

December 21, 2006

Mr. John M. Heffley
Chief Nuclear Officer
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1997 Annapolis Exchange Parkway, Suite 310
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SUBJECT: CALVERT CLIFFS NUCLEAR POWER PLANT, UNIT NOS. 1 AND 2, NINE MILE POINT NUCLEAR STATION, UNIT NOS. 1 AND 2, AND R.E. GINNA NUCLEAR POWER PLANT - APPROVAL OF COMMON QUALITY ASSURANCE PROGRAM (TAC NOS. MC9180, MC9181, MC9182, MC9183, AND MC9184)

Dear Mr. Heffley:

By letter dated December 5, 2005, as supplemented on July 14, September 1, October 9, and December 14, 2006, Constellation Generation Group, LLC, submitted its common Quality Assurance Topical Report (QATR), pursuant to Section 50.54(a) of Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR), for Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2, Nine Mile Point Nuclear Station, Unit Nos. 1 and 2, and R.E. Ginna Nuclear Power Plant. The program described in the QATR would replace the quality assurance (QA) programs at each facility and would be applied to licensed activities under 10 CFR Parts 50, 71, and 72.

In accordance with 10 CFR 50.54(a)(4), the Nuclear Regulatory Commission (NRC) staff has reviewed the information provided in support of the application and finds it acceptable. The enclosed safety evaluation (SE) documents the basis for the NRC staff's conclusion that the common QA program described in the QATR meets the criteria of Appendix B to 10 CFR Part 50. The effectiveness of these QA program provisions will continue to be the subject of NRC review and inspection.

If you have any questions, please contact me at 301-415-1457.

Sincerely,

/RA/

Patrick D. Milano, Senior Project Manager
Plant Licensing Branch I-1
Division of Licensing Project Management
Office of Nuclear Reactor Regulation

Docket Nos. 50-317, 50-318, 50-220,
50-410, and 50-244

Enclosure: As stated

cc w/encl: See next page

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ACCESSION NUMBER: ML063330594

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Constellation Energy Generation Group

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R.E. Ginna Nuclear Power Plant
Nine Mile Point Nuclear Station, Unit Nos. 1 and 2

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SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

CHANGE TO THE QUALITY ASSURANCE PROGRAM

COMMON QUALITY ASSURANCE PROGRAM

CALVERT CLIFFS NUCLEAR POWER PLANT, UNIT NOS. 1 AND 2

NINE MILE POINT NUCLEAR STATION, UNIT NOS. 1 AND 2

R.E. GINNA NUCLEAR POWER PLANT

DOCKET NOS. 50-317, 50-318, 50-220, 50-410, AND 50-244

1.0 INTRODUCTION

By letter dated December 5, 2005, as supplemented by letters dated July 14, September 1, October 9, and December 14, 2006, (Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML053470094, ML062010255, ML062550521, ML062890059, and ML063530450, respectively), Constellation Generation Group (CGG) submitted its common Quality Assurance Topical Report (QATR) to the Nuclear Regulatory Commission (NRC) for review and approval in accordance with the provisions of Section 50.54(a)(4) of Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR). In the July 14, 2006, submittal, CGG revised its original application in response to NRC letter dated May 15, 2006 (ADAMS No. ML061230392).

The QATR would replace and consolidate the current site-specific quality assurance (QA) programs for Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2 (Calvert Cliffs), Nine Mile Point Nuclear Station, Unit Nos. 1 and 2 (Nine Mile Point), and R.E. Ginna Nuclear Power Plant (Ginna). CGG submitted the QATR on behalf of Calvert Cliffs Nuclear Power Plant, Inc., Nine Mile Point Nuclear Station, LLC, and R.E. Ginna Nuclear Power Plant, LLC (the licensees).

2.0 REGULATORY EVALUATION

The Commission's regulatory requirements related to QA programs are set forth in Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, 10 CFR 50.34(b)(6)(ii), and 10 CFR 50.54(a).

Appendix B to 10 CFR Part 50 establishes QA requirements for the design, construction, and operation of structures, systems, and components (SSCs) of the facility. The pertinent requirements of Appendix B to 10 CFR Part 50 apply to all activities affecting the safety-related functions of those SSCs and include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

10 CFR 50.34, "Contents of applications; technical information," requires that every applicant for an operating license include information in its final safety analysis report (FSAR) on the managerial and administrative controls to be used to assure safe operation. The information on the controls shall also include a discussion of how the applicable requirements of Appendix B to 10 CFR Part 50 will be satisfied.

10 CFR 50.54(a) states that licensees may make a change to a previously accepted QA program description included or referenced in the FSAR without prior NRC approval, provided the change does not reduce the commitments in the program description as accepted by the NRC. Changes to the QA program description that do reduce the commitments must be submitted to the NRC and receive NRC approval prior to implementation.

3.0 EVALUATION

3.1 Background

In the QA program described in the QATR, CGG committed to the guidance of the American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) Standard NQA-1-1994, "Quality Assurance Requirements for Nuclear Applications." Part I of NQA-1-1994 sets forth programmatic requirements for the establishment and execution of QA programs for the siting, design, construction, operation, and decommissioning of nuclear facilities. Part II of NQA-1-1994 sets forth non-programmatic QA requirements for the planning and execution of identified tasks during the fabrication, construction, modification, repair, maintenance, and testing of systems, components and structures for nuclear facilities. The guidance of Parts I and II of NQA-1-1994 is similar to that provided by the American National Standards Institute (ANSI) N45.2 series (daughter) standards, which were developed in the 1970s and early 1980s. The licensee proposed to adopt NQA-1-1994 in lieu of certain current commitments to N45.2 daughter standards.

