

February 15, 2008

Mr. Garry Miller, General Manager
Nuclear Plant Development
Progress Energy
P.O. Box 1981
TPP 15
Raleigh, NC 27602-1981

SUBJECT: NUCLEAR REGULATORY COMMISSION AUDIT REPORT ON THE REVIEW OF
PROGRESS ENERGY'S SHEARON HARRIS NUCLEAR PLANT UNITS 2 AND 3
COMBINED LICENSE APPLICATIONS

Dear Mr. Miller:

On October 29 - November 2, 2007, United States Nuclear Regulatory Commission (NRC) staff audited the development programs for Progress Energy's (PE) Shearon Harris Nuclear Plant Units 2 and 3 (Harris) combined license applications (COLA). This audit occurred at the PE's facility in Raleigh, North Carolina. The enclosed audit report presents the details of these activities.

The NRC auditors reviewed the implementation of selected portions of the PE and its contractors' quality assurance (QA) programs related to the Harris COLA development program. During this audit, the NRC staff identified several issues associated with the implementation of the Harris COLA program that should be addressed. These issues are described in this report and are combined into an audit response request (ARR-001). The results of this audit have already been communicated to you; hence, you have 10 calendar days after the receipt of this letter to respond to this ARR.

In accordance with §2.390, "Public inspections, exemptions, requests for withholding," of the *Code of Federal Regulations*, 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," a copy of this letter, and its enclosures will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agency wide Document Access and Management System, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

Serita Sanders, Project Manager
Division of New Reactor Licensing
Office of New Reactors

Project No. 0738

Enclosure:
As stated

cc w/encl.: See next page

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/RA/

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**U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NEW REACTORS**

Audit Report No: Progress Energy (PE) Shearon Harris Nuclear Plant (Harris):
PROJ0740-2007-001

Organizations: Progress Energy

Project Contacts: Robert Kitchen
Licensing Manager
Progress Energy
100 East Davie St
Raleigh, NC 27601

Nuclear Industry: Sargent & Lundy (S&L), Worley Parsons (WP), and CH2MHill (CH2M) are contracted by PE to supply the Harris combined license application (COLA) for submittal to the Nuclear Regulatory Commission (NRC). S&L, WP, and CH2M are engineering, environmental, and technical and management services firms providing a broad range of professional services to commercial and nuclear clients throughout the United States.

Audit Dates: October 29 – November 1, 2007

Auditors: Greg S. Galletti, Audit Team Leader, NRO/DCIP/CQVP
Kenneth Heck, Operations Engineer, NRO/DCIP/CQVP
Michael Morgan, Operations Engineer, NRO/DCIP/CQVP
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Justin Fuller, Senior Inspector, RII
S.K. Mitra, Project Manager, NRO/DNRL

Approved by: Juan Peralta, Chief
Quality and Vendor Branch 1
Division of Construction Inspection & Operational Programs
Office of New Reactors

ENCLOSURE

1.0 AUDIT SUMMARY

The purpose of this audit was to verify that quality assurance (QA) activities were adequately established, documented, and implemented to support the development of the Harris COLA.

The audit was conducted at the PE facility in Raleigh, North Carolina. The audit bases were:

- Appendix B, "QA Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Part 50 of Title 10 of the *Code of Federal Regulations* (Appendix B),
- Part 21, "Reporting of Defects and Noncompliance," of Title 10 of the *Code of Federal Regulations* (Part 21),
- Regulatory Guide 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)" (RG 1.206), and
- Part 50.9, "Completeness and accuracy of information," of Title 10 of the *Code of Federal Regulations* (Part 50.9).

During this audit, the NRC audit team identified several issues associated with the implementation of the Harris COLA development program that should be addressed by PE 10 calendar days after receipt of the audit report. These issues are described in this report and are combined into an audit response request discussed in Section 1.1 of this report (ARR-001).

1.1 AUDIT RESPONSE REQUESTS

As discussed in Section 3.12 of this report, PE performed an audit of CH2M to verify adequate implementation of the QA program requirements supporting the preparation of the Harris COLA. The PE audit identified a number of significant programmatic deficiencies with the CH2M QA program implementation including: (1) document control requirements; (2) training requirements; (3) translation of policies into work instructions; (4) implementation of procedural requirements, and (5) failure of management to prevent these deficiencies. These findings resulted in a stop-work order issued to CH2M, and the implementation of extensive corrective actions to the CH2M QA program.

During the NRC audit of the Harris COLA, the audit team identified several additional deficiencies regarding the implementation of the CH2M QA program supporting the Harris COLA. These deficiencies include the failure to: (1) develop adequate design control procedures reflective of the organizational structure of CH2M (Section 3.2); (2) adequately control the administrative preparation of geological/boring data (Section 3.4); (3) adequately control document revision status related to site field work procedures (Section 3.6); (4) programmatically specify what documents are to be controlled as QA records (Section 3.11); and (5) develop adequate qualification documentation and training records for specific disciplines involved in site work activities (Section 3.13).

These NRC-identified deficiencies combined with the previously identified deficiencies from the PE audits of CH2M indicate that significant programmatic issues continue to persist within the CH2M QA program. The NRC is concerned that these deficiencies may have impacted the completeness and accuracy of the information provided by CH2M in support of the Harris COLA.

The NRC requests that PE provide a detailed discussion that describes the actions taken to correct these noted deficiencies. This discussion should include the methods used to evaluate the adequacy of corrective actions implemented by CH2M and their impact on the accuracy and completeness of the Harris COLA. In responding to this request, PE should specifically describe the approach and basis relied on for concluding that the work performed by CH2M in support of the Harris COLA was adequately controlled and of sufficient quality for such safety-related activities. This request is identified as ARR-001.

2.0 STATUS OF PREVIOUS AUDITS

There were no previous NRC audits in support of the Harris COLA development.

3.0 AUDIT OBSERVATIONS AND OTHER COMMENTS

3.1 QA PROGRAMS

a. Audit Scope

The NRC audit team reviewed the QA program requirements and the implementation process for the Harris COLA activities. Specifically, the NRC audit team reviewed the QA program manuals that govern its implementation of quality activities performed for the Harris COLA activities by PE and its contractors.

b. Observations

The NRC audit team reviewed the PE and its contractors' policies governing QA programs to assure those policies provided an adequate description of the implementation requirements consistent with the applicable requirements of Appendix B.

(i) PE Quality Assurance Program

The PE Nuclear Generation Group Manual, NGGM-PM-0007, "Quality Assurance Program Manual," Revision 12, (NGGM-PM-0007), provides the basis for the control and performance of safety-related and quality-related activities associated with the development of the Harris COLA. The QA provisions in NGGM-PM-007 are based on the American National Standards Institute (ANSI) N45-series quality standards. The ANSI N45-series establish the essential requirements for compliance with Appendix B for contract oversight, design control, corrective actions, document control, and records management.

(ii) S&L Quality Assurance Program

The S&L topical report SL-TR-1A, "Nuclear Quality Assurance Program," Revision 19, dated March 2007 (SL-TR-1A), provides the basis for the control and performance of safety-related and quality-related activities associated with the development of the Harris COLA. The QA provisions in SL-TR-1A are compliant with the requirements of Appendix B and reflect the guidance of the American Society of Mechanical Engineers (ASME), "Quality Assurance Requirements for Nuclear Facility Applications," (NQA-1-1994) for contract oversight, design control, corrective actions, document control, and records management.

