NRC staff finds that Bechtel's NQAM and engineering procedures had adequate design control QA measures.

Bechtel's NQAM prescribes controls required for the development and use of computer software for QA projects. The NRC staff noted that the NQAM adequately delineates the requirements and methodology for software verification and validation, software installation testing, error resolution (corrective actions), and configuration management.

17.3.3.3 MACTEC Engineering and Consulting, Inc.

SNC contracted with MACTEC for geotechnical investigations and laboratory testing for the ESP application. MACTEC utilized the services of four additional suppliers to complete the scope of work outlined in Bechtel's technical specification for subsurface investigation and laboratory testing. These suppliers performed work associated with surveying, drilling, geologic testing, and laboratory analyses.

After a review of the technical specification mentioned above, the purchase order (PO) that described the MACTEC scope of work, and the MACTEC QA Manual and project document, the NRC staff determined that, although MACTEC provided the necessary measures for design control activities in its QAPD, MACTEC did not perform design control activities associated with the development of the ESP. SNC ensured appropriate design interface controls through audits and surveillances of MACTEC activities. Sections 17.7 and 17.18 of this safety evaluation contain additional information regarding surveillances and audits conducted by the applicant.

17.3.4 Conclusion (Design Control)

As described above, the NRC staff reviewed the QA measures used by the applicant and its primary contractors and concludes that they have implemented acceptable design controls which meet the guidance in Section 17.1.1 of RS-002. This provides reasonable assurance that information developed for the ESP application that could be used in the design and/or construction of SSCs important to safety would support satisfactory performance of such SSCs once in service.

17.4 Procurement Document Control

17.4.1 Introduction (Procurement Document Control)

The applicant supplied information on procurement document control in its QA Manual. The QA Manual states that SNC has established procedures that describe the program for completing procurement documents, including review, approval, document control, and change control. The QA Manual states that purchased items and services are subject to quality and technical requirements in accordance with specific drawings, specifications, or instructions. In addition, the QA Manual states that where original technical or QA requirements cannot be determined, an engineering evaluation is conducted and documented to ensure that interfaces, interchangeability, safety, fit, and function, as applicable, are not adversely affected or contrary to applicable regulatory requirements.

The QA Manual states that measures are established to ensure that the documents for procurement of material, equipment, and services (whether purchased by SNC, its contractors, or subcontractors) suitably include or reference the applicable regulatory, design, and other requirements necessary to ensure adequate quality. The QA Manual also states that, to the extent necessary, procurement documents require contractors or subcontractors to provide a QA Program consistent with the pertinent provisions of the QA Manual. In addition, the QA Manual states that procurement document changes are subject to the same degree of control as utilized in the preparation of the original documents.

The QA Manual also says that it complies with ASME NQA-1-1994, Basic Requirement 4 and Supplement 4S-1, pertaining to procurement document control.

17.4.2 Regulatory Basis (Procurement Document Control)

While the NRC does not require an ESP applicant to implement procurement document controls compliant with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the NRC staff to use in evaluating an ESP applicant's procurement document controls. Paragraph 17.1.1.4 of RS-002 outlines the QA measures that constitute an acceptable level of procurement document controls. These controls should include (1) provisions to ensure that applicable technical requirements and QA controls are included or referenced in procurement documents related to activities supporting the ESP application that could affect SSCs important to safety and (2) provisions for the review and approval of procurement documents for activities supporting the ESP application that could affect SSCs important to safety.

17.4.3 Technical Evaluation (Procurement Document Control)

17.4.3.1 *Southern Nuclear Operating Company*

The NRC staff reviewed the SNC QA Manual, which delineates the QA measures for procurement document control. The QA Manual states that administrative procedures describe the program for completing procurement documents, including review, approval, document control, and change control. The applicant also establishes administrative procedures to ensure that procurement documents reference all actions required by a supplier, in accordance

with applicable codes, specifications, and drawings. The NRC staff noted that Section 1 of the NQAM contains detailed information regarding the SNC's organizational responsibilities on procurement activities. This Section states that the Supply Chain Management is responsible for the preparation, review, and approval of documents to verify the inclusion of adequate technical and quality requirements. The procedures also ensure that procurement documents incorporate design-basis, technical, and quality requirements, including applicable regulatory requirements.

As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed the SNC agreement, which authorizes the primary contractor's scope of work. SNC established the work scope and quality requirements for Bechtel in a PO, which contained a detailed description of Bechtel's work scope, including identification of specific sections of the ESP application for which Bechtel was responsible for performing supporting analyses, evaluations, and investigations. The NRC staff reviewed the QA and reporting requirements of the PO for the conduct of project-related activities. SNC specified that materials and services supplied by Bechtel were nuclear safety-related and that Bechtel implement quality controls and a QA Program that complied with Appendix B to 10 CFR Part 50. Specifically, Bechtel was to provide those quality materials and services in accordance with the requirements of the Bechtel NQAM. Additionally, SNC specified that 10 CFR Part 21 be applied to Bechtel. The NRC staff also reviewed the SNC Safety-Related Vendor List and verified that Bechtel is listed as an active safety-related vendor and qualified to supply design and engineering services for major projects, including the ESP application.

In RAI 17.4-1, the NRC staff requested additional information regarding an exception to the requirements of Supplement 4S-1 of NQA-1 proposed by the applicant. Specifically, Section 3 of Supplement 4S-1 requires procurement documents as well as changes to be reviewed before bid or award of contract. Instead, SNC proposed that "the quality assurance review of procurement documents is satisfied through review of the applicable procurement specification, including the technical and quality procurement requirements, prior to bid or award of contract." This statement did not clearly specify if procurement documents as well as changes to procurement documents were part of the proposed QA review. The NRC staff asked the applicant to clarify whether it had performed the proposed QA review of procurement documents including changes.

In response to this RAI, the applicant offered a clarifying sentence which stated that "procurement document changes (e.g., scope, technical, or quality requirements) will be part of the quality assurance review."

The NRC staff evaluated the applicant's response to RAI 17.4-1 and finds that the sentence proposed by the applicant provides assurance that procurement documents as well as changes to those documents are part of the proposed QA review. On the basis of its evaluation, the NRC staff concludes that the applicant's response to RAI 17.4-1 is acceptable. Therefore, RAI 17.4-1 is resolved. The applicant captured this change in revision 2 to the ESP application.

17.4.3.2 Bechtel Power Corporation

As discussed in Inspection Report 05200011/2006001, Bechtel implemented ESP application quality requirements specified by an SNC PO in the project-specific QAPP. The Bechtel QAPP

invoked quality policies contained in the Bechtel NQAM that apply to the ESP application. In accordance with specifications contained in the SNC PO, SNC approved the Bechtel QAPP for use to support the VEGP application.

Bechtel procured engineering services and support from two subcontractors, REI and WLA. As detailed in Inspection Report 05200011/2006001, the NRC staff reviewed the procurement documents for these subcontractors to ensure adequate implementation of procurement document control.

A Bechtel subcontract outlined Bechtel's request for technical services from WLA for the performance of geologic mapping and characterization of seismic sources in support of SSAR Section 2.5. Bechtel requested technical services in the form of field and office studies designed to meet Appendix D of RG 1.165, issued March 1997, of seismic source zones in the region around the Vogtle site. The studies also address investigation of the potential for active tectonic deformation at and within the vicinity of the site in accordance with Appendix D of RG 1.165. The document also outlines the applicable codes, standards, and NRC guidance. Because it did not have its own QA Program that complied with the requirements of Appendix B to 10 CFR Part 50, WLA performed the work in accordance with Bechtel's QA program, as described by the Bechtel QAPP, and the implementing procedures for the QAPP contained in Bechtel's Project Engineering Procedures Manual. On the basis of its review, the NRC staff finds Bechtel's QA measures for the control of the WLA work to be adequate.

A Bechtel subcontract outlined Bechtel's request for technical services from REI for the performance of probabilistic seismic hazard assessments and related sensitivity analyses in support of SSAR Section 2.5. REI provided seismic hazard calculations using original input source models, source parameters, and original ground motion relationships as needed to develop the EPRI 1989 SSE ground motion values. In addition, REI developed a list of the significant seismic sources from the EPRI 1989 seismic source model and performed sensitivity analyses based on the earthquake catalog for the most critical sources. REI also updated site-specific rock hazard curves, computed seismic hazard curves for free-field ground-surface conditions, and computed the SSE spectrum for the free-field ground surface using seismic hazard curves via a methodology acceptable to the NRC—either that of RG 1.165 or the ASCE methodology (i.e., ASCE/SEI 43-05). The NRC staff noted that REI maintained and implemented a QA Manual and a Software Quality Assurance Plan (SQAP) and submitted both to Bechtel. The NRC staff also noted that Bechtel project management and QA personnel reviewed and accepted the REI QA Manual and SQAP. On the basis of its review, the NRC staff finds Bechtel's QA measures for the control of work done by REI to be adequate.