The NRC staff has previously approved the use of NQA-1-1994, as supplemented by the guidance of ANSI N18.7-1976, "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants," for nuclear operating facilities (see References 5, 6, and 7). The most notable changes incorporated into the CGG QATR include: (1) a commitment to ANSI/ASME NQA-1-1994 as the basic QA standard as a replacement for the previous ANSI N45.2 series of standards; (2) a commitment to establish and implement administrative controls and QA requirements within the QATR for the operating phase activities that are consistent with the guidance of Regulatory Guide (RG) 1.33 rather than through a specific commitment to ANSI N18.7-1976/ANS 3.2; (3) the use of generic management position descriptions for implementing programs based more on the function or objective rather than the specific nomenclature used at the facilities, since these program titles vary between locations; (4) the use of generic functional descriptions of the organization rather than specific titles and the use of organization charts to depict the reporting relationships; and (5) the use of alternative methods from those described in NQA-1-1994 to ensure the requirements of Appendix B to 10 CFR Part 50 are satisfactorily implemented.

3.2 Review Criteria

In evaluating the adequacy of the format and level of detail of the revised QA program description, the NRC staff followed the guidance of NRC Report NUREG-0800, "Standard Review Plan [SRP]," Section 17.3 (SRP 17.3), "Quality Assurance Program Description." SRP 17.3 provides an outline of a standardized QA program for construction permit holders, their principal contractors, and operator facility licensees. At Calvert Cliffs, the licensee was committed to RG 1.33, Revision 2, which endorsed ANSI N18.7-1976/ANS-3.2, and was also committed to various daughter standards of ANSI N45.2. At Nine Mile Point, the licensee was committed to ANSI/ANS-3.2-1982, and RG 1.28, "Quality Assurance Program Requirements (Design and Construction)," Revision 3, which endorses ASME NQA-1-1983 and 1983 Addenda. These two QA programs were written to the structure of SRP 17.1 and 17.2 which follows the specific outline of Appendix B to 10 CFR Part 50. Ginna was committed to RG 1.28, Revision 2, which endorsed ANSI N45.2-1977, and its daughter standards, RG 1.33, Revision 0, which endorsed ANSI N18.7-1972. The Ginna QA program was written to the structure of SRP 17.3, which follows NQA-1. CGG used SRP 17.3 to determine the appropriate regulatory guidance that applies to the proposed QATR and to provide other useful insight into QA program requirements.

The NRC staff's review concentrated on three specific aspects of CGG's proposed change and consolidation of the QA program description for Calvert Cliffs, Ginna and Nine Mile Point. These aspects included the proposed program format, attributes and level of detail (SRP 17.3), changes in regulatory commitments, and the basis for the change from ANSI N45.2 to NQA-1-1994, including alternative methods from those described in NQA-1-1994 to ensure the requirements of 10 CFR Part 50, Appendix B are satisfactorily implemented.

The NRC staff also reviewed the proposed change and consolidation of the CGG QA program description for Calvert Cliffs, Ginna, and Nine Mile Point to ensure the requirements of 10 CFR Part 72 are met, using the same criteria described above for review of the Part 50 program. The staff has previously approved the use of the 10 CFR Part 50, Appendix B programs for Calvert Cliffs, Ginna, and Nine Mile Point under the provisions of Section 72.140(d), "Previously-approved programs," of 10 CFR. It is noted that at Calvert Cliffs, the licensee possesses a site-specific-license for its independent spent fuel storage installation (ISFSI). Accordingly, any changes to the QA program described for the ISFSI must also comply with 10 CFR Part 72.

3.3 Acceptability of the QA Topical Report Description

3.3.1 Organization

The QATR is the top-level policy document that establishes the quality policy and assigns major functional responsibilities for the CGG facilities. CGG is committed to establishing and maintaining an organization in accordance with the quality standards described in NQA-1-1994, Basic Requirement 1 and Supplement 1S-1. The organizational structure includes corporate functions and onsite functions at each facility. The Chief Nuclear Officer (CNO) has overall responsibility for safe and reliable operation of CGG nuclear stations including management oversight and support of the day-to-day operation. The organizational relationships of key management and functional groups for corporate and technical support are identified in Appendix E of the QATR. Reporting to the CNO are site vice presidents and executive

managers responsible for operations support, technical services, project management, and quality and performance assessment. The Executive Manager of Operations Support provides direction to the departments for nuclear security, emergency preparedness, training and fleet procedures, in addition to corporate oversight and support provided in the areas of operations, maintenance, refueling services, radiation protection and chemistry, and work management. The Executive Manager of Technical Services is responsible for the engineering functions supporting design and construction activities and long-term nuclear operations. The Executive Manager of Quality and Performance Assessments is responsible the verification of effective company and supplier QA program development, documentation, and implementation.