(iii) WP Quality Assurance Program Plan

WP was contracted by PE to prepare portions of the Harris COLA. The WP Nuclear Quality Manual, NQM-01, "Nuclear Quality Manual," Revision 6, (NQM-01), provides the basis for the control and performance of safety-related items and services associated with the development of the Harris COLA. The QA provisions in NQM-01 are compliant with the requirements of Appendix B and reflect the guidance of ASME NQA-1-1994 for contract oversight, design control, corrective actions, document control, and records management.

(iv) CH2M Engineering and Consulting Quality Assurance Program

PE subcontracted CH2M to provide geotechnical field investigation, laboratory testing, and engineering analyses associated with the characterization of the Harris site. PE qualified CH2M's QA program for the execution and delivery of geotechnical field investigation and laboratory testing. The CH2M Quality Manual, NBG-QA-02-00, "Nuclear Business Group Quality Manual," Revision 5, (NBG-QA-02-00) provides the basis for the control and performance of safety-related items and services associated with the development of the Harris COLA. The QA provisions in NBG-QA-02-00 are compliant with the requirements of Appendix B and the guidance of ASME NQA-1-1994.

c. Conclusions

The NRC audit team concluded that the QA program requirements for quality activities in support of the Harris COLA were consistent with the requirements of Appendix B. The NRC audit team also concluded that the applicant's and/or its sub-suppliers' QA program requirements were appropriately translated into implementing procedures to support the development of the Harris COLA. The NRC audit team did not identify any issues in this area requiring additional actions.

3.2 DESIGN CONTROL

a. Audit Scope

The NRC audit team reviewed the implementation of the PE design control processes for the Harris COLA. Specifically, the NRC audit team reviewed the policies and procedures governing the implementation of PE design control processes and a representative sample of engineering calculation packages.

b. Observations

The NRC audit team reviewed the PE and contractor policies and procedures governing the design process to assure those guidelines provided an adequate description of its implementation consistent with the requirements of Criterion III, "Design Control," of Appendix B.

b.1 Design Control Policies and Procedures

In addition to QA manuals identified in Section 3.1.b, the following additional documents associated with the Harris COLA design control process were reviewed:

- CH2M procedure NBG-QA-03-01; "Design Control," Revision 6.

- S&L Standard Operating Procedure (SOP) SOP 0403, "Control of Design Input," Revision 5.
- WP Nuclear Engineering Procedure (NEP) NEP-01, "Design Criteria/Input," Revision 6.

NGGM-PM-0007 provides PE's methodology for coordinating review, comment, and approval of documents associated with the development of the Harris COLA. Specific requirements governing design input, including site data and calculations, verification, preparation, revision, and retention of design documentation are included.

NQM-01, Section 3.0, provides WP's program direction for the preparation of design inputs, including calculations, and procedural/policy guidance for overall preparation, documentation, revision, and retention of design documentation. NEP-01 addresses development, maintenance, and distribution of design input information that is required to perform engineering design or design modifications for structures, systems, or components (SSC).

SOP 0403 provides S&L's QA process requirements for the control of design input and subsequent revisions. Additional requirements pertaining to nuclear project design input and verification are found in SL-TR-1A, Section 3.0, "Design Control."

NBG-QA-02-00 establishes CH2M's control measures, requirements and responsibilities to ensure applicable design requirements including design basis, statutory or regulatory requirements, applicable codes and standards are correctly translated into the design activities. These specific design activities include design input and output, configuration and design changes, documentation and technical interfaces.

NBG-QA-03-01 provides further and specific guidance to CH2M's engineering calculation package preparers on the process for design control. This procedure was revised in response to significant programmatic deficiencies identified during PE's audit of CH2M. The details of this audit are discussed in more detail in Section 3.11 of this report. However, the NRC audit team observed that the context of this revision included text directly from NQA-1-1994 without proper consideration of the organizational structure of CH2M. Specifically, the revised procedure referenced a "Design Manager," "Project Assistant" and "Project CADD Coordinator" which are positions that do not exist within the CH2M organization. Therefore, the guidance described in NBG-QA-03-01 cannot be implemented as written and is a programmatic deficiency of the CH2M QA program. This is identified as an example of the programmatic deficiencies identified in ARR-001 discussed in Section 1.1 of this report.

b.2 Implementation of Design Controls

The following engineering calculation packages associated with preparation of the Harris COLA were reviewed:

- CH2M Request for Information (RFI) RFI-234, "Lake Levels During a Drought Without Make-up Water," Revision 0, dated August 2007.
- S&L/PE Project Energy Carolina (PEC) document PEC-003, "Harris Lake – Average Annual Flow into Thomas Creek Finger & Volume Between 220.3' – 240' in Thomas Creek Finger of the Lake," Revision 0, dated April 2007.

- S&L/PE PEC-004, "Lake Levels During a Drought Without Make-up Water," Revision 0, dated March 2007.
- WP Design Information Transmittal (DIT) WP-007, "Final Water Usage," Revision 1, dated March 2007.
- WP DIT WP-008; "Final Safety Analysis Report (FSAR) Chapter 2.4.13 - Groundwater," Revision 1, dated July 2007.
- WP DIT WP-009, "Revised Final Water Usage," Revision 0, dated April 2007.

For each of these calculation packages, the audit team verified that the bases, assumptions, and methodology for the associated calculation(s) were adequately described. The NRC audit team verified that the calculation packages were prepared in accordance with the applicable design control procedures.

c. Conclusions

Except for the issue identified in 3.2.b.1, the NRC audit team concluded that the design control process requirements were appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as required by the applicant's and its sub-supplier's procedures to support the Harris COLA development program. However, the NRC audit team did identify an example of a programmatic deficiency requiring additional action.

3.3 PROCUREMENT DOCUMENT CONTROL

a. Audit Scope

The NRC audit team reviewed the implementation of PE procurement document control processes for the development of the Harris COLA. Specifically, the NRC audit team reviewed the policies and procedures governing the implementation of PE procurement document control processes and a representative sample of procurement records.

b. Observations

The NRC audit team reviewed the PE and its contractors' policies and procedures governing the procurement document control processes to assure those guidelines provided an adequate description of the process and implementation consistent with the requirements of Criterion IV, "Procurement Document Control," of Appendix B.

b.1 Policies and Procedures for Procurement Document Control

PE's requirements for controlling activities and documents associated with procurement are established in the NGGM-PM-007. These requirements for procurement include document content, review, vendor selection and qualification, and surveillances. Procurement requirements are implemented through MCP-NGGC-001, "NGG Contract Initiation, Development and Administration," Revision 11, which provides instructions for the initiation, development, and administration of contracts.

For safety-related items and services procured for the Harris COLA, the PE contract specifies compliance with Part 21, Appendix B and associated standards endorsed by the NRC. All safety-related items and services contracted by PE were procured through CH2M. The CH2M "Project Plan for Progress Energy COLA," Revision 4, dated September 2007, describes the CH2M's procurement policy. All work subcontracted by CH2M is reviewed and approved by PE.

