April 18, 2002

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

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION REGARDING CHANGES TO R. E. GINNA NUCLEAR POWER PLANT QUALITY ASSURANCE PROGRAM (TAC NO. MB4239)

Dear Dr. Mecredy:

By letter dated December 18, 2001, you submitted changes to the quality assurance program for the R.E. Ginna Nuclear Power Plant. We have completed our initial review of the submittal and have determined that additional information is necessary to complete the review.

Enclosed is the Nuclear Regulatory Commission staff's request for additional information. This request was discussed with your staff on April 15, 2002, and it was agreed that your response would be provided within 30 days from the date of this letter.

Sincerely,

/RA/

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

Docket No. 50-244

Enclosure: As stated

cc w/encl: See next page

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DATE	4/18/02	4/18/02	4/18/02	4/18/02

Official Record Copy

R.E. Ginna Nuclear Power Plant

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REQUEST FOR ADDITIONAL INFORMATION

R.E. GINNA NUCLEAR POWER PLANT

REVISED QUALITY ASSURANCE PROGRAM

By letter dated December 18, 2001, RG&E submitted an alternative to the guidance provided in ANSI N45.2.12-1977, Section 4.5.1 for vendor audit corrective action which states that:

> *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 recurrences 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 follow-up report stating the corrective action taken and the date corrective action was completed.*

The alternative to Section 4.5.1 proposed by the licensee is:

> *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 Suppliers List.*

To fully evaluate the proposed alternative, the NRC staff requests the following additional information:

1. The compensatory actions should be implemented in conformance with the licensee's Appendix B quality assurance program. With respect to compensatory actions, discuss the following:

    a. How the compensatory actions conform with the licensee's corrective action program, including provisions for cause determination, recurrence control, documentation, and reporting of significant conditions to appropriate levels of management.

    b. How procurement documents are revised to reflect actions which compensate for deficiencies in a supplier's quality assurance program.

    c. Provisions for revising vendor documents (e.g., design documents, vendor manuals) to reflect compensatory actions.

2. Records of audits are generated and retained as quality assurance records. Compensatory

actions taken to resolve deficiencies in a supplier's quality assurance program should be retained as part of the audit record. Discuss the provisions that will ensure that a complete audit record is retained, including documentation of compensatory actions.

3. The proposed alternative compensates for a supplier's "failure to comply." Describe the audit process for reinspecting areas of noncompliance, with specific reference to ANSI N45.2.12, section 4.3.2.7 and Regulatory Guide 1.144, section 4.b.

4. The proposed alternative should be revised to address timeliness requirements and inclusion of completed compensatory actions in the follow-up report.