CGG site organizations are directed by the site vice presidents. Each site vice president reports directly to the CNO. This position is responsible for station compliance with NRC operating license, governmental regulations, and ASME Boiler and Pressure Vessel Code (ASME Code) requirements, if applicable, and provides day-to-day direction and management of plant operations activities. The plant general manager reports to the site vice president and is responsible for plant operations and maintenance. As supplemented in its letter dated September 1, 2006, CGG stated that the plant general manager has stop work authority for all activities performed in operating its respective stations, including the final responsibility for the overall evaluation of shutting down an operating unit. The site reporting structure and management positions responsible for plant operations, training, business support, engineering, regulatory affairs, performance assessment, and nuclear oversight are identified in Appendix E of the QATR. Responsibility and authority for executing an effective overall QA program and delegation of program responsibilities are clearly described and defined.

3.3.2 Quality Assurance Program

CGG establishes a QA program for the nuclear power stations and independent spent fuel storage installations. The QA program comprises those planned and systematic actions necessary to provide confidence that structures, systems and components will perform their intended safety function. The QA program consists of the NRC-approved regulatory documents that describe the regulatory assurance elements, along with the associated corporate, fleet, and site implementing documents. Provisions for establishing and maintaining formal indoctrination and training programs for personnel performing, verifying or managing activities within the scope of the QATR are described to assure that suitable proficiency is achieved and maintained. In establishing qualification and training programs, CGG commits to implementing the QA program in accordance with the quality standards described in NQA-1-1994, Basic Requirement 2, and Supplements 2S-1, 2S-2, 2S-3, and 2S-4, including alternatives described in section 3.3 of this SE. CGG staff qualifications for positions within the scope of 10 CFR 50.120 are delineated in plant technical specifications. CGG staff training for positions identified in 10 CFR 50.120 is accomplished according to programs accredited by the National Nuclear Accrediting Board of the National Academy for Nuclear Training.

3.3.3 Design Control

CGG establishes and implements administrative controls to assure quality is achieved in establishing and changing the design for the nuclear facilities in accordance with industry standards and regulatory requirements. The CGG design control applies to preparation, review and revision of design documents, including the correct translation of applicable regulatory requirements and design bases into design, procurement and procedural documents. In

establishing its program for design control, CGG commits to meeting the standards of NQA-1-1994, Basic Requirement 3, Supplement 3S-1.

CGG establishes and implements provisions to assure that computer software used in applications affecting safety are prepared, documented, verified and tested, and used such that the expected outputs are obtained and configuration control maintained. CGG commits to comply with the standard of NQA-1-1994, Supplement 11S-2.

3.3.4 Procurement Document Control

CGG establishes and implements administrative controls and processes to assure that applicable regulatory, technical, and QA program requirements are included or referenced in procurement documents. CGG commits to meeting the QA standards for procurement document control of NQA-1-1994, Basic Requirements 4 and 7, and Supplements 4S-1 and 7S-1, including alternatives described in Section 3.3 of this safety evaluation (SE).

3.3.5 Instructions, Procedures, and Drawings

CGG establishes and implements administrative controls to assure that activities affecting quality are prescribed by and performed in accordance with documented instructions, procedures, and drawings. As stated in position C.1 of RG 1.33, Revision 2, CGG commits to use Appendix A of RG 1.33 as guidance for establishing the types of procedures that are necessary to control and support plant operation.

3.3.6 Document Control

CGG establishes and implements administrative controls to assure the review, approval, and issuance of controlled documents. Measures are provided to assure that documents, including revisions or changes, are reviewed for adequacy by independent knowledgeable personnel other than those who originated or prepared the document, approved for release by authorized personnel, and distributed in accordance with current approved methods. In establishing provisions for document control, CGG commits to meeting the QA standards for document control of NQA-1-1994, Basic Requirement 6 and Supplement 6S-1.

3.3.7 Control of Purchased Material, Equipment, and Services

CGG establishes and implements programs, procedures, and processes for the control of purchased items and services, selection of Suppliers, and assessing the acceptability of quality. Purchased items (components, spares, and replacement parts necessary for plant operation, refueling, maintenance and modifications) and services are subject to quality and technical requirements at least equivalent to those specified for original equipment or specified by properly reviewed and approved revisions to assure the items are suitable for the intended service, and are of acceptable quality, consistent with their effect on safety. CGG commits to meeting the QA standards for control of purchased material, equipment, and services contained in NQA-1-1994, Basic Requirement 7, and Supplement 7S-1, with the exceptions described in Section 3.3 of this SE.

3.3.8 Identification and Control of Materials, Parts, and Components

CGG establishes and implements administrative controls and processes for the identification and control of items such as materials, including consumables and items with limited shelf life, parts, components, and partially fabricated subassemblies. The identification of items is maintained throughout fabrication, erection, installation and use so that the item can be traced to its documentation, consistent with the item's effect on safety. CGG commits to meeting the QA standards for identification and control of items contained in NQA-1-1994, Basic Requirement 8 and Supplement 8S-1.

3.3.9 Control of Special Processes

CGG establishes and implements programs, procedures, and processes to assure that special processes that require interim process controls to assure quality, such as welding, heat treating, chemical cleaning, and nondestructive examinations, are controlled in accordance with the applicable codes, specifications, and standards of the specific work. CGG commits to meeting the QA standards for control of special processes from NQA-1-1994, Basic Requirement 9 and Supplement 9S-1, as well as the applicable ASME Code provisions established per 10 CFR 50.55a.