CH2M's procedure NBG-QA-04-01, "Procurement Document Control," Revision 4, dated April 30, 2007 provides guidance for the preparation, review, approval and issue of procurement documents for quality related services. Procurement documents provide provisions for defining the scope of work, technical and quality requirements, right of access, documentation requirements, and the reporting of nonconformance. Procurement documents and any subsequent revisions are reviewed by originating engineer(s), the contractor administrator, and the project QA manger to assure that compliance with applicable requirements.

b.2 Implementation of Procurement Document Control

The NRC audit team reviewed the following procurement documents associated with the development of the Harris COLA:

PE Master Contract Number 255934

The NRC audit team reviewed the original master contract as well as all amendments through January 23, 2007. The NRC audit team determined that the original master contract and all amendments conformed to PE's procedural requirements. The master contract required implementation of QA programs conforming to the requirements of Appendix B and Part 21, with the requirement to report nonconformance items to PE. In addition to the review of the documentation, the NRC audit team interviewed PE procurement personnel with regards to contracts and supplier qualifications. The NRC audit team reviewed qualification audits for the three contractors. The qualification audits were determined to be complete and adequate for the scope of work authorized by the contracts.

CH2M PO Number 914052

CH2M administered all subcontracted safety-related site activities. Laboratory analysis of soil and rock samples were awarded to Safety & Material Engineering Inc. (S&ME) under CH2M PO number 914052 on the basis of a qualification audit of S&ME facilities on March 2, 2007. S&ME performed laboratory analysis of soil and rock samples under the requirements of its own QA program. CH2M PO Number 914052 imposes regulatory requirements, including the provisions of Appendix B, Part 21 and other provisions similar to those discussed for the PE master contract. Based on its review of contract documents, the NRC audit team determined the contract provisions to be complete and adequate for the scope of work authorized.

c. Conclusions

The NRC audit team concluded that procurement document control requirements were appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as required by the applicant's procedures to support the Harris COLA development program. The NRC audit team did not identify any issues in this area requiring additional actions.

3.4 DOCUMENT CONTROL

a. Audit Scope

The NRC audit team reviewed the implementation of PE document control processes for the development of the Harris COLA. Specifically, the NRC audit team reviewed the policies and procedures governing the implementation of the PE document control process to verify the overall extent and effectiveness of the program.

b. Observations

The NRC audit team reviewed the PE and contractor policies and procedures governing the document control processes to assure those guidelines provided an adequate description of its implementation consistent with the requirements of Criterion VI, "Document Control," of Appendix B.

b.1 Policies and Procedures

In addition to the QA manuals identified in Section 3.1.b, the following document control policies and procedures associated with preparation of the Harris COLA were reviewed:

- CH2M No. 338884-QAPP-001, "QA Project Plan for Progress Energy Combined License Applications," Revision 4, dated September 25, 2007.
- CH2M No. 338884-PI-03-02, "Project Instruction for Design Information Transmittal Process," Revision 1, Dated September 28, 2007.
- CH2M No. 338884-PI-03-08, "Control of Documents," Revision 1, dated September 28, 2007.
- CH2M No. 338884-PI-03-12, "Project Instruction for Measurement and Test Equipment," Revision 0, dated August 6, 2007.
- PE NGGS-NPD-0001, "Process for Document Reviews and Affirmation," Revision 0.
- PE NGGS-NPD-0002, "Change Control for COL Application Information," Revision 0.
- PE NGGS-PRO-0003, "Nuclear Plant Development Information Exchange," Revision 0.
- PE NGGS-PRO-0001, "NGGS Procedure Review & Approval Process," Revision 7.
- S&L PWP-1194, "Project Work Plan," Revision 9, dated September 28, 2007.
- S&L SOP 0204, "Computer Software Quality Policies & Requirements," Revision 7A, dated September 31, 2004.
- S&L SOP-0301, "Contracts," Revision 9, dated August 30, 2006.

- S&L SOP-0402, "Preparation, Review, and Approval of Design Calculations," Revision 7A, dated August 15, 2006.
- S&L SOP-0403, "Control of Design Inputs," Revision 5 dated January 8, 2007.
- S&L SOP-0404, "Design Reviews," Revision 3A, dated December 5, 2005.
- WP/PE COLA-1-HB-013-0001, "Project Quality Plan for COLA-Progress Energy," Revision 4, dated June 6, 2007.
- WP NEP-01, "Design Certification," Revision 1, dated December 28, 2005.
- WP PI-PE-002, "Project Instruction for Project no. 11940-011, 11945-011," Revision 2, dated October 17, 2007.

The QA program descriptions and implementing procedures of PE and its contractors' were reviewed by the NRC audit team and found to provide adequate implementation guidance consistent with PE's QA program requirements.

b.2 Implementation of Document Control Programs

The NRC audit team reviewed a representative sample of QA documents to verify that implementation of the review, approval, issuance, and revision process were consistent with applicable QA guidance. Although the document control systems of PE and its contractors are different, all documents are electronically controlled and are transmitted using a "read only" format. Documents and their revisions are electronically distributed, with electronic acknowledgment of the recipient.

The electronic document systems of PE and its contractors' were verified by the NRC audit team through objective evidence of system outputs. The following types of documents were reviewed: design input, design data, audit reports, corrective actions, design calculation, contract documents, purchase orders and vendor supplied documents. The NRC audit team reviewed the stated scope of the documents, verified that revisions were reviewed and approved by the originating organization, distributed to and acknowledged by those affected personnel, and that superseded documents were removed from the electronic database. Additionally, the NRC audit team reviewed the document exchange process between PE and its contractors. The following documents were reviewed:

- CH2M Engineering Design File (EDF) EDF No.338884-EDF-005, Revision A, dated June 15, 2007,
- S&L Software Verification & Validation Report Certification (SVVRC) for Slope Stability Analysis Program #03.7.747-5.11, "New Program for Engineering Application,"
- S&L SVVRC Certification for Culvert Design & Analysis Software Program # 03.7.71.3.3.0, Revision 0,
- S&L DIT No. PEC-001-01, "Revised Harris Lake- Elevation Area," and

- WP DIT describing Environmental Report Section 5.4 and validation package, Revision 0, dated October 4, 2007.

Examples of administrative deficiencies, such as incomplete, unclear, and inconsistent information were identified by the NRC audit team during the review of geological/boring data and were brought to the attention of PE project personnel. These administrative deficiencies were entered into the corrective action program as corrective action reports (CARs) 338884-CR-007-07, 338884-CR-009-07, and 338884-CR-012-07. At the conclusion of the NRC audit, these CAR items remained open. The failure of PE and CH2M to adequately control the preparation of geological/boring data is considered an example of the programmatic deficiency identified in ARR-001 discussed in Section 1.1 of this report.

c. Conclusions

Except for the issues identified in 3.4.b.2 (CAR 338884-CR-007-07, CAR 338884-CR-009-07, and CAR 338884-CR-012-07), the NRC audit team concluded that document control requirements were appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as required by the applicant's procedures to support the Harris COLA development program. However, the NRC audit team did identify examples of programmatic deficiencies requiring additional actions.