17.4.3.3 MACTEC Engineering and Consulting, Inc.

SNC subcontracted to MACTEC to obtain geological testing support. As discussed in Inspection Report 05200011/2006001, a Bechtel technical specification documented the scope and specifications for MACTEC activities for subsurface investigation and laboratory testing. The technical specification stated that MACTEC was required to prepare a QA plan that met Appendix B to 10 CFR Part 50 requirements and 10 CFR Part 21 requirements. In addition, MACTEC was required to submit a QA program that conformed to the provisions of ANSI/ASME N45.2-1977, "Quality Assurance Program Requirements for Nuclear Facilities." As detailed in Inspection Report 05200011/2006001, the NRC staff reviewed the MACTEC QAPD

and the project work plan to assess the adequacy of the specified QA measures, particularly those associated with procurement control. The NRC staff finds that MACTEC has identified a reasonable scope of procurement document control measures to ensure the integrity and reliability of site geological test data.

MACTEC utilized the services of four additional suppliers to complete the work outlined in the Bechtel project technical specification. These suppliers performed work associated with surveying, drilling, geologic testing, and laboratory analyses. The MACTEC project principal engineer, the project manager, and a representative from the QA organization reviewed the MACTEC work instructions provided to these subcontractors. In general, the subcontractors conducted field and laboratory testing activities in accordance with recognized testing methods from the ASTM or the U.S. EPA. As detailed in Inspection Report 05200011/2006001, the NRC staff reviewed the PO work scope and concludes that MACTEC imposed the applicable QA measures on each of its four subcontractors.

17.4.4 Conclusion (Procurement Document Control)

As described above, the NRC staff reviewed the QA measures used by the applicant and its primary contractors and concludes 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 information developed for the ESP application that could be used in the design and/or construction of SSCs important to safety would support satisfactory performance of such SSCs once in service.

17.5 Instructions, Procedures, and Drawings

17.5.1 Introduction (Instructions, Procedures, and Drawings)

The applicant supplied information on controls for instructions, procedures, and drawings in its QA Manual. The applicant states that it has established measures to ensure that activities supporting the ESP application that could affect quality are prescribed by and performed in accordance with instructions, procedures and drawings. In addition, the applicant states that the QA Manual considers, where applicable, quantitative and qualitative acceptance criteria for determining the satisfactory completion of important activities.

The QA Manual states that an appropriate level of management will review instructions, procedures, and drawings for adequacy and approve them for use. The QA Manual also states that administrative procedures prescribe revisions to procedures and provide controls in instances where procedures cannot be followed as written.

The QA Manual also says that it complies with ASME NQA-1-1994, Basic Requirement 5, pertaining to instructions, procedures, and drawings.

17.5.2 Regulatory Basis (Instructions, Procedures, and Drawings)

While the NRC does not require an ESP applicant to have instructions, procedures, and drawings compliant with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the NRC staff to use in evaluating an ESP applicant's instructions,

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

17.5.3 Technical Evaluation (Instructions, Procedures, and Drawings)

17.5.3.1 Southern Nuclear Operating Company

The NRC staff reviewed the SNC QA Manual, which describes the measures that the applicant established for control of procedures, instructions, and drawings to provide for their review, approval, issuance, and changes. The NRC staff noted that the QA Manual provides measures for the preparation and control of instructions, procedures, and drawings. Section 17.6 of this safety evaluation discusses these controls.

The NRC staff noted that SNC administrative procedures cover procedure adherence and identify activities where such procedures are implemented. The NRC staff also noted that the QA Manual addresses how procedures are temporarily revised. As discussed in Inspection Report 05200011/2006001, the NRC staff conducted reviews to verify that procedures and instructions were checked for adequacy, approved for release, and appropriately distributed and used at the location of the prescribed activity. From its review of the instructions, procedures, and drawings related to activities supporting the ESP application, the NRC staff verifies that they are adequate for the task being performed and are properly controlled.

17.5.3.2 Bechtel Power Corporation

Bechtel's QA Manual and procedures provide requirements for the preparation, application, control, maintenance, and compilation of procedures related to activities supporting the ESP application. The NRC staff noted that Section Q-5.1 of Bechtel's NQAM sets forth provisions to ensure that instructions, procedures, etc. include quantitative and qualitative acceptance criteria, when appropriate to the function or activity, to determine that important activities have been satisfactorily accomplished. In addition, the NRC staff reviewed several procedures, as detailed in Inspection Report 05200011/2006001, to determine the adequacy of the procedures to perform the stated purpose. Applicable Bechtel procedures require (1) approval of procedure revisions in the same manner as specified for new procedures; (2) control and distribution of procedure; and (3) verification by users that copies downloaded or printed from the corporate database are the latest revision. The NRC staff finds that the instructions, procedures, and drawings developed and used for activities supporting the ESP application by Bechtel are adequate.

17.5.3.3 MACTEC Engineering and Consulting, Inc.

The MACTEC QA Manual provides requirements that describe the essential points for development and use of instructions, procedures, and drawings. As discussed in Inspection Report 05200011/2006001, the NRC staff conducted reviews to verify that MACTEC

procedures and instructions were checked, approved for release, and implemented where required. The NRC staff noted that controls are in place to ensure that activities are conducted using technical standards, instructions, procedures, or other appropriate means commensurate with the complexity of the activity. In addition, the NRC staff noted that the MACTEC QA Manual contains provisions to ensure that activities affecting quality are prescribed by and performed in accordance with documented instructions or procedures of a type appropriate to the circumstances. During the inspection, the NRC staff noted that individuals are required to use approved procedures to complete activities affecting quality. Also, MACTEC developed procedures in accordance with ASTM to complete laboratory analyses and used approved procedures for the validation of software output calculations. On the basis of its review, the NRC staff finds that the MACTEC measures for instructions, procedures, and drawings are adequate for the conduct of activities supporting the ESP application.

17.5.4 Conclusion (Instructions, Procedures, and Drawings)

As described above, the NRC staff reviewed the QA measures used by the applicant and its primary contractors and concludes 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 guidance provides reasonable assurance that information developed for the ESP application that could be used in the design and/or construction of SSCs important to safety would support satisfactory performance of such SSCs once in service.

17.6 Document Control

17.6.1 Introduction (Document Control)

The applicant supplied information regarding document control measures in its QA Manual. The QA Manual sets forth the scope of the document control program for ESP activities and describes controls for review, approval, and issuance of documents that specify quality requirements or that prescribe the control of activities affecting quality. These measures also address changes to documents before their release. The QA Manual requires that changes be approved by the same organization that performed the original review and approval, although this responsibility may be delegated to other qualified, responsible organizations.

The QA Manual also says that it complies with ASME NQA-1-1994, Basic Requirement 6 and Supplement 6S-1, pertaining to document control.

17.6.2 Regulatory Basis (Document Control)

While the NRC does not require an ESP applicant to implement document control procedures compliant with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the NRC staff to use in evaluating an ESP applicant's document controls.

Paragraph 17.1.1.6 of RS-002 describes the QA measures that constitute an acceptable level of document control. Acceptable document controls should include provisions to ensure that documents related to activities supporting the ESP application 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 of the prescribed activity.

17.6.3 Technical Evaluation (Document Control)

The NRC staff reviewed the applicant's document control program to verify that it provides for the review, approval, and issuance of documents related to activities supporting the ESP application that would affect SSCs important to safety. The SNC QA Manual includes provisions for preparing, issuing, and changing quality-related documents. These controls include the identification of documents to be controlled, their specified distribution, assignment of responsibility for their preparation, review, approval, and distribution, and the review of documents for adequacy by authorized personnel before approval and issuance.

Each section of this safety evaluation describes (or references a relevant discussion in Inspection Report 05200011/2006001) the specific documents the NRC staff reviewed and also discusses their adequacy. The NRC staff's review included documents from the applicant as well as from contractors and subcontractors. As detailed in Inspection Report 05200011/2006001, the NRC staff reviewed documents that the applicant had reviewed and approved for issuance to ensure that the process was followed. The NRC staff noted that procedures describing the document control program identify all the document types covered by the program. The NRC staff also noted that procedures and instructions are reviewed for adequacy, approved for release, and appropriately distributed and used at the location where the prescribed activity is performed. The NRC staff finds that the procedures provide adequate guidance for document control and the applicant has adequately implemented the procedural requirements.

