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April 26, 2002

Mr. Robert L. Clark  
Office of Nuclear Regulatory Regulation  
U.S. Nuclear Regulatory Commission  
ATTN: Document Control Desk  
Washington, D.C. 20555-0001

SUBJECT: Revised Submittal of Quality Assurance Program for Station Operation  
R. E. Ginna Nuclear Power Plant  
Docket Number 50-244

- REFERENCES:
- a. Letter from R.C. Mecredy, RG&E, to R.L. Clark, NRC, Subject: "Revised Submittal of Quality Assurance Program for Station Operation," dated December 18, 2001.
  - b. Letter from R.L. Clark, NRC, to R.C. Mecredy, RG&E, Subject: "Request For Additional Information Regarding Changes to R. E. Ginna Nuclear Power Plant Quality Assurance Program (TAC No. MB4239)," dated April 18, 2002.

Dear Mr. Clark:

In Revision 29 of the QA Program for Station Operation (Reference a), RG&E requested the following changes:

- Revise commitment to Regulatory Guide 1.144, Rev. 1 and ANSI N45.2.12-1977. These changes were made to provide alternative methods to be used when vendor corrective action to audit findings are unacceptable.

On April 18, 2002, the NRC requested additional information concerning these changes (Reference b). RG&E is modifying the changes requested in Reference a and is providing the additional information requested.

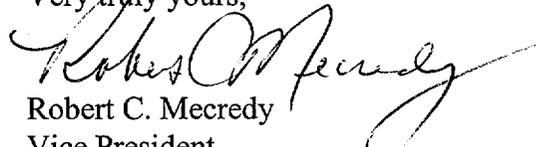
The modified changes and the additional information requested are described in Attachment 1. Changes made to Revision 28 of the Quality Assurance Program for Station Operation are denoted by highlighted text in Attachment 2.

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If you should have any questions regarding this submittal, please contact Mr. Tom Harding, 585-771-3384.

Very truly yours,



Robert C. Mecredy  
Vice President  
Nuclear Operations Group

- Attachments: 1. RG&E Response to Request for Additional Information Proposed  
Alternative to ANSI/ASME N45.2.12-1977 (Section 4.5, Audit Followup)
2. Rev. 29 of the Quality Assurance Program for Station Operation, Page 24

xc: Mr. Robert Clark (Mail Stop O-8-C2)  
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## Attachment 1

### **RG&E Response to Request for Additional Information Proposed Alternative to ANSI/ASME N45.2.12-1977 (Section 4.5, Audit Followup)**

The following additional information was requested by NRC:

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.

***Response: The Ginna Station corrective action process will be utilized to document compensatory actions taken including cause determination, documentation and reporting of significant conditions to appropriate levels of management. Recurrence is controlled by placing restrictions on vendor activities.***

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

***Response: Quality Assurance places restrictions on the supplier. These restrictions are required to be reflected in the purchase orders issued to the suppliers, in accordance with RG&E procedures. Compliance with the restrictions is accomplished through source surveillance, receipt inspection or other means.***

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

***Response: Any deviations regarding design are addressed through the station's corrective action process or design change process.***

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.

***Response: Records of compensatory actions are retained in the same manner as other audit records in accordance with ANSI N45.2.12 and N45.2.9, which is controlled by RG&E procedures.***

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.

***Response: As specified in ANSI N45.2.12, section 4.3.2.7 and Regulatory Guide 1.144, section 4.b, program deficiencies that are identified during audits are reviewed during follow-up and periodic audits, in accordance with RG&E procedures. Special attention is paid to those areas in which compensatory actions are required to determine whether the compensatory actions continue to be necessary, or if additional actions are required.***

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

***Response: RG&E proposes to revise the proposed alternative to include:***

- ***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.***

**Attachment 2**

**Rev. 29 of the Quality Assurance Program for Station Operation, Page 24**

TABLE 17.1.7-1 (cont'd)

<u>Standard, Requirement, or Guide</u>	<u>Conformance Status</u>	<u>Remarks</u>
<p>Regulatory Guide 1.144 Rev.(1)-Auditing of Quality Assurance Programs for Nuclear Power Plants</p>	<p><u>Alternate Alternative</u></p>	<p>RG 1.144 Rev.(1) incorporates ANSI N45.2.12-1977. Ginna conforms to RG 1.144 Rev.(1) and ANSI N45.2.12-1977 with the following exceptions:</p> <ul style="list-style-type: none"> <li>• A grace period of 90 days may be applied to the performance of triennial supplier audits and annual supplier evaluations described in Section C.3.b.(2).</li> <li>• In lieu of the 30 day requirement of Section 4.5.1 of ANSI N45.2.12-1977 the following is used: Corrective action response due dates and priority shall be based on safety significance. For audit findings that are determined to be significant conditions adverse to quality, the audited organization's response shall be provided within 30 days. In the event that the corrective action for an audit finding cannot be completed by the response due date, the audited organization's response shall include a scheduled date for corrective action.</li> <li>• 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: <u>RG&amp;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.</u></li> </ul> <p><u>The following additional controls shall be applied when this alternative is used:</u></p> <ul style="list-style-type: none"> <li>• <u>Supplier program deficiencies that require compensatory actions by RG&amp;E shall be documented in the station's corrective action process.</u></li> <li>• <u>Compensatory actions to be taken shall be established within 30 days of discovery by RG&amp;E of a condition that requires such actions.</u></li> <li>• <u>Records of compensatory actions taken shall be retained as records in accordance with ANSI N45.2.9.</u></li> </ul>