3.5 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

a. Audit Scope

The NRC audit team reviewed the implementation of the PE process for controlling purchased material, equipment, and services for the development of the Harris COLA. Specifically, the NRC audit team reviewed the policies and procedures associated with this process.

b. Observations

The NRC audit team reviewed the PE and contractor policies and procedures governing the process for controlling purchased material, equipment and services to assure those guidelines provided an adequate description of the process and implementation consistent with the requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B.

b.1 Policies and Procedures for Control of Purchased Material, Equipment, and Services

The NRC audit team reviewed CH2M's policies and procedures governing the control of activities at the proposed Harris COLA site. Section 7 of CH2M's NBG-QA-02-00 describes the controls for assuring that material, equipment, and services conform to specified requirements. Section 10 of CH2M's "Project Plan for Progress Energy's COLA" identifies NBG-QA-04-01 and NBG-QA-07-01, "Control of Purchased Items and Services," Revision 7, as the applicable implementing procedures.

NBG-QA-07-01 requires that procurement planning include the identification of the scope of work to be accomplished, the responsibilities for conduct of the activities, and a description of

the required actions necessary to accomplish those activities. Project planning integrates the following elements:

- Procurement document preparation, review and change control,
- Selection of procurement sources,
- Bid evaluation and award,
- Surveillance, inspection or audit activities
- Control of nonconformance,
- Corrective actions,
- Acceptance criteria for items or services, and
- QA records.

The NRC audit team verified that PE and its contractors adequately developed policies and procedures that described the requirements for the control of purchased materials, equipment, and services in accordance QA program requirements.

b.2 Review of Supplier Activities

Sixteen subcontractors performed services associated with the Harris COLA site characterization. Of these subcontractors, only S&ME performed laboratory analyses of soil and rock samples under the requirements of its own QA program. S&ME's QA program description was evaluated by CH2M prior to S&ME's performance of any laboratory analyses. The CH2M qualification audit of S&ME's QA program determined it to be compliant with Appendix B and effectively implemented for the specified scope of the contracted services.

Contracts for all sixteen contractors were reviewed by the NRC audit team and determined to conform to the requirements imposed through the Harris COLA Project Plan. The contracts reviewed were found to adequately specify the scope of work to be performed, technical and quality requirements, and contract deliverables. Contracting parties were required to develop technical procedures for the contracted tasks and document staff training of these procedures and applicable industry standards. Other contract provisions included requirements for calibration of measurement and testing equipment, controls for material handling, acquisition and reporting of data and project closure documentation. The NRC audit team determined that all contract provisions were adequately incorporated into the technical procedures.

Supplier evaluations for all contracts and contract revisions were performed by CH2M in accordance with the requirements of NBG-QA-07-02, "Supplier Quality Assurance Program Evaluation," Revision 4, dated September 30, 2007. All activities conducted on the Harris COLA site were conducted in accordance to the CH2M Field Work Plan and QA program under CH2M supervision. Typical contracted activities included land surveying, subsurface investigations, and geological and seismic studies.

c. Conclusions

The NRC audit team concluded that requirements for control of purchased material, equipment and service requirements were appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as required by the applicant's procedures to support the Harris COLA development program. The NRC audit team did not identify any issues in this area requiring additional actions.

3.6 TEST CONTROL

a. Audit Scope

The NRC audit team reviewed the implementation of the test control requirements for Harris COLA activities. Specifically, the NRC audit team reviewed the policies and procedures governing the process and the quality of testing records associated with the development of the Harris COLA.

b. Observations

The NRC audit team reviewed the PE and contractor policies and procedures governing the test control processes to assure those guidelines provided an adequate description of the process and implementation consistent with requirements of Criterion XI, "Test Control," of Appendix B

b.1 Policies and Procedures for Test Control

CH2M's 338884-QAPP-001, Chapter 14 "Test Control," Revision 3, and NBG-QA-11-01, "Test Control," Revision 5, describe the measures for controlling tests performed on materials and equipment and test conformance requirements. These QA program requirements were implemented through the Harris COLA Site Investigation Work Plan, Revision 3. The test control program descriptions and implementing procedures of PE and its contractors' were reviewed and found to be consistent with the applicant's QA program requirements.

b.2 Implementation of Sub-Supplier Programs for Test Control

The NRC audit team reviewed a sample of testing procedures used for the collection of geotechnical data. These testing procedures were included as attachments in the Harris COLA Site Specific Work Plan, Revision 3. Below is a list of the test procedures reviewed:

- OYO P-S Suspension Seismic Velocity Logging; Revision 1.31
- Down-hole Seismic Velocity Logging Procedure Revision 1.1
- ROCTEST TELEMAC Instruction Manual for Model PROBEX-1
- Hi-RAT Field Procedure, Revision 1.0

The NRC audit team noted that different procedure revisions were identified in the final report than what was prescribed in the Harris COLA Site Investigation Work Plan. The OYO P-S Suspension Seismic Velocity Logging procedure was revision 1.31 in the final report and revision 1.2 in the work plan. The Down-hole Seismic Velocity Logging Procedure was Revision 1.1 in the final report and revision 1.0 in the work plan. At the time of the NRC audit, neither PE nor CH2M were aware of this discrepancy. This issue was immediately entered into PE's corrective action program as CAR 338884-CR-011-07. At the conclusion of the NRC audit, this CAR item remained open. The failure of PE and CH2M to adequately control document revision status is considered an example of the programmatic deficiency identified in ARR-001 described in Section 1.1 of this report.

The NRC audit team also determined that there was no formal QA review completed of the Harris COLA Site Investigation Work Plan. Additionally, it was noted that technical procedures used by two subcontractors, for rock pressure meter testing and suspension logging, did not clearly specify training and qualification requirements for the test operators. These deficiencies

were entered into PE's corrective action program as CAR 338884-CR-010-07. At the conclusion of the NRC audit, this CAR item remained open. The failure of PE and CH2M to perform a formal QA review of the completed Harris COLA Site Investigation Work Plan is considered an example of the programmatic deficiency identified in ARR-001 described in Section 1.1 of this report.

The NRC audit team also reviewed the completed test records to verify that the final test reports were complete, accurate and properly documented the results of the on-site work activities. Below is a list of the test records reviewed:

- BPA-47 Boring Geophysics Field Log Summary
- BPA-47 Acoustic Televiewer Field Log
- BPA-47 Suspension Velocity Field Log
- BPA-48 Boring Geophysics Field Log Summary
- BPA-48 Acoustic Televiewer Field Log
- BPA-48 Suspension Velocity Field Log

c. Conclusions

Except for the issues identified in 3.6.b.2 (CAR 338884-CR-011-07, CAR 338884-CR-010-07), the NRC audit team concluded that test control requirements were appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as required by the applicant's and sub-supplier's procedures to support the Harris COLA development program. However, the NRC audit team did identify several examples of programmatic deficiencies requiring additional actions.