In RAI 17.6-1, the NRC staff asked the applicant for additional information about the distribution of new and revised documents. Section 17.1.1 of RS-002, paragraph 6, states that provisions should exist to ensure that documents related to activities supporting the ESP application that would affect SSCs important to safety, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location of the prescribed activity. Section 6 of the SNC QA Manual did not provide guidance for controlling the distribution of new and revised documents, including superseded documents, to preclude the possibility or use of inappropriate documents. The NRC staff asked the applicant to discuss how SNC planned to control the distribution of new and revised documents consistent with Section 17.1.1 of RS-002.

In response to this RAI, the applicant proposed additional controls for the distribution of new and revised documents. The applicant revised Part II, Section 6, of the QA Manual to specify a method to identify the correct document (including revision) to be used and to control superseded documents, a method for providing feedback from users to continually improve procedures and work instructions, and controls for coordinating and controlling interface documents and procedures. The applicant also revised Section 6.1 to include the following text:

Prior to issuance or use, documents including revisions thereto, shall be approved by the designated authority. A listing of all controlled documents identifying the current approved revision, or date, is maintained so personnel can readily determine the appropriate document for use.

The NRC staff evaluation of the applicant's response to RAI 17.6-1 and revisions to the application determined that sufficient measures are provided to control the distribution of new and revised documents consistent with Section 17.1.1 of RS-002. On the basis of its evaluation, the NRC staff concludes that the applicant's response to RAI 17.6-1 is acceptable. Therefore, RAI 17.6-1 is resolved.

17.6.4 Conclusion (Document Control)

As described above, the NRC staff reviewed the QA measures used by the applicant and its primary contractors and concludes that they have implemented acceptable document controls which meet the guidance in Section 17.1.1 of RS-002. This provides reasonable assurance that information developed for the ESP application that could be used in the design and/or construction of SSCs important to safety would support satisfactory performance of such SSCs once in service.

17.7 Control of Purchased Material, Equipment, and Services

17.7.1 Introduction (Control of Purchased Material, Equipment, and Services)

The applicant supplied information on control of purchased material, equipment, and services in its QA Manual, which states that SNC has established procedures to control the procurement of items and services to assure conformance with specified requirements. These controls include inspection, identification, and storage of items; provisions for accepting purchased items and services, such as source verification, receipt inspection, pre- and post-installation tests, certificates of conformance, and document reviews; controls for the selection, determination of suitability for intended use, evaluation, receipt, and acceptance of commercial-grade services or "off-the-shelf" items; evaluation of prospective suppliers to ensure that only qualified suppliers are used; audit of qualified suppliers; and controls for the use of audits conducted by outside organizations.

The QA Manual also says that it complies with ASME NQA-1-1994, Basic Requirement 7 and Supplement 7S-1, pertaining to control of purchased material, equipment, and services.

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

While the NRC does not require an ESP applicant to implement control of purchased material, equipment, and services compliant with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the NRC staff to use in evaluating an ESP applicant's control of purchased material, equipment, and services. Paragraph 17.1.1.7 of RS-002 provides the QA measures that constitute an acceptable level of control of purchased material, equipment, and services. Such controls should include (1) provisions for the control of purchased material, equipment, and services related to activities supporting the ESP application that could affect SSCs important to safety which apply to selecting suppliers and assessing the adequacy of quality of materials, equipment, and services and (2) provisions to ensure the onsite availability of documented evidence of the conformance to procurement specifications of material and equipment related to activities supporting the ESP application that could affect SSCs important to safety before their installation or use.

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

The NRC staff reviewed the SNC QA Manual to verify that provisions exist for the control of purchased material, equipment, and services related to activities supporting the ESP application that would affect SSCs important to safety, for selection of suppliers, and for assessing the adequacy of quality. The NRC staff noted that the QA Manual provides controls for source evaluation and selection, evaluation of objective evidence of quality furnished by suppliers (such as certificates of conformance), source inspection, audit, examination of items or services upon delivery or completion, pre- and post- installation testing where appropriate, and provisions for the use of commercial-grade items. Section 17.4.3 of this safety evaluation provides additional discussion of the SNC controls related to purchased material, equipment, and services applicable to its primary contractors.

The following subsections focus on the other subcontractors engaged in activities supporting the ESP application for the Vogtle site. As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed documented surveillances and interviewed key project personnel with respect to contractor activities in acquiring data to support the ESP application. These reviews assessed the scope and depth of the applicant's oversight of contractor activities consistent with the importance, complexity, and scope of the contracted services and thoroughness of the surveillances in identifying and resolving deficiencies. The NRC staff reviewed a sample of surveillances of activities performed by Bechtel, MACTEC, and their subcontractors Bay Geophysical and SRNL. The following subsections address the results of these surveillances.

17.7.3.1 Seismic Boring Activities (QA Surveillance No. V-2005-031)

As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed the surveillance of activities associated with seismic boring activities. The scope of the surveillance was limited to equipment calibration and labeling and storage of soil samples. The borings, drilled to obtain representative soil samples and to measure soil resistance to penetration, were conducted in accordance with ASTM D 1586. The MACTEC subcontractor GEOVision performed the work using Bechtel's technical specification. The NRC staff reviewed Bechtel's technical specification in conjunction with the surveillance and found that it provided sufficient detail for controlling contractor activities. The NRC staff noted that the surveillance identified deficiencies in sample labeling and sample storage and an inconsistency between the calibration date of the seismic recorder/logger and the calibration data sheet. The NRC staff also noted that these deficiencies were clearly described, documented in the applicant's corrective action program, and included appropriate action taken to resolve the identified conditions.

17.7.3.2 Soil and Water Sampling (QA Surveillance Report No. V-2006-017)

As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed a surveillance of water- and soil-sampling activities. Field activities were conducted under augmented quality controls as specified in a purchase requisition and field test procedure. Bechtel project personnel and a MACTEC geologist supervised field drilling activities. Preservation, handling, and transporting of soil samples complied with industry standard ASTM D 4220, "Standard Practice for Preserving and Transporting Soil Samples." The NRC staff noted that the surveillance verified compliance with the above-cited quality control procedures and the technical guidelines of ASTM D 4220. The surveillance confirmed that chain of custody sheets

were completed for each sample and that the MACTEC geologist delivered the samples to MACTEC and SRNL on the day of sampling. The NRC staff finds that the field activities were adequately controlled.

17.7.3.3 Seismic Reflection/Refraction Survey (QA Surveillance No. V-2006-09)

As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed the surveillance of seismic reflection/refraction survey activities conducted in accordance with the technical scope of work specified under a Bay Geophysical proposal. A principal geologist from SRNL provided onsite oversight of survey activities to ensure that activities followed industry standard practices and procedures. The NRC staff noted that the surveillance documented the conclusions of the principal geologist, who concluded from his observations that the contractor had satisfactorily performed the technical activities described in its proposal and had taken due care in performing tests and inspections of monitoring instrumentation and in monitoring the quality of the data to ensure that the data were accurate, reliable, and repeatable.

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

As described above, the NRC staff reviewed the QA measures used by the applicant and its contractors and concludes 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 guidance provides reasonable assurance that information developed for the ESP application that could be used in the design and/or construction of SSCs important to safety would support satisfactory performance of such SSCs once in service.

17.8 Identification and Control of Materials, Parts, and Components

17.8.1 Introduction (Identification and Control of Materials, Parts, and Components)

The applicant supplied information on identification and control of materials, parts, and components in its QA Manual. The QA Manual provides measures to identify and control items to prevent the use of incorrect or defective items, including consumable materials and items with limited shelf life. In addition, the QA Manual provides controls to ensure that an item is traceable to its documentation, consistent with the item's effect on safety.

The QA Manual also says that it complies with ASME NQA-1-1994, Basic Requirement 8 and Supplement 8S-1, pertaining to identification and control of materials, parts, and components.

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

While the NRC does not require an ESP applicant to implement a program for identification and control of materials, parts, and components that complies with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the NRC staff to use in evaluating an ESP applicant's identification and control of materials, parts, and components. Paragraph 17.1.1.8 of RS-002 provides the QA measures that constitute an acceptable level of identification and control of materials, parts, and components. Such controls should include provisions to (1) identify and control materials, parts, and components related to activities supporting the ESP application that could affect SSCs important to safety and (2) ensure that

incorrect or defective items are not used in activities supporting the ESP application that could affect SSCs important to safety.

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

17.8.3.1 Southern Nuclear Operating Company

The NRC staff reviewed the SNC QA Manual, which describes the measures to identify and control materials (including consumables), parts, and components related to activities supporting the ESP application that would affect SSCs important to safety. The NRC staff noted that the QA Manual provides controls for consumable materials and items with limited shelf life, including identification methods, locations, and traceability to prevent the use of incorrect or defective items. These controls are maintained throughout fabrication, erection, installation, and use so that the item can be traced to its documentation. As detailed in Inspection Procedure 05200011/2006001, the NRC staff reviewed procedures that describe the controls implemented by SNC, contractors, and suppliers to verify that controls were in place, as required, for the work performed, for the identification and control of materials, parts, and components. The NRC staff noted that the Supply Chain Management is responsible for the identification and control of materials, parts, and components. The NRC staff also noted that quality requirements imposed on the various companies differed depending on their scope of work. On the basis of its review, the NRC staff finds that the measures for the identification and control of materials, parts, and components are adequate for the conduct of activities supporting the ESP application.