3.3.10 Inspection

CGG establishes and implements administrative controls and processes to inspect activities for the nuclear facilities that affect quality to verify conformance with the approved documents for accomplishing the activities including specifications and quality standards. CGG commits to comply with the programmatic standards for inspection of NQA-1-1994, Basic Requirement 10, and Supplement 10S-1. In addition, for situations comparable to original construction, CGG commits to comply with the requirements of Subpart 2.8 for establishing appropriate inspection requirements.

3.3.11 Test Control

CGG establishes and implements programs, procedures, and processes to control tests that assure the nuclear facility structures, systems, and components (items) function satisfactorily in service, that the plant can be operated safely and as designed, and that the coordinated operation of the plant as a whole is satisfactory. CGG commits to comply with the programmatic standards for test control of NQA-1-1994, Basic Requirement 11, and Supplements 11S-1.

3.3.12 Control of Measuring and Test Equipment

CGG establishes and implements administrative controls and processes for the calibration, maintenance, and use of measuring and test equipment (including instruments, tools, gauges, fixtures, reference and transfer standards, and non-destructive test equipment). CGG commits to meeting the standards for control of measuring and test equipment of NQA-1-1994, Basic Requirement 12, Supplement 12S-1.

3.3.13 Handling, Storage, and Shipping

CGG establishes and implements programs, procedures, and processes to control handling, storage, shipping, cleaning, and preservation of items to prevent inadvertent damage, loss or deterioration. CGG commits to meeting the standards for handling, storage, and shipping of NQA-1-1994, Basic Requirement 13, Supplement 13S-1, and Subparts 2.3, with the alternatives described in Section 3.3 of this SE. At Calvert Cliffs and Ginna, the licensees also commit to RG 1.38 as described in the approved FSAR or license. At Nine Mile Point, the licensee also commits to ANSI/ASME NQA-2-1983, Part 2.2.

3.3.14 Inspection, Test, and Operating Status

CGG establishes and implements administrative controls and processes to indicate and document the inspection, test, and operating status of structures, systems, and components to prevent their inadvertent use or the bypassing of inspections and tests. CGG commits to implementing an audit program in accordance with the quality standards described in NQA-1-1994, Basic Requirement 14.

3.3.15 Nonconforming Materials, Parts, or Components

CGG establishes and implements administrative controls and processes to assure that nonconforming items, services or activities are reviewed and accepted, rejected, repaired, or reworked, and are identified and controlled to prevent their inadvertent test, use or installation in CGG nuclear facilities. In addition, results of evaluations of conditions adverse to quality are analyzed to identify quality trends, documented and reported to upper management in accordance with applicable procedures. CGG commits to comply with the standards for control of nonconforming items of NQA-1-1994, Basic Requirement 15 and Supplement 15S-1.

3.3.16 Corrective Action

CGG establishes and implements corrective active programs, procedures, and processes to assure that conditions adverse to quality at CGG nuclear facilities are promptly identified and corrected. Provisions also include verification of resolution of significant issues. CGG commits to meeting the standards for corrective action of NQA-1-1994, Basic Requirements 15 and 16, and Supplement 15S-1.

3.3.17 Quality Assurance Records

CGG establishes and implements administrative controls and processes to ensure sufficient records of items and activities for the nuclear facilities that reflect completed work are generated, identified, retained, maintained, and retrievable. Records stored electronically will comply with NRC guidance given in Regulatory Issue Summary 2000-18. CGG commits to implement a QA records program in accordance with the quality standards of NQA-1-1994, Basic Requirement 17 and Supplement 17S-1, with the alternatives described in Section 3.3 of this SE.

3.3.18 Quality Assurance Audits

CGG establishes and implements administrative controls and processes for audits to systematically verify compliance with and determine the effectiveness of all aspects of the QA program for CGG nuclear facilities. Assessments are conducted using predetermined criteria. Use of relevant industry and in-house operating experience information is reviewed during periodic assessments. Audits of selected aspects of operational phase activities are performed with a frequency commensurate with their strength of performance and safety significance and in such a manner as to assure that an audit of all safety-related functions is completed within a period of 2 years. Assessment results are documented and reviewed by the assessor's management and by management having responsibility in the area assessed. Internal audits include verification of compliance and effectiveness of the administrative controls established for implementing the requirements of the QATR; regulations and license provisions; provisions for training, retraining, qualification, and performance of personnel performing activities covered by the QATR; corrective actions taken following abnormal occurrences; and, observation of the performance of operating, refueling, maintenance and modification activities. CGG commits to comply with an audit program in accordance with the quality standards described in NQA-1-1994, Basic Requirement 18 and Supplement 18S-1.

Based on the NRC staff's review of the QATR outlined above, the staff concludes that the QATR adequately describes the licensee's QA program.

3.4 Changes to Current Quality Assurance Commitments

Attachment 2 of the December 5, 2005, application, as supplemented by the letter dated July 14, 2006 (Reference 1), provides a comparison of each facility's approved QA program with the new QATR. Changes are characterized as: (1) a reduction in commitment, (2) not a reduction in commitment, or (3) an increase in commitment. The regulatory change control process described in 10 CFR 50.54(a) classifies changes as non-reductions [50.54(a)(3)] or reductions [50.54(a)(4)] in commitment. Changes that increase commitments (i.e., are clearly more conservative in meeting Appendix B requirements) are made at the discretion of the licensee.