3.7 CONTROL OF MEASURING AND TEST EQUIPMENT

a. Audit Scope

The NRC audit team reviewed the implementation of the PE process for control of measuring and test equipment for the Harris COLA. Specifically, the NRC audit team reviewed the policies and procedures governing the PE process for control of measuring and test equipment and a representative sample of calibration records.

b. Observations

The NRC audit team reviewed the PE and contractor policies and procedures governing the process for controlling measuring and test equipment to assure those guidelines provided an adequate description of the process and implementation consistent with the requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B.

b.1 Policies and Procedures for Control of Measuring and Test Equipment

In addition to the QA manuals identified in Section 3.1.b, the NRC audit team reviewed the following policies and procedures associated with the control of measuring and test equipment:

- CH2M 33884-QAPP-001, Chapter 15, "Control of Measuring and Test Equipment," Revision 4.

- CH2M NBG-QA-12-01, "Control of Measuring and Test Equipment," Revisions 2 and 5.
- Harris Site investigation Work Plan, Revisions 3 and 5.
- Project Instruction 338884-PI-03-12, "Measuring and Test Equipment," Revision 0.

The NRC audit team verified that procedures used for laboratory or field testing equipment required the use of calibrated tools, gages, instruments, and other measuring and test equipment. Additionally, the NRC audit team verified that the measuring and test equipment procedures provided requirements for both the calibration of the equipment to nationally recognized standards as well as the control and disposition of out-of-calibration equipment.

b.2 Implementation of Sub-Supplier Programs for Control of Measuring and Test Equipment

The NRC audit team reviewed a representative sample of calibration records to verify compliance with the requirements of the measuring and test equipment procedures and effective implementation of those requirements. Below is a list of the calibration records reviewed:

- Suspension Seismic Velocity Logger
- Seismograph
- Dynamic Signal Analyzer
- Rock Pressure meter Test Device
- Topcon Transit and Level Clinic

The NRC audit team found no discrepancies in the calibration records reviewed and determined that they had been completed in compliance with applicable procedures.

c. Conclusions

The NRC audit team concluded that the measuring and test equipment requirements were appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as required by the applicant's and sub-supplier's procedures to support the Harris COLA development program. No issues were identified in this area which require additional action by the applicant prior to submittal of the Harris COLA.

3.8 HANDLING, STORAGE, AND SHIPPING

a. Audit Scope

The NRC audit team reviewed the implementation of the process for handling, storage, and shipping of soil samples during Harris COLA site activities. Specifically, the NRC audit team reviewed the policies and procedures governing the handling, storage, and shipment of samples and a representative sample of soil sample records.

b. Observations

The NRC audit team reviewed the PE and contractor policies and procedures governing the handling, storage, and shipping processes to assure those guidelines provided an adequate description of the process and implementation consistent with the requirements of Criterion XIII, "Handling, Storage and Shipping," of Appendix B.

b.1 Policies and Procedures for Handling, Storage, and Shipping

Program requirements are implemented by CH2M's NBG-QA-13-01, "Handling, Storage, and Shipping," Revision 2, as implemented through QA Project Plan, Chapter 16. Applicable site activities are controlled through the Harris Site Work Plan, Revision 3. All handling, storage and shipping requirements for soil samples are provided in the Harris Site Work Plan section 2.2.4, "Sample Handling, Storage, and Transfer," Appendix B-2, "Logging, Preserving, and Transporting of Soil and Rock Samples, and Appendix B-3, "Sample Storage and Custody."

The NRC audit team verified that instructions for marking, labeling, packaging, handling, and storage of soil and rock samples were adequate to identify, maintain, and preserve the samples supporting data relative to the Harris COLA site. The NRC audit team also verified that special protective measures were appropriately specified for the storage and transportation of soils and rock samples.

b.2 Implementation of Sub-Supplier Procedures for Handling, Storage, and Shipping

The NRC audit team reviewed a representative sample of soil and rock sample records to verify that handling, storage, and shipping program requirements specified in the Harris Site Investigation Work Plan were properly implemented. The specific records reviewed include soil and rock boring logs, daily inspection diaries, and sample storage check in/out logs.

The NRC audit team reviewed the NRC's letter dated June 27, 2006 which detailed the results of a site visit conducted by NRC Region II and NRR personnel. This letter noted that the NRC site visit team identified three Shelby tube samples, which were not properly logged in accordance with the Harris Site Investigation Work Plan. The NRC audit team reviewed CAR PES CA002, dated 5/18/2006, which documented this issue. CAR PES CA002 adequately described the NRC's observation and the applicant's corrective actions.

c. Conclusions

The NRC audit team concluded that handling, storage, and shipping requirements were appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as required by project procedures. No issues were identified in this area, which require additional action by the applicant prior to submittal of the Harris COLA.

3.9 NONCONFORMING MATERIALS, PARTS, COMPONENTS OR SERVICES

a. Audit Scope

The NRC audit team reviewed the implementation of processes for controlling nonconforming materials, parts, components and services associated with the development of the Harris COLA. Specifically, the NRC audit team reviewed the policies and procedures governing nonconforming materials, parts, components or services and a representative sample of CARs.

b. Observations

The NRC audit team reviewed the PE and contractor policies and procedures governing the processes for nonconforming items to assure those guidelines provided an adequate description of the process and implementation consistent with the requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," of Appendix B.

b.1 Policies and Procedures for Nonconforming Materials, Parts, Components or Services

In addition to the QA manuals identified in Section 3.1.b, the following documents associated with nonconforming items were reviewed:

- S&L document SOP-1405; "10 CFR 21 Defects, Non-Compliances, and Reportable Conditions," Revision 4 (SOP-1405), and
- CH2M NBG-QA-15-01; "Control of Nonconforming Material," Revision 4.

NGGM-PM-007 requires that non-conformances reported by a supplier are evaluated by the individual/group within the PE organization that is responsible for that requirement. Written approval of a supplier's disposition or an alternate PE disposition shall be provided to the supplier and retained as a QA record.

NQM-01 requires that items that do not conform to specified requirements be identified and controlled to prevent inadvertent installation or use. WP procedures include provisions to identify, document, segregate, review, disposition, and notify organizations affected by the nonconforming items.

SOP-1405 describes the process for identifying non-complying items subject to Part 21 notification requirements and the Part 21 reporting process.

NBG-QA-15-01 establishes a process to identify, document, review, and disposition nonconforming material or items discovered during the performance of onsite work, operations, inspections, maintenance, and /or test activities.

These QA program descriptions and implementing procedures of PE and its contractors were reviewed by the audit team and found to provide adequate implementation guidance consistent with the applicant's QA program requirements.

b.2 Review of Nonconforming Deficiencies

The NRC audit team reviewed a representative sample of nonconformance deficiency reports. The following CARs identify deficiencies and non-compliance issues that were reviewed:

- CH2M CAR 324884-CAR-013-07; "PE Audit No. 126402-04, Deficiency No. 17," dated March 2007
- S&L CAR PIP #2006-0402; "Inaccurate Building Dimensions on Site GA," Dated April 2006

- WP CAR #N2007-20; “Non-Compliance with NQM-1,” “NQA Manual Document Control Requirements,” Revision 6, dated May 2007

The NRC audit team verified that the CARs adequately documented each discrepancy, identified the proposed corrective action, and the completion status of each nonconformance item in accordance with QA program requirements.

c. Conclusions

The NRC audit team concluded that requirements for control of nonconforming material, parts, components or services requirements were appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as required by the applicant’s procedures to support the Harris COLA. No issues were identified in this area which require additional actions.