17.8.3.2 Bechtel Power Corporation

The NRC staff reviewed Bechtel's QA Manual and project instructions describing controls for the identification and control of materials, parts, and components important to safety. As discussed in Inspection Report 05200011/2006001, the NRC staff noted that Bechtel's QA Manual contains provisions for physical identification of items, traceability, control of items with limited life, and stored items. The NRC staff also noted that Bechtel imposes the requirements of Appendix B to 10 CFR Part 50 on all of the subcontractors it used to support the ESP application for work important to safety. The NRC staff finds that these measures provide assurance that materials, parts, and components are adequately controlled.

17.8.3.3 MACTEC Engineering and Consulting, Inc.

The MACTEC QA Manual describes the measures for identification and control of items and samples. The NRC staff noted that measures are provided to (1) identify samples to prevent the use of incorrect or defective samples; (2) allow for their proper identification by subsequent users; (3) provide unique physical identification attached to the samples when possible, or in documents traceable to the samples; and (4) maintain chain of custody documentation in the project files.

As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed the MACTEC QAPD to verify the controls associated with the identification and control of materials, parts, and components. The NRC staff noted that the QAPD describes the measures to control soil

samples for use in preparation of the ESP application and to identify samples with clear markings and traceability to origin and location at all times, consistent with the QA Manual. On the basis of its review, the NRC staff finds the controls for the identification and control of materials, parts, and components adequate for the conduct of activities supporting the ESP application.

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

As described above, the NRC staff reviewed the QA measures used by the applicant and its contractors and concludes that they have implemented acceptable controls for the identification and control of materials, parts, and components which meet the guidance in Section 17.1.1 of RS-002. This guidance provides reasonable assurance that information developed for the ESP application that could be used in the design and/or construction of SSCs important to safety would support satisfactory performance of such SSCs once in service.

17.9 Control of Special Processes

17.9.1 Introduction (Control of Special Processes)

The applicant supplied information on control of special processes in its QA Manual, which provides measures for the control of special processes, such as welding, heat treating, and nondestructive examination. These controls include procedures, equipment, personnel, verifications, and record retention requirements to ensure satisfactory performance of activities affecting quality. The QA Manual contains provisions to ensure that qualified personnel accomplish special processes using qualified procedures and equipment. Also, the QA Manual provides controls to ensure that special processes are conducted in accordance with applicable codes, standards, specifications, or other specially established requirements.

The QA Manual also says that it complies with ASME NQA-1-1994, Basic Requirement 9 and Supplement 9S-1, pertaining to control of special processes.

17.9.2 Regulatory Basis (Control of Special Processes)

While the NRC does not require an ESP applicant to implement control of special processes compliant with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the NRC staff to use in evaluating an ESP applicant's control of special processes. Paragraph 17.1.1.9 of RS-002 provides the QA measures that constitute an acceptable level of control of special processes. Acceptable control of these processes should include provisions to (1) ensure the acceptability of special processes used for activities supporting the ESP application that could affect SSCs important to safety and (2) ensure that qualified personnel using qualified procedures and equipment perform special processes related to activities supporting the ESP application that could affect SSCs important to safety.

17.9.3 Technical Evaluation (Control of Special Processes)

Considering that the development of the ESP application did not involve safety-related construction activities requiring control of special processes, the NRC staff finds that no QA measures are necessary to control special processes.

17.9.4 Conclusion (Control of Special Processes)

The NRC staff reviewed the need for QA measures on special processes by the applicant and its contractors and concludes that, based on the scope of work for the ESP application, QA requirements for control of special processes are not required.

17.10 Inspection

17.10.1 Introduction (Inspection)

The applicant supplied information on inspection controls in its QA Manual, which states that administrative procedures describe the requirements for inspections to ensure that items, services, and activities affecting safety meet established requirements. The QA Manual states that the types of inspections may include verifications related to procurement, such as source, in-process, final, and receipt inspection, as well as construction and installation activities. Also, the QA Manual contains measures to ensure that qualified individuals carry out inspections independent of those who performed the work and includes requirements to maintain records of inspection results.

The QA Manual also says that it complies with ASME NQA-1-1994, Basic Requirement 10, Supplement 10S-1, and Subpart 2.4, pertaining to inspection.

17.10.2 Regulatory Basis (Inspection)

While the NRC does not require an ESP applicant to implement inspection controls compliant with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the NRC staff to use in evaluating an ESP applicant's controls for inspection. Paragraph 17.1.1.10 of RS-002 provides the QA measures that constitute an acceptable level of inspection control. Acceptable inspection controls should include (1) provisions for the inspection of activities affecting the quality of activities supporting the ESP application that could affect SSCs important to safety, including the items and activities to be covered, (2) organizational responsibilities and qualifications for individuals or groups inspecting activities supporting the ESP application 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)

Considering that the development of the ESP application did not involve safety-related material, product processing, or inspection hold points, the NRC staff finds that these controls need not be applied to the development of the ESP application.

17.10.4 Conclusion (Inspection)

The NRC staff reviewed the need for QA measures on inspection by the applicant and its primary contractors and concludes that, based on the scope of work, the development of the ESP application does not require QA controls for inspection.

17.11 Test Control

17.11.1 Introduction (Test Control)

The applicant supplied information on test controls in its QA Manual, which states that measures and governing procedures are established for determining when testing is required, such as proof tests before installation, preoperational tests, postmaintenance tests, postmodification tests, inservice tests, and operational tests. The QA Manual also states that tests are performed according to applicable procedures that include (1) instructions and prerequisites to perform the test; (2) use of proper test equipment; (3) acceptance criteria, and (4) mandatory verification points as necessary to confirm satisfactory test completion.

The QA Manual contains provisions to document and evaluate test results. The organization performing the test evaluates the results, and a responsible authority conducts reviews to ensure that test requirements have been satisfied. The manual also includes provisions to ensure that, if acceptance criteria are not met, retesting is performed as needed to confirm acceptability, following correction of the system or equipment deficiencies that caused the failure.

The QA Manual also says that it complies with ASME NQA-1-1994, Basic Requirement 11 and Supplements 11S-1 and 11S-2, and Subpart 2.7, pertaining to test control.

17.11.2 Regulatory Basis (Test Control)

While the NRC does not require an ESP applicant to implement test controls compliant with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the NRC staff to use in evaluating an ESP applicant's test controls. Paragraph 17.1.1.11 of RS-002 provides the QA measures that constitute an acceptable level of test control. Acceptable test controls should include provisions to ensure that (1) tests performed related to activities supporting the ESP application that could affect SSCs important to safety are appropriately controlled to provide confidence that these SSCs will perform adequately in service and (2) written test procedures provide prerequisites and test results are documented and evaluated for activities supporting the ESP application that could affect SSCs important to safety.

17.11.3 Technical Evaluation (Test Control)

17.11.3.1 *Southern Nuclear Operating Company*

The NRC staff reviewed the applicant's test controls described in the QA Manual. The NRC staff noted that the scope of the test program includes measures to ensure the appropriate control of tests related to activities supporting the ESP application that would affect SSCs important to safety. In addition, the NRC staff noted that controls are in place to ensure that tests are performed using procedures that include (1) the use of standards and acceptance criteria; (2) instructions for performing the test; (3) test prerequisites, including the use of proper test equipment; (4) inspection hold-points; (5) acceptance and rejection criteria; and (6) methods of documenting or recording test data and results. The NRC staff also noted that the QA Manual includes controls to ensure that test results are documented and evaluated and their acceptability is determined by a responsible individual or group. The NRC staff also noted

that the ND QA Project Engineer is responsible individual for assuring compliance with regulatory requirements and procedures through audits and technical reviews. These reviews include the adequacy of the implementation of M&TE procedures.

As detailed in Inspection Report 05200011/2006001, the NRC staff reviewed the QA controls specified in the POs for each vendor to verify that controls were in place, as applicable to the work performed, for test activities as described in the following subsections.

17.11.3.2 Bechtel Power Corporation

The NRC staff reviewed Bechtel's QAPP and noted that it establishes testing requirements applicable to the development of the VEGP application. Bechtel stated in the QAPP that, for test control, it performs quality-related activities associated with the preparation of the ESP application in accordance with Bechtel's NQAM with no modifications. The NRC staff reviewed the Bechtel NQAM and procedures describing the requirements and responsibilities for the control of tests. As discussed in Inspection Report 05200011/2006001, the NRC staff noted that the NQAM describes the control of tests within Bechtel's scope. Specifically, it describes the interface responsibilities between Bechtel and the applicant, applicable test requirements and prerequisites, standards and acceptance criteria, including the use of calibrated instruments and suitable test equipment, documentation and evaluation of test results, and handling of test deviations. On the basis of its review, the NRC staff finds Bechtel's test procedures adequate for the conduct of activities supporting the ESP application.