Many of the changes that are not reductions in commitment are the result of changes in format or level of detail. The regulation as described in 50.34(b)(6)(ii) requires that QA program descriptions discuss how the requirements of Appendix B regarding managerial and administrative control will be satisfied.

Several changes, which were previously reviewed by the NRC staff for other licensees, were characterized as non-reductions under the provisions of 50.54(a)(3)(ii). Several NRC SEs that approved QA changes were cited by the licensee, including:

1. NRC SE for Exelon (Reference 5) stated that NQA-1-1994 was equivalent to NQA-1-1983. As such, CGG replaced the references in its commitments to RG 1.8, Revision 3, and RG 1.28, Revision 3, to NQA-1-1994.
2. NRC SE for Nuclear Management Company (Reference 6) provides for RG 1.28, Revision 3, Regulatory Position C.3.2.2, to review ongoing supplier's furnished documents such as certificates of conformance, nonconformance notices, and

correctives, as well as evaluating the results of previous source surveillance/ verifications, audits/surveys, and receiving inspections as the evaluation of the supplier's performance, rather than an annual evaluation. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted). Additionally, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.

This exception to Regulatory Position C.3.2.2 provides for a documented ongoing evaluation of the supplier performance, rather than a delayed annual evaluation. As supplemented in the response to a request for additional information (RAI) dated September 1, 2006 (Reference 2), if no items are received from a vendor in a course of a year, vendors may be removed from the Approved Vendor's List either because of re-evaluation, which resulted in removal, or due to inactivity.

3. NRC SE for Dominion Nuclear Connecticut and Virginia Electric and Power Company (Reference 7) provides for exception to RG 1.116 to substitute ANSI N45.2.8 for NQA-1-1994 Subpart 2.8.
4. NRC SE for Ginna (Reference 8) provides a grace period of 90 days for the performance of annual evaluations of inspection, examination and testing of personnel qualifications, annual lead auditors re-certifications, triennial supplier audits, and internal audits. The grace period does not allow the "clock" for a particular activity to be reset forward. However, the "clock" for an activity is reset backwards by performing the activity early.
5. NRC SE for Indian Point and James A. FitzPatrick (Reference 9) provides exception to RG 1.33, Revision 2, Regulatory Position C.4 to perform biennial internal audits in lieu of the 6- and 12-month audit frequency specified for some activities. This exception allows the audit frequency to be adjusted based on the safety significance and the assessed area's performance. This exception was approved for Ginna on March 22, 1995, under a 10 CFR 50.54(a) submittal.
6. NRC SE for Ginna dated March 22, 1995 (Reference 11) and NRC SE for Calvert Cliffs dated September 25, 1996 (Reference 12) provide an exception to Generic Letter (GL) 82-21 regarding fire protection audit frequencies. In lieu of the 12, 24, and 36-month fire protection audits described in GL 82-21, CGG will combine the scope of the three audits into one by performing a biennial audit of the facility fire protection program and implementing procedures. The biennial audit includes all the required elements of the 12, 24, and 36-month audits, including the use of an outside qualified fire protection consultant.

The NRC staff reviewed the basis cited by the licensee in Attachment 4 to the letter dated December 5, 2005, as supplemented by letter dated July 14, 2006 (Reference 1), and as supplemented in letters dated September 1 (Reference 2), October 9 (Reference 3), and December 14, 2006 (Reference 4). The staff concluded that the basis for each of the changes is applicable to the licensee's facilities.

The licensee also established a commitment to RG 4.15, "Quality Assurance for Radiological Monitoring Programs (Normal Operations) - Effluent Streams and the Environment," Revision 1, dated February 1979, Section C, with certain exceptions/alternatives, for Ginna, Nine Mile Point and Calvert Cliffs. The three areas of exception/alternative are: (1) an alternative to evaluation of gamma spectroscopy instrumentation background results by plotting background parameters, (2) not requiring use of the NRC's independent sampling and analysis program, and (3) performing source check calibrations at least once per refueling interval rather than once per 18 months. The NRC staff has reviewed the proposed exceptions and found that:

- The alternative method of evaluating ambient background radiation levels and instrumentation responses to ambient background is an acceptable method that performs the same function in identifying measurement values falling outside of a predetermined control range and correcting instrumentation response in such instances, given that the adequacy and accuracy of such results are checked in an inter-laboratory test program to determine bias in instrumentation responses;
- Since the NRC has discontinued its Confirmatory Measurements Program, the licensee is no longer required to submit split environmental media samples to the NRC; however, this exclusion does not relieve the licensee from maintaining and participating in its own inter- and intra-laboratory test programs, as currently implemented, or from having to participate inter-laboratory comparison tests whenever directed to do so by the NRC; and
- The change of frequency for source check calibrations from 18 to 24 months is consistent with the currently approved refueling interval at Calvert Cliffs and is sufficient to ensure calibration accuracy of the instruments and periodically confirm, during operation, instrumentation readings against concentrations and/or release rates of radioactive materials present in monitored effluent and process streams.

The effectiveness of the revised QA program provisions, as described in exception for RG 4.15, will continue to be the subject of NRC review and routine inspections as part of the reactor oversight program.