3.10 CORRECTIVE ACTIONS

a. Audit Scope

The NRC audit team reviewed the corrective action process and implementation associated with the development of the Harris COLA. Specifically, the NRC audit team reviewed the policies and procedures governing corrective action reporting and a representative sample of CARs.

b. Observations

The NRC audit team reviewed the PE and contractor policies and procedures governing corrective action to assure those guidelines provided an adequate description of the process and implementation consistent with the requirements of Criterion XVI, “Corrective Actions,” of Appendix B.

b.1 Policies and Procedures for Corrective Action

In addition to the QA manuals identified in Section 3.1.b, the following documents associated with corrective action reporting were reviewed:

- PE CAP-NGGC-0200, “Corrective Action Program,” Revision 19,
- WP NOM-08, “Corrective Action Program,” Revision 2,
- S&L SOP-1401; “Performance Improvement Process,” Revision 8A, and
- CH2M NBG-QA-16-01, “Condition Reporting and Resolution,” Revision 4.

These QA program descriptions and implementing procedures were reviewed by the NRC audit team and found to provide adequate implementation guidance consistent with the applicant’s QA program requirements.

b.2 Implementation of Corrective Action Program

The NRC audit team reviewed a representative sample of CARs associated with the development of the Harris COLA including:

- PE #AR00224047, "NPD Vendor Audit Findings (SL)"; Dated February 2007.
- S&L PIP #2007-0032, "Calculation Reviewer RS Qualification," Dated January 2007.
- S&L PIP #2007-0190, "Project Work Plan Discrepancy," Dated February 2007.
- WP CAR #N2006-10-01, "RFI Process Not Addressed In PQP," Dated July 2006.
- WP CAR #N2006-49, "Indoctrination Issues/Indoctrination Documentation Issues on Projects," Dated October 2006.
- CH2M CAR #338884-CAR-078-07, "Internal Audit Finding 3: Organization," dated September 2007.

The NRC audit team verified that: (1) the CARs adequately documented the deficiencies and proposed corrective actions; (2) the corrective actions taken appropriately addressed identified deficiencies; and (3) the rationale for closure of a condition report, including objective evidence and verification of actions taken, was adequately documented.

c. Conclusions

The NRC audit team concluded that requirements for corrective action were appropriately translated into implementing procedures and, for those CAR documents reviewed by the NRC audit team, implemented as required by the applicant's procedures to support the Harris COLA. No issues were identified in this area which require additional actions.

3.11 QA RECORDS

a. Audit Scope

The NRC audit team reviewed the QA program record controls to verify that the QA program provides for the preparation of sufficient records to furnish documentary evidence of activities affecting quality for the development of the Harris COLA. Specifically, the NRC audit team reviewed a representative sample of QA records to verify compliance with program requirements and assurance that these requirements were being effectively implemented.

b. Observations

The NRC audit team reviewed the PE and contractor policies and procedures governing the processes for QA record control to assure those guidelines provided an adequate description of the process and implementation consistent with the requirements of Criterion XVII, "Quality Assurance Records," of Appendix B.

b.1 Policies and Procedures for QA Records

In addition to the QA manuals identified in Section 3.1.b, the following documents associated with control of QA records were reviewed:

- PE RDC-NGG-0001, NGG Standard Records Management Program, Revision 17,
- S&L SOP-1602, "Records Control," Revision 10B, dated February 5, 2007,
- S&L SOP -0505, "Control of Safeguards Information For Nuclear Facilities," Revision 8A dated October 19, 2005,
- WP NOM-05, "Nuclear Records Management," Revision 5, dated July 6, 2007,
- WP PECOLA-1-HB-013-0004, "Document Storage," Revision 0,
- WP PECOLA-1HB-013-0001, "Project Quality Plan," Revision 4 dated June 6, 2007,
- CH2M NBG-QA-17-01, "Records Management," Revision 6, dated September 29, 2007,
- CH2M Document No. NBG-QA-17-01, "Records Management", Revision 6 dated 09/29/07.

These QA program descriptions and implementing procedures were reviewed by the NRC audit team and found to provide adequate implementation guidance consistent with the applicant's QA program requirements.

b.2 Review of QA Records

The NRC audit team selected a sample of Harris COLA records to verify that procedural requirements were adequately implemented. The sample included records for: (1) the Project Planning Document, including Project Instructions for the principal contractors; (2) Audits Reports and Surveillances; (3) Design Information Transmittal records; (4) Corrective Actions records; (5) Procurement Document records; (6) Computer Software Development, Acquisition, Verification and Validation records; (7) Training and Qualification records; (8) Measurement & Test Equipment logs; and (9) Geologic Boring data.

Project QA managers for PE and its contractors were interviewed with regard to their processes for the collection, storage, and maintenance of QA records. Although the NRC audit team verified that most records sampled were developed and controlled in accordance with the applicable program guidance, the team did identify an area of concern regarding the records generated by CH2M and its subcontractors. Specifically, the NRC audit team identified that CH2M's QA record program did not specify what documents were to be controlled as QA records. PE immediately entered this issue into its corrective action program as CAR 338884-CR-014-07. At the conclusion of the NRC audit, this CAR remained open. The failure by CH2M to specify what documents were to be controlled as QA records is identified as an example of the programmatic deficiency identified in ARR-001 described in Section 1.1 of this report.

c. Conclusions

Except for the issue identified in 3.11.b.2 (CAR 338884-CR-014-07), the NRC audit team concluded that the QA record control requirements were appropriately translated into implementing procedures and, for those activities reviewed by the audit team, implemented as required by the applicant's procedures to support the Harris COLA. However, the NRC audit team did identify an example of a programmatic deficiency requiring additional actions.

3.12 AUDITS

a. Audit Scope

The NRC audit team reviewed a representative sample of external and internal audits conducted by PE and its contractors to determine the effectiveness of the audit process and timely completion of audits. These audits were reviewed for any impact they may have on the results of the Harris COLA. Corrective actions to resolve deficiencies identified by the audits were reviewed for reasonableness and timely resolution.

b. Observations

The NRC audit team reviewed the PE and contractor policies and procedures governing the audit processes to ensure those guidelines provided an adequate description of the process and implementation consistent with the requirements of Criterion XVIII, "Audits," of Appendix B.

b.1 Audit Policies and Procedures

In addition to the QA manuals identified in Section 3.1.b, the following documents associated with control of audit processes were reviewed:

- PE NGGM-PM-0030, "Quality Assurance Plan for New Nuclear Plant Development and Construction Activities," Revision 0.
- PE REG-NGGC-0004, "Assessment Process," Revision 10.
- PE NUA-NGGC-1511, "Assessment and Independent Review Personnel Training and Development, Qualification, and Certification Program," Revision 0.
- PE REG-NGGC-0011, "Performance Evaluation Support Conduct of Operations," Revision 3.
- PE MCP-NGGC-0406, "Supplier Qualification, Surveillance, and Audits," Revision 10.
- WP PECOLA-1-HB-013-0001, "Project Quality Plan," Revision 6.
- WP NQP-01, "Nuclear Quality Audits and Surveillance," Revision 5.
- WP NQP-02, "Certification of Nuclear Quality Auditors," Revision 4.
- WP NOM-04, "Management Review of the Nuclear Quality Assurance Program," Revision 3.