17.11.3.3 MACTEC Engineering and Consulting, Inc.

As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed the MACTEC QA Manual which describes the measures for controlling tests performed on materials or equipment and verifying test conformance to specified requirements. The NRC staff noted that measures are provided to ensure that (1) tests are conducted in accordance with written procedures or instructions; (2) responsible personnel review and approve the procedures; and (3) test results are documented and reviewed for accuracy and completeness.

The NRC staff also reviewed the MACTEC QAPD, which describes the measures to control the tests of soil samples for use in preparation of the ESP application. The NRC staff noted that tests are performed using industry standard methods such as those of ASTM. The NRC staff also noted that controls are in place to (1) ensure that testing criteria and requirements were followed, (2) evaluate exceptions to these criteria and requirements, and (3) notify the client for consultation and permission before tests are conducted. As detailed in Inspection Report 05200011/2006001, the NRC staff noted that MACTEC activities are controlled by adequate procedures and standards with an appropriate level of supervisory and QA oversight. On the basis of its review, the NRC staff finds the MACTEC test controls adequate.

17.11.4 Conclusion (Test Control)

As described above, the NRC staff reviewed the QA measures used by the applicant and its primary contractor and concludes that they have implemented acceptable test controls which meet the guidance in Section 17.1.1 of RS-002. This guidance provides reasonable assurance that information developed for the ESP application that could be used in the design and/or

construction of SSCs important to safety would support satisfactory performance of such SSCs once in service.

17.12 Control of Measuring and Test Equipment

17.12.1 Introduction (Control of Measuring and Test Equipment)

The applicant supplied information on control of measuring and test equipment in its QA Manual, which states that provisions are in place to control the calibration, maintenance, and use of measuring and test equipment (M&TE). These provisions, in the form of procedures, cover equipment such as indicating and actuating instruments and gauges, tools, reference and transfer standards, and nondestructive examination equipment. The QA Manual describes measures to control the calibration of M&TE which include labeling and tagging controls, traceability controls, use of nationally recognized standards, and controls on the use of M&TE found to be out of calibration.

The QA Manual also says that it complies with ASME NQA-1-1994, Basic Requirement 12, and Supplements 12S-1 and Subpart 2.16, pertaining to control of M&TE.

17.12.2 Regulatory Basis (Control of M&TE)

While the NRC does not require an ESP applicant to implement controls of M&TE compliant with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the NRC staff to use in evaluating an ESP applicant's control of M&TE. Paragraph 17.1.1.12 of RS-002 details the QA measures that constitute an acceptable level of control of M&TE. Acceptable control of M&TE should include provisions to ensure that tools, gauges, instruments, and other measuring and testing devices are properly identified and controlled and are calibrated and adjusted at specified intervals.

17.12.3 Technical Evaluation (Control of M&TE)

17.12.3.1 *Southern Nuclear Operating Company*

The NRC staff's review of the applicant's QA Manual noted that it establishes measures to calibrate M&TE at specified intervals on the basis of the item's required accuracy, intended use, frequency of use, stability characteristics, or other conditions affecting its performance. The NRC staff also noted that the QA Manual provides controls to label or tag M&TE to indicate its calibration status and provide traceability to calibration test data or records. Additionally, controls are in place to tag or segregate M&TE found to be out of calibration until it is successfully recalibrated.

The NRC staff noted that the QA Manual includes provisions to ensure that calibrations are performed against nationally recognized standards. Calibrations are performed with an accuracy of at least four times the required accuracy of the equipment being calibrated, when this is not possible, the accuracy of the standards ensure that the equipment being calibrated will be within the required tolerance.

The NRC staff noted that the ND QA Project Engineer is the responsible individual for assuring compliance with regulatory requirements and procedures through audits and technical reviews. These reviews include the adequacy of the implementation of M&TE procedures.

As detailed in Inspection Report 05200011/2006001, the NRC staff reviewed the implementation of QA measures associated with control of M&TE. Specifically, the NRC staff reviewed procedures that describe the controls implemented by the applicant, contractors, and suppliers to ensure that M&TE used in activities supporting the ESP application that would affect SSCs important to safety are adequately controlled. On the basis of its review, the NRC staff finds that the guidance for control of M&TE is adequate for the conduct of activities supporting the ESP application.

17.12.3.2 Bechtel Power Corporation

The NRC staff reviewed Bechtel's QA measures associated with the control of M&TE. Bechtel's QAPP establishes M&TE requirements applicable to the development of the VEGP application. Bechtel states in the QAPP that it performs quality-related activities associated with the preparation of the ESP application and involving the control of M&TE in accordance with its NQAM with no additional modifications.

As detailed in Inspection Report 05200011/2006001, the NRC staff reviewed the Bechtel NQAM and procedures describing the requirements and responsibilities for the control of M&TE. The NRC staff noted that the NQAM adequately defines the responsibilities for the maintenance, control, calibration, documentation, and identification of tools, gauges, and other M&TE used in activities affecting quality. The NQAM requires that calibration procedures define the calibration method, means of identification, recalibration frequency of the M&TE, and issuance of tools, gauges, and test equipment. Additionally, the NQAM describes the evaluation of M&TE found to be outside calibration limits, calibration against certified equipment having known relationships to nationally recognized standards, and documentation of M&TE usage in test records. The NRC staff also reviewed a sample of calibration records related to the performance of geologic tests, seismic test activities, and laboratory testing completed in support of the ESP application. Based on the review of Bechtel's administrative controls and sample of calibration records, the NRC staff finds that Bechtel has implemented adequate measures to provide reasonable assurance that it properly controls M&TE.

17.12.3.3 MACTEC Engineering and Consulting, Inc.

The NRC staff reviewed the MACTEC controls applied to M&TE. As discussed in Inspection Report 05200011/2006001, Bechtel's technical specification describes the scope of the MACTEC required services, which include maintaining calibration documentation of field and laboratory equipment. The MACTEC QAPD invokes additional measures for the control of M&TE. Specifically, the NRC staff noted that these measures include provisions for evaluating measurement and test results obtained from equipment found to be out of calibration. Such equipment is not to be used until it has been repaired or recalibrated and found acceptable for use. Any results determined to be invalid because of calibration errors are required to have a nonconformance written and processed as specified in the applicable portions of the MACTEC QAPD. Also, the NRC staff noted a requirement that the M&TE equipment utilized was to be listed on the test data sheet and meet the criteria specified in the chosen test method.

As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed a sample of calibration records from MACTEC and three of its subcontractors, GEOVision, Applied Research Associates, and GRL Engineering. The NRC staff finds that none of the reviewed equipment was out of calibration and all reviewed calibrations were performed within the specified frequency. The NRC staff also reviewed test data sheets to verify that the equipment utilized was identified on the record. On the basis of its review, the NRC staff finds that MACTEC control of M&TE is adequate for the conduct of activities supporting the ESP application.

17.12.4 Conclusion (Control of M&TE)

As described above, the NRC staff reviewed the QA measures used by the applicant and its primary contractors and concludes that they have implemented acceptable control of M&TE which meets the guidance in Section 17.1.1 of RS-002. This guidance provides reasonable assurance that information developed for the ESP application that could be used in the design and/or construction of SSCs important to safety would support satisfactory performance of such SSCs once in service.

17.13 Handling, Storage, and Shipping

17.13.1 Introduction (Handling, Storage, and Shipping)

The applicant supplied information on handling, storage, and shipping controls in its QA Manual, which describes the administrative procedures and requirements for control of handling, storage, and shipping of items important to safety. These procedures control the cleaning, handling, storage, packaging, shipping, identification, and preservation of materials, components, and systems to preclude damage, loss, or deterioration by environmental conditions when required to maintain acceptable quality. The QA Manual also provides measures in its administrative procedures for housekeeping practices during construction and preoperational activities.

The QA Manual also says that it complies with ASME NQA-1-1994, Basic Requirement 13, and Supplements 13S-1, Subpart 2.1, Subpart 2.2, and Subpart 2.3, pertaining to handling, storage, and shipping.