Although not a requirement, CGG identified changes that were characterized as being an increase in commitment. The identified increases in commitment are as follows:

- For Calvert Cliffs, records of reactor tests and experiments are increased to a lifetime record.
- For Ginna, a discussion on the Employee Concerns Program was included.
- For Ginna, computer software control was included in commitment to NQA-1-1994, Supplement 11S-2.

The NRC staff reviewed the basis for each increase in commitment and concluded that the revised commitments continue to meet Appendix B requirements and, therefore, are acceptable.

3.5 Constellation Generation Group Quality Assurance Topical Report and ASME NQA-1-1994

The currently approved QA programs for Calvert Cliffs, Ginna, and Nine Mile Point follow the guidance of ANSI N18.7-1976, ANSI N45.2 series of standards, ANSI/ASME-1-1983 and corresponding RGs. Since the proposed QATR is based on a newer standard of NQA-1, understanding the evolution is important to establishing the acceptability of the proposed basis for the QATR.

In 1979, the ASME Committee on Nuclear Quality Assurance issued a new standard NQA-1-1979, based on N45.2-1977 and seven programmatic standards of the N45.2 series. In 1983, ASME revised and reissued the standard as NQA-1-1983. In 1985, NRC RG 1.28 Revision 3 endorsed NQA-1-1983 as an acceptable method for complying with the provisions of Appendix B with regard to implementing the requisite QA program for the design and construction of nuclear power plants. In 1994, NQA-1-1994 incorporated an additional seven, non-programmatic N45.2 standards. As such, NQA-1-1994 sets forth requirements and nonmandatory guidance for the establishment and execution of QA programs for nuclear facility applications. In addition, NRC RG 1.33, Revision 2 endorsed ANSI N18.7-1976 as an acceptable basis for complying with the QA program provisions of Appendix B for the operations phase of nuclear power plants. In December 2002, the NRC approved NQA-1-1994, in conjunction with ANSI N18.7-1976, as a method acceptable to the staff for complying with the Commission's regulations for Exelon's operational QA programs (Reference 3). The need for ANSI N18.7-1976 is that administrative controls were not incorporated into NQA-1-1994.

As stated in CGG's application, the proposed QATR is based on NQA-1-1994. Attachment 2 of the submittal provides a comparison of the current QA programs, to which the CGG current QA programs have made commitments, with NQA-1-1994. The administrative requirements of ANSI N18.7-1976 are incorporated into the text of the QATR. Attachment 3 to the QATR illustrates the QA requirements of N18.7-1976 as addressed through commitments to NQA-1-1994 or inclusion of equivalent requirements within the text of the QATR.

Based on its review, the NRC staff concludes that CGG's adoption of NQA-1-1994, as implemented through the QATR, adequately addresses the commitments to the subject N45.2 standards and is, therefore, an acceptable method of implementing the applicable Appendix B requirements.

3.5.1 Exceptions and Alternatives to NQA-1-1994

Where CGG has taken an exception or alternative to the guidance of NQA-1-1994 or an existing ANSI standard, it is addressed in the applicable section of the QATR. Attachment 4 of the original submittal, as supplemented by letters dated July 14, September 1, October 9, and December 14, 2006 (References 1, 2, 3, and 4), provides the basis for each QATR alternative or exception to NQA-1-1994. These alternatives and exceptions have been previously approved by the NRC via license amendments and include the following:

- For NQA-1-1994 Supplement 2S-1: Inspections, examinations or tests may be performed by individuals in the same organization as that which performed the work, provided that: (a) the qualifications of the inspector for an activity are equal to or better than the minimum qualifications for persons performing the activity, in addition to being

a certified inspector, (b) the work is within the skills of personnel and/or is addressed by procedures, and (c) if work involves breaching a pressure-retaining item, the quality of the work can be demonstrated through a functional test. When a, b, and c are not met, inspections, examinations, or tests are carried out by individuals certified in accordance with Supplement 2S-1.

As supplemented in the response to RAIs dated September 1, 2006 (Reference 2), the purpose of this exception is to allow line personnel, who are in the same organization as that which performed the work, to conduct verification inspections, examinations, measurements, or test on material products activities. CGG will apply this exception to line personnel performing quality control inspections. It does not apply to QA personnel. This alternative was approved for Nuclear Management Company by letter dated March 24, 2005 (Reference 6).

- For NQA-1-1994 Non-mandatory Appendix 2A-1: In lieu of being certified as Level I, II, or III in accordance with Non-mandatory Appendix 2A-1 of NQA-1-1994, personnel performing the operations-phase independent quality verification inspections, examinations, measurements, or tests on material products or activities, that are in the same organization as which performed the work, will be required to possess the same minimum level qualification as that required for the task being verified, in addition to being a certified inspector. The verification shall be within the skills of these personnel and/or is addressed by procedures. These individuals will not be responsible for the planning of quality verification inspections and tests (i.e., establishing hold points and acceptance criteria in procedures, or determining who will be responsible for performing the inspections), evaluating inspections training programs, or certifying inspection personnel.