- S&L Project Manual, "COL Application Preparation for Shearon Harris Nuclear Power Plant Units 2 and 3 Progress Energy," Revision 1.
- CH2M "Quality Assurance Project Plan for Progress Energy Combined License Applications," Revision 4.
- CH2M NBG-QA-18-01, "Audit Program," Revision 5.

These QA program descriptions and implementing procedures of PE and its contractors were reviewed by the NRC audit team and found to provide adequate implementation guidance consistent with the applicant's QA program requirements.

b.2 Review of Audit Activities

The NRC audit team selected a representative sample of audits performed during the preparation of the Harris COLA. Both external and internal audits were reviewed, including:

- PE audit of S&L conducted February 19–22, 2007, to evaluate and verify implementation and effectiveness of the quality program and project controls;
- PE audit of CH2M, Idaho Falls conducted March 5–9, 2007, to evaluate the adequacy and implementation of the CH2M QAP for providing engineering and consulting services;
- S&L internal audits 2006-034 and 2007-039 performed to ensure adequate implementation of S&L requirements for COLA activities;
- WP internal audits/surveillance performed from July 2006 through May 2007 to evaluate and verify implementation and effectiveness of the quality program and project controls related to the Harris COLA development process; and
- CH2M internal audits performed from September 24-26, 2007 to review the Nuclear Business Group QA Program.

The NRC audit team noted that these audits identified a number of issues, including findings in the areas of: (1) document control requirements; (2) training requirements; (3) translation of policies into work instructions; (4) implementation of procedural requirements; and (5) failure of management to prevent these deficiencies. The NRC audit team reviewed the resolution of these findings and found them to be reasonable and timely. With exception of the recent CH2M internal audits, all findings had been closed at the time of the NRC audit.

As a result of significant programmatic deficiencies identified during the PE audit of CH2M in March 2007, PE issued a stop work order. In response, CH2M developed a recovery plan (338884-PLN-001), dated March 23, 2007, which identifies several corrective actions documented in a CH2M Common Cause Report, dated April 17, 2007. The Common Cause Report identified major causal factors, including management, human performance, communication issues, and training deficiencies. The NRC audit team reviewed a representative sample of CARs and procedural revisions, which correspond to the CH2M findings, and found them to be satisfactory.

The NRC audit team reviewed a sample of qualification records for Lead Auditors, and identified a qualification deficiency for several Lead Auditors. Specifically, these Lead Auditors did not meet the CH2M programmatic requirement for performing five audits within the last three-year period. Although the CH2M qualification records indicated that these individuals had performed five audits; the date of performance was at least three years beyond the Lead Auditor certification date. PE acknowledged that they had previously identified this issue during an audit of CH2M. The NRC team reviewed the corrective action report associated with this issue and determined that the corrective actions taken by PE and CH2M were effective in correcting the identified deficiency.

c. Conclusion

The NRC audit team concluded that audit control requirements were appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as required by the applicant's procedures to support the Harris COLA. No issues were identified in this area which require additional actions.

3.13 Training and Qualification

a. Audit Scope

The NRC audit team reviewed the PE and its contractors QA programs to verify that they provided for indoctrination and training of personnel performing activities affecting quality to assure that proficiency was achieved and maintained. Specifically, a representative sample of training records were reviewed to verify compliance with program requirements and to assure that these requirements were being effectively implemented.

b. Observations

The NRC audit team reviewed the PE and contractor policies and procedures governing the training and qualification of PE and contractor personnel performing quality activities to assure those guidelines provided an adequate description of the process and implementation consistent with the requirements of Criterion II, "Quality Assurance Program," of Appendix B.

b.1 Policies and Procedures for Training and Qualification

In addition to the QA manuals identified in Section 3.1.b, the following documents associated with QA indoctrination, qualification, and the certification of project personnel were reviewed:

- PE TRN-NGGC-0008, "Conduct of On-the-Job Training and Task Performance Evaluation", Revision 4.
- PE TRN-NGGC-0007, "Engineering Support Personnel Training/ Qualification Program and Common Qualification Process," Revision 4.
- PE TRN-NGGC-0012, "Project Manager Qualification Program," Revision 0.
- PE MCP-NGCC-0409, "Access Authorization/Fitness for Duty NEI Audit Participation and Lead Auditor Certification," Revision 2.

- S&L SOP-1803 Revision 4, Dated February 6, 2007.
- S&L SOP-1801 Revision 5B, Dated January 8, 2007.
- WP NOM-02 Revision 2, Dated October 12, 2006.
- WP NQP-02 Revision 2, Dated March 22, 2007.
- CH2M NBG-QA-18-01 Revision 5, dated October 3, 2007.

These QA program descriptions and implementing procedures of PE and its contractors were reviewed by the NRC audit team and found to provide adequate implementation guidance consistent with the applicant's QA program requirements.

b.2 Review of Training Activities and Records

The NRC audit team reviewed a sample of training and qualification records for PE and its contractors to verify that individuals were qualified to perform safety related work and that training records were maintained and retained in accordance with project procedures. Records reviewed included QA briefing agendas, checklists, resumes, projected procedures, update memos; procedure update presentations, personnel training records, and personnel attendance certifications.

The NRC audit team identified several deficiencies in the CH2M training and qualification program. Specifically, the CH2M QA program did not contain adequate qualification and training records for personnel qualified as "Calibration Personnel", "Geologists", "Field Engineers", and "Software Verifiers." The NRC audit team identified that there was no apparent training program established for qualifying personnel to perform calibration of measuring and test equipment, nor were there any on-the-job training records that would indicate that personnel were qualified to perform the calibration activity. Additionally, the quality records for the positions of "Geologist", "Field Engineer", and "Software Verifier," consisted only of resumes and a training log indicating attendance at an indoctrination session on CH2M QA programs. The NRC audit team was unable to identify specific qualification records for individuals classified under these job titles. The failure of CH2M to develop adequate qualification and training records are considered examples of the programmatic deficiencies identified in ARR-001 described in Section 1.1 of this report.

c. Conclusions

Except for the issues identified in 3.13.b.2, the NRC audit team concluded that the training and qualification requirements were appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as required by the applicant's procedures to support the Harris COLA. However, the NRC audit team did identify several examples of programmatic deficiencies requiring additional actions.

3.14 10 CFR PART 21 IMPLEMENTATION

a. Audit Scope

The NRC audit team reviewed the process for implementing Part 21 regulations for reporting defects and noncompliance. These reviews were performed to verify that requirements for quality-related activities, consistent with Part 21, were being adequately implemented.

b. Observations

b.1 Contractual Imposition of Part 21 Requirements

PE master contract No. 255934 imposes Part 21 requirements on the contractors responsible for development of the Harris COLA. These requirements are incorporated in provisions of the master contract, and must be passed on by the contractors to any sub-contractors.

b.2 Policies and Procedures for Part 21 Implementation

The NRC audit team reviewed procedures used by PE and its contractors for evaluating and reporting defects and noncompliance in accordance with Part 21. PE procedure REG-NGGC-0013, Revision 1, establishes the methods to ensure that potential deviations or failures to comply, as defined in Part 21, are evaluated for potential substantial safety hazards and that notification and reporting to the NRC are made pursuant to the requirements of Part 21.