17.13.2 Regulatory Basis (Handling, Storage, and Shipping)

While the NRC does not require that an ESP applicant implement controls for handling, storage, and shipping compliant with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the NRC staff to use in evaluating an ESP applicant's controls for handling, storage, and shipping. Paragraph 17.1.1.13 of RS-002 provides the QA measures that constitute an acceptable level of handling, storage, and shipping control. Such controls should include provisions to control the handling, storage, shipping, cleaning, and preservation of items related to activities supporting the ESP application 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 Southern Nuclear Operating Company

The NRC staff reviewed the applicant's QA Manual, which states that the applicant has established measures for classifying, packaging, cleaning, preserving, shipping, storing, and handling materials and equipment. The QA Manual also states that administrative procedures define responsibilities, levels of cleanliness, tagging, and storage levels. The QA Manual also provides for measures to preclude damage, loss, or deterioration by environmental conditions.

As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed procedures implemented by SNC to control the handling, storing, and shipping of materials and equipment. The NRC staff noted that the procedures contain measures for the classification, packaging, cleaning, preservation, shipping, storage, and handling of materials and equipment. The procedures also contain provisions to prevent damage or loss caused by environmental conditions. On the basis of its review, the NRC staff finds that the guidance for handling, shipping, and storage of items important to safety is adequate for the conduct of activities supporting the ESP application.

17.13.3.2 Bechtel Power Corporation

As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed the quality measures described in Bechtel's technical specification. This technical specification describes the controls for the handling, shipping, and storage of soil samples collected for use in the preparation of the ESP. Although Bechtel did not conduct any activities supporting the ESP application associated with handling, storage, and shipping, Bechtel developed this technical specification for the development of the VEGP application. MACTEC conducted its work in accordance with the Bechtel technical specification. The NRC staff reviewed the technical specification provided by Bechtel and the MACTEC implementation of this technical specification during the collection, transportation, and preservation of soil samples. The NRC staff finds it to be adequate for handling, storage, and shipping controls related to activities supporting the ESP application.

17.13.3.3 MACTEC Engineering and Consulting, Inc.

As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed the MACTEC QA Manual. The NRC staff noted that the QA Manual establishes requirements to ensure that methods for the handling, storage, preservation, packaging, and shipping of items or samples conform with nationally recognized standards. Additionally, the MACTEC QAPD provides controls for the handling, storage, and shipping of items as described in Bechtel's technical specification. The QAPD states that samples are identified, traceable to the origin and location, maintained in the chain of custody, and stored in a locked facility with controlled access. The NRC staff noted that, as part of the controls MACTEC implemented for the collection of soil samples, it utilized ASTM D 4220 to control and preserve, transport, and handle the samples. On the basis of its review, the NRC staff concludes that MACTEC implemented adequate measures to provide reasonable assurance of proper control of soil samples collected, analyzed, and used in the ESP application.

17.13.4 Conclusion (Handling, Storage, and Shipping)

As described above, the NRC staff reviewed the QA measures used by the applicant and its major contractors and concludes that they have implemented acceptable controls for handling, storage, and shipping which meet the guidance in Section 17.1.1 of RS-002. This guidance provides reasonable assurance that information developed for the ESP application that could be used in the design and/or construction of SSCs important to safety would support satisfactory performance of such SSCs once in service.

17.14 Inspection, Test, and Operating Status

17.14.1 Introduction (Inspection, Test, and Operating Status)

The applicant supplied information on inspection, test, and operating status controls in its QA Manual, which states that procedures are established to identify the inspection, test, and operating status of items and components. These procedures require verification of the inspection, test, or operating status before release, fabrication, receipt, installation, test, or use to preclude inadvertent bypassing of inspections or tests, or to preclude inadvertent operation. In addition, the QA Manual provides the necessary authorities and controls for the application and removal of status indicators or labels.

The QA Manual says that it complies with ASME NQA-1-1994, Basic Requirement 14, pertaining to inspection, test, and operating status.

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

While the NRC does not require an ESP applicant to implement controls for inspection, test, and operating status compliant with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the NRC staff to use in evaluating an ESP applicant's controls for inspection, test, and operating status. Paragraph 17.1.1.14 of RS-002 provides the QA measures that constitute an acceptable level of controls for inspection, test, and operating status. Such controls should include provisions to indicate the inspection, test, and operating status of items related to activities supporting the ESP application that could affect SSCs important to safety to prevent inadvertent use or bypassing of inspection and tests.

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

Considering that the development of the ESP application did not involve the inspection, testing, or operation of SSCs of a nuclear power plant, the NRC staff does not find these controls necessary for the development of the ESP application.

17.14.4 Conclusion (Inspection, Test, and Operating Status)

The NRC staff reviewed the need for QA measures for inspection, test, and operating status by the applicant and its primary contractors and concludes that, based on the scope of work for the development of the ESP application, QA requirements for inspection, test, and operating status are not required.

17.15 Nonconforming Materials, Parts, or Components

17.15.1 Introduction (Nonconforming Materials, Parts, or Components)

The applicant supplied information on nonconforming materials, parts, or component controls in its QA Manual, which states that the applicant's administrative procedures describe the requirements for control of materials, parts, or components that do not conform to specified requirements. These controls provide for identification, documentation, evaluation, segregation, and notification to affected organizations. The QA Manual also provides controls to evaluate nonconformances for impact on operability of SSCs. The QA Manual provides measures for the conditional release of nonconforming items, disposition of nonconformances, and identification and reporting of significant trends to management.

The QA Manual also says that it complies with ASME NQA-1-1994, Basic Requirement 15, and Supplement 15S-1, pertaining to nonconforming materials, parts, and components.

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

While the NRC does not require that an ESP applicant implement controls of nonconforming materials, parts, or components compliant with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the NRC staff to use in evaluating an ESP applicant's control of nonconforming materials, parts, or components. Paragraph 17.1.1.15 of RS-002 provides the QA measures that constitute acceptable provisions for addressing nonconforming materials, parts, or components control. Such controls should include provisions to control the use or disposition of nonconforming materials, parts, or components related to activities supporting the ESP application that could affect SSCs important to safety.

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

Considering that the development of the ESP application did not involve fabrication, erection, installation, and use of materials, parts, or components that required identification and controls for nonconforming conditions, the NRC staff does not find that these controls are necessary for the development of the ESP application.

17.15.4 Conclusion (Nonconforming Materials, Parts, or Components)

The NRC staff reviewed the need for QA measures on nonconforming materials, parts, or components by the applicant and its primary contractors and concludes that, based on the scope of work for the development of the ESP application, QA requirements for control of nonconforming materials, parts, or components are not needed.

17.16 Corrective Action

17.16.1 Introduction (Corrective Action)

The applicant supplied information on corrective action controls in its QA Manual. The QA Manual states that procedures are established to identify, control, document, classify, and correct conditions adverse to quality. These procedures ensure that corrective action is

documented and initiated following the determination of a condition adverse to quality in accordance with regulatory guidance and applicable quality standards. In addition, controls are in place to ensure that significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management. The results of evaluations of conditions adverse to quality are analyzed to identify trends.

The QA Manual includes provisions to ensure that QA and inspection personnel have the authority to stop work not being done in accordance with approved procedures. The QA Manual also states that administrative procedures describe a program to identify, evaluate, and report defects and noncompliances in accordance with 10 CFR Part 21. The QA Manual further states that this reporting program applies to safety-related activities and services performed by SNC and/or SNC suppliers/subsuppliers providing input to the ESP application development.

The QA Manual also says that it complies with ASME NQA-1-1994, Basic Requirement 16, pertaining to corrective action.

17.16.2 Regulatory Basis (Corrective Action)

While the NRC does not require an ESP applicant to implement a corrective action program compliant with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the NRC staff to use in evaluating an ESP applicant's corrective action program. Paragraph 17.1.1.16 of RS-002 provides the QA measures that constitute an acceptable corrective action program. This program should include provisions to ensure that the applicant promptly identifies and corrects conditions adverse to quality. For significant conditions adverse to quality, those provisions should preclude recurrence.

17.16.3 Technical Evaluation (Corrective Action)

17.16.3.1 Southern Nuclear Operating Company

The NRC staff reviewed the SNC QA Manual, procedures, and instructions covering the identification and correction of the causes of deviations. The NRC staff noted that the QA Manual outlines the process for identifying, screening, documenting, resolving, and tracking discrepancies associated with the development of the ESP application. It also details the process for identifying and determining the operability and reportability of conditions potentially adverse to quality and operability. The NRC staff also noted that the QA Manual provides controls for timely documentation and evaluation of issues in accordance with regulatory guidance and applicable standards.

As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed the corrective action programs and the identified problems for the identification and resolution of generic deviations and documentation of corrective actions. The VEGP application QA instruction provides for controls on the identification and correction of conditions adverse to quality. SNC addresses any conditions adverse to quality pertaining to the actions or functions specific to activities supporting the ESP application in accordance with the SNC corrective action program. In addition, the corrective action program implementing procedure requires the identification, documentation, and correction of conditions adverse to quality. The procedure requires that identified issues be documented in a condition report (CR). Actions that need to be taken

associated with a CR must be documented in an action item (AI) report. The procedure provides for the assignment of a severity level (SL) on a scale from 1 to 5, based on the risk significance and consequence of the condition (SL 1 is the highest risk significance level). The procedure also states that CRs documenting QA audit findings will be classified as SL 3, CRs documenting QA audit comments will be classified as SL 4, and CRs documenting QA audit recommendations will be classified as SL 5.