The purpose of this exception is to allow CGG line personnel at Nine Mile Point, Ginna, and Calvert Cliffs who (1) perform inspections and are in the same organization as that which performed the work, (2) are qualified in an accredited systematic approach training-based program that meets 10 CFR 50.120, (3) have the same level of qualification as the individual performing the task, in addition to being a certified inspector, (4) have the necessary skills, and (5) have the verification requirements specified in procedures, to be exempt from being certified Level I, II, or III as required in NQA-1-1994 Non Mandatory Appendix 2A-1. CGG will apply this exception to line personnel performing quality control inspections. It does not apply to QA personnel. This alternative was approved for Nuclear Management Company by letter dated March 24, 2005 (Reference 6). As supplemented in letter dated December 14, 2006 (Reference 4), the inspector, in addition to possessing the same level of qualification as that required for performing the task to be verified, will be trained and certified to perform inspections in a manner consistent with a Level I quality inspector. Also, these inspectors will be authorized to accept or reject work being inspected. The results of inspections by these individuals will be reviewed by a certified Level II or higher quality inspector.

- NQA-1-1994, Supplement 2S-2: Supplementary Requirements for the Qualification of Nondestructive Examination Personnel, subsection 2.1, requires application of Recommended Practice SNT-TC-1A, June 1980 Edition to NDE personnel. The company will implement the qualification program required by this supplement in

accordance with the applicable standard for the facility's commitment to the ASME Code or other applicable code governing the activity. This alternative was approved for Nuclear Management Company by letter dated March 24, 2005 (Reference 6).

- For NQA-1-1994 Supplement 2S-3: As supplemented in the response to RAIs dated September 1, 2006 (Reference 2), the requirements that prospective lead auditors have participated in a minimum of five (5) audits in the previous three (3) years is replaced by the following:

"The prospective lead auditor shall demonstrate his/her ability to effectively lead and implement the audit process according to section C.2 of the QATR, and to effectively organize and report results, including participation in at least one nuclear audit within the year preceding the date of qualification. Constellation Generation Group describes this process in written procedures and shall evaluate and document the results of the demonstration."

This exception relates to the qualification of individuals with appropriate experience as lead auditors. The exception meets the intent of Section 3.3 of NQA-1-1994 to have prospective lead auditor demonstrate the ability to effectively implement the audit process and to lead an audit team. This exemption has been previously approved for Ginna in an SE dated April 6, 1999 (Reference 10). The inclusion of the exception in the CGG QATR extends the exception to Calvert Cliffs and Nine Mile Point.

- For NQA-1-1994 Supplement 4S-1, Section 2.3: In lieu of the requirement of procurement documents to require a quality program that complies with NQA-1, CGG may apply other nationally recognized and NRC endorsed quality standards as appropriate to the circumstances of the procurement.

This exception establishes alternate standards on which to base the procurement documents. For existing long-term plant purchases that have imposed ANSI N45.2, or other NRC endorsed standard that can be shown to be equivalent to NQA-1, CGG is not required to change the procurement. For new procurement documents, CGG will specify the requirements of NQA-1 or Appendix B to 10 CFR Part 50. This alternative was approved for Nuclear Management Company by letter dated March 24, 2005 (Reference 6).

- For NQA-1-1994 Supplement 7S-1, Section 8.1: Documentary evidence that items conform to procurement requirements need not be available at the site prior to installation, but will be available at the site prior to placing reliance on the item for its intended safety function. This alternative was approved for Nuclear Management Company by letter dated March 24, 2005 (Reference 6).
- For NQA-1-1994 Supplement 7S-1: Paragraph 8.2.4 states "...post-installation test requirements and acceptance documentation shall be mutually established by the Purchaser and Supplier." In exercising ultimate responsibility for its QA program, CGG establishes post-installation test requirements, giving due consideration to supplier recommendations. This exception does not eliminate the participation of the supplier in developing post-installation test requirements and acceptance documents. Rather, this exception only clarifies that the final responsibility for the QA program resides with CGG.

This alternative was approved for Niagara Mohawk Power Corporation by letter dated December 31, 1985 (Reference 13). This exception was already implemented at Nine Mile Point.

- NQA-1-1994, Supplement 7S-1, Section 10: This section addresses requirements for Commercial Grade Items. Based on GL 89-02 and its endorsement of Electric Power Research Institute (EPRI) Report NP-5652, "Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications," CGG will use the guidance contained in EPRI NP-5652 instead of the NQA-1-1994 requirements in addition to NRC guidance provided in GL 95-02. This alternative was approved for Dominion by letter dated September 9, 2005 (Reference 7).
- NQA-1-1994 Supplement 17S-1, Section 4.2(b): This section requires records to be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers. For hard-copy records maintained by the licensee, the records are suitably stored in steel file cabinets or on shelving in containers, except that methods other than binders, folders or envelopes may be used to organize the records for storage. This alternative was approved for Nuclear Management Company by letter dated March 24, 2005 (Reference 6).
- For NQA-1-1994 Subpart 2.3: In lieu of the five-level zone designation, CGG may base its control over housekeeping activities on a consideration of what is necessary and appropriate for the activity involved. The controls are implemented through procedures or instructions. Factors considered in developing the procedures and instructions include cleanliness control, personnel safety, fire prevention and protection, radiation control and security. The procedures and instructions make use of standard janitorial and work practices to the extent possible. This alternative was approved for Nuclear Management Company by letter dated March 24, 2005 (Reference 6).
- For ANSI N45.2.4-1972 Section 6.2.1: The calibration program proposed by CGG does not use calibration stickers on installed plant instrumentation that contain the date of the calibration and identity of person that performed the calibration. Calibration of instruments are scheduled and tracked by a computer data base. The information in the database insures the calibration information meets the requirements of the standard and is correlated with the equipment by unique identification number. The currently approved QA programs for Calvert Cliffs and Nine Mile Point includes this exception. The inclusion of the exception to CGG QATR will extend the exception to Ginna.