PE personnel are responsible for reporting potential defects, failures to comply, and/or deviations they discover to their supervisors and documenting these occurrences on a condition report. Condition reports are also generated for potentially reportable conditions when they are discovered through external correspondence or generic information that may apply to PE licensees. Activities involved in evaluating conditions for Part 21 reporting include: (1) screening to determine if a deviation or failure to comply exists; (2) evaluating to determine if the condition could cause a substantial safety hazard; and (3) determining the appropriate reporting activities. The responsibilities of processing potentially reportable conditions are defined for directors and responsible officers that are subject to the notification provisions of section 21.21(d)(5). The procedure addresses the posting requirements of section 21.6 and provides guidance for adhering to the explicit timing requirements of Part 21.

The NRC audit team noted that the Part 21 regulations were posted, as required, in conspicuous places at the PE Raleigh North Carolina offices where COLA personnel were assigned. The Part 21 programs of the principal contractors were also reviewed and found to provide a level of detail sufficient for evaluating and notifying the NRC of Part 21 potential defects and noncompliance. The S&L Part 21 process is described in SOP-1405, Revision 4, dated February 27, 2007; the WP process is described in NOM-06, Revision 4, dated October 26, 2006; and the CH2M process is described in NBG-QA-1602, Revision 6, dated October 15, 2007. In addition, for commercial nuclear work the CH2M corrective action program described in NBG-QA-1601, Revision 4, dated October 1, 2007, requires that the QA organization evaluate any significant condition adverse to quality for Part 21 reportability requirements.

c. Conclusions

The NRC audit team concluded that Part 21 requirements were appropriately translated into implementing procedures and, for those activities reviewed by the NRC audit team, implemented as required by the applicant's procedures to support the Harris COLA. No issues were identified in this area which require additional actions.

3.15 Consistency with Regulatory Guide 1.206, "Combined License Applications For Nuclear Power Plants," October 2007

a. Audit Scope

The NRC audit team reviewed selected parts of the Harris COLA, Final Safety Analysis Report (FSAR), and compared the draft with the guidance contained in RG 1.206. The NRC audit team discussed with the applicant and its contractors the results of the NRC audit team's review of the FSAR, including any differences or discrepancies identified.

b. Observations

The NRC audit team used the following chapters of RG 1.206 for its review. Part I: Standard Format and Content of Combined License Applications: C.I.2.1, "Geography and Demography," C.I.2.2, "Nearby Industrial, Transportation, and Military Facilities," C.I.2.3, "Meteorology," C.I.2.4, "Hydrologic Engineering," C.I.7, "Instrumentation and Control," C.I.8, "Electrical Power," C.I.10, "Steam and Power Conversion," C.I.13, "Conduct of Operations" and C.I.14, "Initial Test Program."

The NRC audit team performed a review of the applicant's method for revising each FSAR section and discussed this review process with members of the Harris COLA development staff. Specifically, FSAR sections and chapters are developed by the Harris COLA contractors and submitted to PE for the Owners Acceptance Review (OAR), typically at the Revision C level. The OAR process is described in Procedure NGGS-NPD-0001. Technical and licensing comments are provided on this revision and returned to the contractor for resolution. During the next revision, Revision D, the contractors' resolution to previous revision comments are reviewed by PE and returned for an additional round of comments. In addition to licensing and technical reviews, an administrative review is conducted to ensure conformance with the format and content guidance. Plant-specific sections (Emergency Plan, Security Plan, Environmental Report and FSAR Chapter 2) were also provided to other NuStart utility members for peer review. The draft Revision E, constituting a resolution of previous comments, is submitted to the PE for a "page-turn" review. The "page-turn" review is a final technical, administrative and licensing review which identifies any open items ensures all comments are resolved and that commitments are identified and entered in the database. A final Revision E is prepared and acceptance of this revision is documented through affirmation by the lead technical reviewer and the licensing reviewer. Once all FSAR sections and chapters and other COLA parts are accepted and affirmed and the COLA is deemed ready for submittal by the applicant, Revision 0 of the COLA is prepared for submittal under oath and affirmation to the NRC.

The NRC audit team reviewed draft FSAR, Section 2.1, "Geography and Demography," Revision E, Section 2.2, "Identification of Potential Hazards in Site Vicinity," Revision E, Section 2.3, "Meteorology" Revision E, and Section 2.4, "Hydrologic Engineering", Revision E against

corresponding Chapters in RG 1.206, found that these sections were consistent with the guidance in RG 1.206.

Other draft FSAR chapters reviewed include: (1) Chapter 8, "Electrical Power", Revision C; (2) Chapter 10, "Steam and Power Conversion", Revision C; (3) Chapter 13, "Conduct of Operations," Revision C; and (4) the Harris COLA Emergency Plan. The NRC audit team determined that these draft FSAR chapters were consistent with the guidance in RG 1.206.

With respect to the draft FSAR Chapter 14, "Initial Test Program," the NRC audit team reviewed the internal review process applied to the development of individual sections within Chapter 14. PE used Westinghouse's AP1000 DCD Revision 16 to identify COLA actions items. PE also used NUREG-0800 "Standard Review Plan 14.2 Initial Test Program- Design Certification and New License Applicants" (SRP) and RG 1.206 to ensure the entire scope was identified and addressed.

At the time of the NRC audit approximately 85 percent of the draft FSAR sections and chapters for Harris COLA were completed. The NRC staff will be reviewing the COLA relative to its conformance to the SRP and RG 1.206 as part of its formal acceptance review process.

c. Conclusions

The NRC audit team concluded that the FSAR sections and chapters of the Harris COLA reviewed are consistent with the guidance in RG 1.206.

4.0 ENTRANCE AND EXIT MEETINGS

In the entrance meeting on October 29, 2007, the NRC audit team discussed the scope of the audit, outlined the areas to be reviewed, and established interfaces with management and staff from PE and its contractors involved in the Harris COLA development. In the exit meeting on November 1, 2007, the NRC audit team discussed the activities conducted during the audit, and issues associated with the COLA development process with PE management and staff and contractor personnel.

4.1 PARTIAL LIST OF PERSONS CONTACTED

| Name | Position | Organization |
|----------------|--|-----------------|
| R. Kitchen * | Manager Nuclear Plant Licensing | Progress Energy |
| M. Janus * | Nuclear Plant Development & License Renewal | Progress Energy |
| A.K. Singh * | Vice President and Project Director Nuclear Consulting | Sargent & Lundy |
| R. Kurtz * | Quality Assurance Manager | Sargent & Lundy |
| J. Archer * | Senior Project Manager | Worley-Parsons |
| H.A. Manning * | Nuclear Quality Program Manager | Worley-Parsons |
| M. Keating * | Principal Project Manager | CH2MHill |
| G. Grant* | Quality and Safety Assurance Manager | CH2MHill |
| J. McElroy | Document Records Management | CH2MHill |
| J. Donahue** | Vice President | Progress Energy |
| M. Launi** | Senior Manager | Sargent & Lundy |
| Garry Miller** | General Manager, Nuclear Plant Development | Progress Energy |

* Attended entrance and exit meeting

** Attended exit meeting

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