As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed all of the CRs and AIs that SNC generated during SNC activities in support of the ESP application. These include CRs and AIs generated by personnel in the course of activities supporting the ESP application, surveillances, internal audits, and external audits. As part of this effort, the NRC staff reviewed CR's generated by MACTEC that were documented in the SNC's corrective action program. Section 17.18 of this safety evaluation addresses external audits separately. For all of the CRs, the NRC staff found the proposed corrective action and subsequent resolution to be adequate to address the identified problem. The NRC staff noted that all the CRs were of low risk or had minimal impact on activities supporting the ESP application. Most of them were administrative in nature and were designated as SL 4 or SL 5. The NRC staff did note that the one audit and two surveillances performed during activities supporting the ESP application generated most of the CRs. Personnel involved in activities supporting the ESP application generated only a few CRs. Because of the minor administrative nature of the CRs, the NRC staff finds that they do not have a significant impact on activities supporting the ESP application.

Although MACTEC provided corrective action controls in its QA Manual and these were found adequate by the NRC staff, the NRC staff focused its review on activities documented in the SNC's corrective action program that related to MACTEC's activities. To that end, the NRC staff reviewed audits and surveillances conducted by SNC on MACTEC to verify adequate implementation of corrective action controls by MACTEC. The review of an audit conducted by SNC is documented below.

SNC conducted a limited scope audit of MACTEC. The audit focused on selected elements of the MACTEC QA Program and associated implementation. The audit determined that the findings did not have an impact on the work provided by MACTEC. As discussed in Inspection Report 05200011/2006001, the audit report contained five findings. The NRC staff reviewed the MACTEC response to the findings and the SNC Audit Report Closeout memorandum. On the basis of its review, the NRC staff finds that both documents are sufficiently detailed to determine that adequate corrective action has been taken and that there was no impact on information supplied in the ESP application.

As discussed in Inspection Report 05200011/2006001, SNC also conducted a limited scope audit of Bechtel to address issues specific to activities supporting the ESP application. There were no findings associated with the audit; however, there was one issue associated with subsupplier audits. Bechtel's triennial audit of REI, the primary contractor for the probabilistic seismic hazards analysis in support of the development of the ESP application, had expired. Bechtel documented the issue in a CR. Bechtel subsequently conducted a full-scope triennial audit for placement of REI on Bechtel's Nuclear Evaluated Suppliers List. On the basis of its review, the NRC staff finds that Bechtel's actions adequately addressed the audit finding.

Section 17.7 and 17.18 of this report details of additional surveillance and audit activities reviewed by the NRC staff. As stated in both Sections, the NRC staff concluded that SNC adequately provided oversight of contractors' activities affecting quality. This included a review of the thoroughness of audits and surveillances in identifying and resolving deficiencies.

The NRC staff reviewed the SNC policies and procedures to ensure an adequate description of the process for implementing 10 CFR Part 21. Additionally, the NRC staff reviewed the SNC imposition of 10 CFR Part 21 on its subcontractors. The applicant's QA Manual states that 10 CFR Part 21 shall apply to safety-related activities and services performed by SNC and/or suppliers providing input to the ESP application development. As detailed in Inspection Report 05200011/2006001, the NRC staff reviewed several procedures that describe the identification and evaluation of defects and failures to comply pursuant to 10 CFR Part 21. In addition, the NRC staff reviewed the POs to verify the appropriate imposition of 10 CFR Part 21. Bechtel was the only contractor performing work directly for SNC on which SNC imposed 10 CFR Part 21. The other contractors were gathering data and information and channeling it through Bechtel for review. The NRC staff finds this process acceptable.

17.16.3.2 *Bechtel Power Corporation*

As detailed in Inspection Report 05200011/2006001, the team reviewed the Bechtel procedure for processing corrective action reports (CARs). The procedure provides directions for identifying and reporting conditions that adversely affect quality. The procedure also provides guidance for documentation and determination of the root cause of issues, the development and implementation of effective corrective action plans, and the performance of followup activities to determine if the corrective action has effectively resolved the issue. The NRC staff finds that the procedural guidance is adequate for the conduct of a corrective action program.

The NRC staff reviewed all the CARs that Bechtel generated during SNC activities that supported the ESP application. The NRC staff noted that one recently opened CAR concerned specific ESP SAR sections submitted to SNC for submittal to NRC, without the incorporation of a manager's comments. The NRC staff was concerned that the comments might affect technical information provided in the ESP application. After an interview with a Bechtel manager involved in activities supporting the ESP application, the NRC staff concludes that this issue does not have a significant impact on activities supporting the ESP application.

As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed one limited scope audit that Bechtel performed of MACTEC. The audit resulted in two findings. The first finding noted the absence of written procedures for electronic distribution of the MACTEC QA Manual and implementing procedures, control of procurement documents related to approval and placement into the electronic database, and storage of records in the electronic database. The NRC staff determined that this finding was administrative in nature and had no impact on the ESP application. The NRC staff found that the MACTEC response to improve its administrative procedures adequately addressed the finding. The second finding was that the MACTEC supplier quality program allowed approval of suppliers based on historical data and/or third-party accreditation. MACTEC did perform audits for approval of suppliers but had not revised the QA Manual to reflect the change. Additionally, MACTEC suppliers always worked under MACTEC supervision. The NRC staff determined that this finding had no impact on the VEGP application.

Bechtel's NQAM outlined the responsibilities for reporting significant deviations; a Bechtel Instruction also covered this process. As detailed in Inspection Report 05200011/2006001, the NRC staff reviewed the instruction, which defines responsibilities, establishes requirements, and provides guidance for action necessary to implement 10 CFR Part 21. The NRC staff also reviewed Bechtel's Engineering Department Procedure for 10 CFR Part 21 reporting. This procedure explains the implementation of Bechtel's instruction, defines responsibilities, and provides guidance for identifying and evaluating deviations, defects and noncompliances, and reporting. The procedure applies to activities and services performed by Bechtel in the offices and job sites involving basic components, which include nuclear safety-related design, analysis, inspection, testing, fabrication, replacement parts, or consulting services. The procedure applies to personnel in the supply chain involved in the particular activity. This includes subtier suppliers and organizations providing consulting, testing, or inspection services. The NRC staff finds that the procedure provides adequate guidance for identifying and evaluating issues related to 10 CFR Part 21.

During the inspection, the NRC staff did make one observation concerning the REI 10 CFR Part 21 evaluation procedure. The procedure lacked sufficient detail to guide an adequate evaluation. The NRC staff identified the issue to Bechtel personnel responsible for the oversight of SNC activities that support the ESP application. The responsible Bechtel personnel reviewed all of the applicable CARs and found no potential 10 CFR Part 21 issues related to activities performed by REI. Bechtel detailed this conclusion in a memorandum to ensure that the review was documented and that no potential 10 CFR Part 21 deviations were identified. The NRC staff considers Bechtel's response to be acceptable for addressing the observation.

17.16.4 Conclusion (Corrective Action)

As described above, the NRC staff reviewed the QA measures used by the applicant and its primary contractors and concludes that they implemented an acceptable corrective action program which meets the guidance in Section 17.1.1 of RS-002. This guidance provides reasonable assurance that information developed for the ESP application that could be used in the design and/or construction of SSCs important to safety would support satisfactory performance of such SSCs once in service.

17.17 Quality Assurance Records

17.17.1 Introduction (Quality Assurance Records)

The applicant supplied information on QA records controls in its QA Manual, which states that procedures are established to ensure that sufficient records of items and activities affecting quality are developed, reviewed, approved, issued, used, and revised to reflect completed work. These procedures contain provisions for records administration, including receipt, preservation, retention, storage, safekeeping, retrieval, and final disposition. Examples of QA records include design, engineering, procurement, manufacturing, construction, inspection and test, installation, preoperation, startup, and audits. The QA Manual also contains provisions for the use of electronic records storage and retrieval systems in accordance with current industry standards.

The QA Manual says that it complies with ASME NQA-1-1994, Basic Requirement 17, pertaining to QA records.

17.17.2 Regulatory Basis (Quality Assurance Records)

While the NRC does not require an ESP applicant to control QA records compliant with the criteria of Appendix B, Section 17.1.1 of RS-002 contains guidance for the NRC staff to use in evaluating an ESP applicant's QA records. Paragraph 17.1.1.17 of RS-002 provides the QA measures that constitute an acceptable level of QA record control. Acceptable control of QA records should provide for the identification, retention, retrieval, and maintenance of quality records.

