June 21, 2002

Dr. Robert C. Mecredy
Vice President, Nuclear Operations
Rochester Gas and Electric Corporation
89 East Avenue
Rochester, NY 14649

SUBJECT: REVISION 29 TO THE QUALITY ASSURANCE PROGRAM FOR R.E. GINNA NUCLEAR POWER PLANT (TAC NO. MB4239)

Dear Dr. Mecredy:

By letters dated December 18, 2001, and April 26, 2002, Rochester Gas and Electric Corporation submitted changes to the quality assurance program for the R. E. Ginna Nuclear Power Plant in accordance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.54(a). Pursuant to 10 CFR 50.54(a)(4), the licensee has identified one change that constitutes a reduction in commitment and, therefore, requires Nuclear Regulatory Commission (NRC) approval prior to implementation. The reduction in commitment proposes an alternative to the guidance of ANSI N45.2.12-1977, "Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants," concerning followup of adverse audit findings.

The NRC's review and basis for finding the proposed alternative to be acceptable are documented in the enclosed safety evaluation. The reduction in commitment continues to satisfy the audit requirements of Appendix B to 10 CFR Part 50 and, is therefore, acceptable.

Sincerely,

/RA/

Robert Clark, Project Manager, Section 1
Project Directorate I
Division of Licensing Project Management
Office of Nuclear Reactor Regulation

Docket No. 50-244

Enclosure: Safety Evaluation

cc w/encl: See next page

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Official Record Copy

R.E. Ginna Nuclear Power Plant

cc:

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SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

PROPOSED REVISION 29 TO THE QUALITY ASSURANCE PROGRAM

ROCHESTER GAS AND ELECTRIC CORPORATION

GINNA NUCLEAR POWER PLANT

DOCKET NUMBER 50-244

1.0 INTRODUCTION

By letter dated December 18, 2001, Rochester Gas and Electric Corporation (RG&E, the licensee) submitted changes to the quality assurance program for the R. E. Ginna Nuclear Power Plant, in accordance with the provisions of Titles 10 of the *Code of Federal Regulations* (10 CFR) Section 50.54(a). The submittal was supplemented by letter dated April 26, 2002, which revises the original submittal.

The licensee has determined that one of the changes to the quality assurance program constitutes a reduction in commitment, as specified by 10 CFR 50.54(a)(4), and requires Nuclear Regulatory Commission (NRC) approval prior to implementation. This change would revise the licensee's commitment to American National Standards Institute (ANSI) N45.2.12-1977, "Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants," with regard to the conduct of external audits.

2.0 BACKGROUND

Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50 establishes requirements for conducting audits of quality assurance programs. Criterion XVIII requires, in part, that a comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. Criterion XVIII further requires that audit results shall be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, shall be taken where indicated.

Regulatory Guide (RG) 1.144, Revision 1, "Auditing of Quality Assurance Programs for Nuclear Power Plants," dated September 1980, describes a method acceptable to the NRC staff for complying with the Commission's regulations with regard to auditing of quality assurance programs for nuclear power plants. RG 1.144 endorses the guidelines of ANSI N45.2.12-1977, subject to the regulatory position of RG 1.144, Section C. The licensee's audit program conforms to RG 1.144, Revision 1.

The mechanics involved in implementation of an audit are described in Section 4 of ANSI N45.2.12-1977. Section 4.5 of this standard describes the process for the resolution of audit findings. The responsibilities of the audited organization for resolution of audit findings are described as follows:

> Management of the audited organization or activity shall review and investigate any adverse audit findings to determine and schedule appropriate corrective action including action to prevent recurrence and shall respond as requested by the audit report, giving results of the review and investigation. The response shall clearly state the corrective action taken or planned to prevent recurrence. In the event that corrective action cannot be completed within thirty days, the audited organization's response shall include a scheduled date for the corrective action. The audited organization shall provide a followup report stating the corrective action taken and the date corrective action was completed. They shall also take appropriate action to assure that corrective action is accomplished as scheduled.

The licensee has found that suppliers are sometimes reluctant to take corrective actions and sometimes the corrective actions taken are not satisfactory. In order to secure the item or service under these circumstances, the licensee proposes to assume the responsibility of the audited organization for ensuring that acceptable actions are taken. The proposed alternative is as follows:

> In lieu of the requirements of Section 4.5.1 of ANSI N45.2.12-1977, the following is used in cases where the audited organization is a supplier: RG&E shall evaluate the acceptability of actions taken to address findings from audits of suppliers. In cases where corrective actions are not taken or are not satisfactory, and the product or service of the supplier is still desired, compensatory actions shall be taken to ensure the quality of the products or services. These actions may include: commercially dedicating the product or service, restrictions placed on supplier activities, surveillance of supplier activities, or inspection/testing of supplier products and services. In cases where the vendor does not comply with 10CFR21, the vendor shall be removed from the Qualified Supplier List.
>
> - *Supplier program deficiencies that require compensatory actions by RG&E shall be documented in the station's corrective action process.*
>
> - *Compensatory actions to be taken shall be established within 30 days of discovery by RG&E of a condition that requires such actions.*
>
> - *Records of compensatory actions taken shall be retained as records in accordance with ANSI N45.2.9.*

3.0 EVALUATION

The proposed alternative allows the licensee to procure a service or product when a supplier is reluctant to take the actions necessary to resolve a licensee-identified deficiency. In essence, the licensee assumes the responsibility of the supplier for these actions. The licensee has described the process followed in implementing the alternative, by letter dated April 26, 2002.

The licensee would use its corrective action program, which conforms to the requirements of Criterion XVI of Appendix B, in resolving the audit-identified deficiency. Resolution includes documenting the deficiency, determining the cause, and reporting significant conditions to appropriate levels of management. Recurrence controls are implemented through restrictions placed on supplier activities. These restrictions are reflected in purchase orders, as controlled by licensee procurement documents. Compliance with these restrictions is ensured through source surveillance, receipt inspection, or other appropriate means. Audit findings impacting the design process would be addressed through the licensee's corrective action process or design change process.

Audits are documented and retained as quality assurance records. Compensatory actions taken are retained in the same manner as other audit records in accordance with ANSI N45.2.12 and N45.2.9. Audit findings are reviewed during follow-up and periodic audits in accordance with ANSI N45.2.12, Section 4.3.2.7 and Regulatory Guide 1.144, Section 4.b.

Based on the licensee's description of the process for implementing the proposed alternative, the NRC staff finds the proposed alternative to be acceptable. The only substantive difference from the guidance of ANSI N45.2.12 for audit followup is that the licensee is assuming the responsibility of the supplier for correcting the audit-identified deficiency. The implementing process follows the requirements of the licensee's approved QA program.

4.0 CONCLUSION

The proposed alternative provides a means for the licensee to resolve an audit-identified deficiency in a supplier's program in order to obtain a desired product or service that conforms to Appendix B requirements. The proposed alternative is acceptable in that the reduction in commitment continues to satisfy the audit requirements of Appendix B to 10 CFR Part 50.

Principal Contributor: K. Heck

Date: June 21, 2002