The NRC staff has examined CGG's basis for adopting NQA-1-1994 as implemented through the QATR and finds it to be an acceptable method for complying with the Commission's regulations with regard to overall QA program requirements for the operation phase of CGG nuclear power plants. The staff has also reviewed the basis for the applicability of each exception and alternative to NQA-1-1994 to each CGG facility and concluded that the exceptions and alternatives continue to meet Appendix B requirements and, therefore, are acceptable.

4.0 CONCLUSION

The QATR follows the guidance and conforms to the format of SRP 17.3. Appendices to the QATR address commitments and review functions for independent review, procedures, definitions of terms in additions to those provided in NQA-1-1994, and additional QA record requirements for operating facilities. The NRC staff used acceptance criteria of SRP 17.3 as the basis for evaluating the acceptability of the QATR in conformance with the provisions of 50.34(b)(6)(ii). On the basis of its review of the CGG QATR, the NRC staff concludes that:

1. The QATR acceptably describes the authority and responsibility of management and supervisory personnel, performance/verification personnel, and self-assessment personnel.
2. The organizations and persons responsible for performing the verification and self-assessment functions have the authority and independence to conduct their activities without undue influence from those directly responsible for costs and schedules.
3. The QATR applies to activities and items that are important to safety.
4. The QATR establishes controls that, when properly implemented, comply with the requirements of Appendix B and Criterion 1 of Appendix A to 10 CFR Part 50, 10 CFR Part 21, 10 CFR 50.55a, and 10 CFR 50.55(e), with the criteria contained in SRP 17.3, and with the commitments to regulatory guidance.

Based on review of CGG's consolidated QA program, described in the proposed QATR, the NRC staff concludes that the single QA program can be applied to Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2, Nine Mile Point Nuclear Station, Unit Nos. 1 and 2, and R.E. Ginna Nuclear Power Plant. On the basis of its review, the staff concludes that the QATR adequately describes the licensee's QA program. Accordingly, the staff concludes that the CGG QATR complies with the applicable NRC regulations and industry standards and can be implemented for Calvert Cliffs, Ginna and Nine Mile Point nuclear facilities.

5.0 REFERENCES

1. CGG letter, J. M. Heffley to NRC, "Request for Approval of a Common Quality Assurance Program for Constellation Generation Group, LLC," December 5, 2005, as supplemented by letter dated July 14, 2006.
2. CGG letter, J. M. Heffley to NRC, "Response to Request for Additional Information Regarding Common Quality Assurance Program (TAC Nos. MC9180, MC9181, MC9182, MC9183, and MC9184)," dated September 1, 2006.
3. CGG letter, B. S. Montgomery to NRC, "Response to Request for Additional Information Regarding Common Quality Assurance Program (TAC Nos. MC9180, MC9181, MC9182, MC9183, and MC9184)," dated October 9, 2006.
4. CGG letter, B. S. Montgomery to NRC, "Change to Common Quality Assurance Program (TAC Nos. MC9180, MC9181, MC9182, MC9183, and MC9184)," dated December 14, 2006.

5. SE by NRC Office of Nuclear Reactor Regulation (NRR) of Proposed Change to the Quality Assurance Program, "Approval of Proposed Revision 70 of Quality Assurance Topical Report EGC-1A, Rev. 70, in Accordance with 10 CFR 50.54(a) Requirements for Exelon/Amergen Plants," (ADAMS Accession Number ML023440300), December 24, 2002.
6. NRR SE of Proposed Change to the Quality Assurance Program, "Approval of Nuclear Management Company Quality Assurance Topical Report," (ADAMS Accession Number ML050700416), March 24, 2005.
7. NRR SE of Proposed Change to the Quality Assurance Program, "Approval of Dominion Nuclear Connecticut and Virginia Electric and Power Company Quality Assurance Program Description Quality Assurance Topical Report," (ADAMS Accession Number ML052490337,) dated September 9, 2005.
8. NRR SE, "Proposed Revision 25 to the Rochester Gas & Electric Corporation Quality Assurance Program for Station Operation, R. E. Ginna Nuclear Power Plant," dated July 22, 1998.
9. NRR SE, "Proposed Revisions to the Quality Assurance Program Descriptions Power Authority of the State of New York Indian Point Nuclear Generating Unit No. 3 and James FitzPatrick Nuclear Power Plant," dated March 5, 1999.
10. NRR SE, "Revised Submittal of Quality Assurance Program for Station Operation, Ginna Nuclear Power Plant," dated December 21, 1998.
11. NRR SE for Ginna, "10 CFR 50.54 Quality Assurance Program Change Review," dated March 22, 1995.
12. NRR SE for Calvert Cliffs, "10 CFR 50.54 Quality Assurance Program Change Review," dated September 25, 1996.
13. NRR SE for Niagara Mohawk Power Corporation Quality Assurance Topical Report, Revision 1, dated December 31, 1985.

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