17.17.3 Technical Evaluation (Quality Assurance Records)

17.17.3.1 Southern Nuclear Operating Company

The NRC staff reviewed the SNC QA Manual. In addition, the NRC staff conducted reviews to verify that procedures and instructions for the control and retention of QA records addressed appropriate attributes of QA record control. As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed the SNC records procedure. This procedure states the policy for the retention of records. The Record Type (R-Type) Table controls the retention duration for records classified as QA records. When the R-Type was developed or chosen for each document, the retention time was defined. SNC stated that ESP-related QA records are retained for the life of the plant. Preliminary drafts determined by the COL/ESP Project Engineer not to be needed for future activities are purged/discarded within 30 days following application submittal.

The NRC staff reviewed the applicant's procedure for establishing administrative controls for the receipt, processing, and storage of SNC QA and non-QA records. This procedure applies to all departments/groups within the SNC corporate offices that perform work under the SNC QA Manual. This procedure provides for the storage of records in .pdf format in the Documentum database to meet long-term storage requirements. Records are stored at an SNC offsite location, which is an approved vault located at Iron Mountain Records Facility in Birmingham, Alabama. From interviews with document service personnel, the NRC staff learned that most of the documents at the offsite facility are stored in the Documentum database and easily retrievable. A procedure also provides for a Record Control Log (RCL) to track project records transmitted to Document Services (DS) for storage and retention. As detailed in Inspection Report 05200011/2006001, the NRC staff noted that the procedure does not provide a method to track and control records received by contractors before being officially transmitted and processed by DS. Based on the NRC staff's observation, SNC documented the finding and stated that it will start using the RCL to track the documents received from contractors and records transmitted to DS for storage and retention. The NRC staff finds this action acceptable.

The RCL procedure also states that the SNC DS Supervisor is responsible for implementing a record program in accordance with applicable regulatory requirements that meet the guidance in the QA Manual. The project procedure states that the Vogtle Deployment Administrative Assistant is responsible for distributing project correspondence, transmitting records related to

licensing activities, maintaining the RCL, maintaining project files, and verifying that records processed in accordance with this procedure are available in the Documentum database. The project procedure states that the Project Manager is responsible for identifying project records that should be retained for permanent storage. The NRC staff noted from discussions with SNC personnel that they are aware of specific roles and responsibilities for the proper control of records.

The NRC staff noted that Section 11 and Section 11 of the NQAM contain a commitment to NQA-1-1994, Supplement 10S-1 and Supplement 11S-1, respectively. These Supplements specify requirements for records that include (1) a description of the type of observation; (2) date and results of the inspection or test; (3) identification of the inspector or data recorder; (4) evidence of the acceptability of the results; and (5) information related to actions taken to resolve any deficiencies noted. The NRC staff finds this adequate requirements for QA records.

The NRC staff reviewed the requirements that SNC imposes on contractors for turning over ESP quality records. An SNC project procedure states that upon submittal of the ESP application, contractors supporting development of the application submit to SNC copies of supporting calculations and applicable source and reference documents. SNC collects and retains engineering calculations and supporting information developed by SNC for the life of the plant. On the basis of its review, the NRC staff finds that the SNC records controls are adequate for the conduct of activities supporting the ESP application.

17.17.3.2 Bechtel Power Corporation

As discussed in Inspection Report 05200011/2006001, the NRC staff reviewed Bechtel's records procedure. The procedure describes administrative requirements for processing Bechtel documents that require control, distribution, and retention. The procedure states that the lead individual in the administration functional area for a project has the overall responsibility for implementation of this procedure. Functional disciplines and group supervisors are responsible for ensuring that documents have been submitted for processing and retention. The NRC staff noted that Bechtel personnel adequately control records related to the VEGP application development activities in accordance with their administrative requirements. On the basis of its review, the NRC staff finds Bechtel's control of QA records adequate for the scope of activities supporting the ESP application conducted.

17.17.4 Conclusion (Quality Assurance Records)

As described above, the NRC staff reviewed the QA measures used by the applicant and its primary contractors and concludes 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 guidance provides reasonable assurance that information developed for the ESP application that could be used in the design and/or construction of SSCs important to safety would support satisfactory performance of such SSCs once in service.

17.18 Audits

17.18.1 Introduction (Audits)

The applicant supplied information on audit controls in its QA Manual, which states that procedures are established to implement audits to verify that activities covered by the QA Manual are performed in conformance with the requirements established. The QA Manual also states that the QA organization is responsible for conducting periodic internal and external audits on a formal, preplanned audit schedule. Under these procedures, the applicant periodically reviews and revises the audit system as necessary to ensure coverage commensurate with current and planned activities. The applicant may perform additional audits as deemed necessary by management. The quality status and safety importance of the activities being performed determines the scope of the audit. Trained personnel who do not have direct responsibilities in the area being audited conduct the investigation in accordance with preplanned and approved audit plans or checklists.

The QA Manual states that the QA organization conducts periodic internal and external audits. It conducts internal audits to determine the adequacy of programs and procedures and whether they are meaningful and in compliance with the overall QA program. External audits determine the adequacy of vendor and contractor QA programs. Audits must be performed in those areas where the requirements of Appendix B to 10 CFR Part 50 apply.

The QA Manual states that the applicant's management responds to all audits and initiates corrective action when indicated. The applicant documents followup of applicable areas through inspections, review, reaudits, or other appropriate means to verify implementation of the assigned corrective action.

The QA Manual also says that it complies with ASME NQA-1-1994, Basic Requirement 18, and Supplement 18S-1, pertaining to audits.

17.18.2 Regulatory Basis (Audits)

While the NRC does not require an ESP applicant to control audits in accordance with the criteria of Appendix B to 10 CFR Part 50, Section 17.1.1 of RS-002 contains guidance for the NRC staff to use in evaluating an ESP applicant's control of audits. Paragraph 17.1.1.18 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 measures and to determine the effectiveness of these measures and (2) responsibilities and procedures for conducting, documenting, and reviewing the results of audits (including designating management levels to review and assess audit results).

17.18.3 Technical Evaluation (Audits)

The NRC staff reviewed the applicant's QA Manual and procedures or instructions covering the preparations for and conduct of audits. The NRC staff noted that the QA Manual includes provisions for audits to verify compliance with all aspects of QA measures and to determine the effectiveness of the QA measures. The QA Manual also states that during the early portions of

nuclear development activities, audits will focus on areas including, but not limited to, site investigation, procurement, and corrective action.

The NRC staff noted that the QA Manual provides controls to assign responsibilities and develop procedures for conducting, documenting, and reviewing results of audits. Controls are also provided to conduct periodic internal and external audits on a formal, preplanned audit schedule, using approved checklists and trained personnel not having responsibilities in the area being audited.

The NRC staff noted that the QA Manual includes controls for documenting, evaluating, and reporting audit results to management. Personnel report audit results in writing to the Senior Vice President for Nuclear Development, the Nuclear Technology Startup Director, the Vogtle Deployment Director, and the Vogtle Licensing Manager, as appropriate. In addition, the QA Manual describes controls to ensure that management responds to all audit findings, initiates corrective action when indicated, and verifies implementation of assigned corrective action.

As detailed in Inspection Report 05200011/2006001, the NRC staff reviewed a sample of completed audits to verify adequate implementation of controls for the performance of audits. In addition, the NRC staff interviewed SNC QA personnel who audited the activities that supported the ESP application and reviewed personnel training and qualification records. The audits reviewed include (1) an SNC internal audit of quality-related activities associated with the ESP; (2) an SNC limited scope audit of MACTEC; and (3) a Nuclear Procurement Issues Committee audit of Bechtel. The NRC staff determined by review of the limited scope audits that the audited elements were in compliance with Appendix B to 10 CFR Part 50. In particular, the NRC staff noted that audit activities included a review of significant quality attributes, such as design and software control, procurement activities, training, record retention, and corrective action. On the basis of its review, the NRC staff finds the audit process adequate for the conduct of activities supporting the ESP application.

17.18.4 Conclusion (Audits)

As described above, the NRC staff reviewed the QA measures used by the applicant and its primary contractors and concludes that they have implemented acceptable audit controls which meet the guidance in Section 17.1.1 of RS-002. This guidance provides reasonable assurance that information developed for the ESP application that could be used in the design and/or construction of SSCs important to safety would support satisfactory performance of such SSCs once in service.

17.19 Conclusions

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

- The organizations and persons performing QA functions have the independence and authority necessary to carry out effective 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 activities supporting the ESP application 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.

The NRC staff concludes that the applicant's QA measures conform to the guidance in RS-002 and appropriate industry standards and are being implemented for the ESP.