



ROCHESTER GAS AND ELECTRIC CORPORATION • 89 EAST AVENUE, ROCHESTER, N.Y. 14649-0001



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ROBERT C. MECREDDY
Vice President
Nuclear Operations

August 5, 1996

U.S. Nuclear Regulator Commission
Document Control Desk
Attn: Guy S. Vissing
Project Directorate I-1
Washington, D.C. 20555

Subject: Additional Response to NRC Integrated Inspection Report
50-244/96-01, dated May 8, 1996
R.E. Ginna Nuclear Power Plant

Dear Mr. Vissing:

The purpose of this letter is to provide clarification of issues concerning the performance of Quality Assurance audits that were identified in the Plant Support Summary and Section 4.1.7 of the subject Integrated Inspection Report. This letter addresses the question of whether holding pre-audit discussions with audited groups jeopardizes the independence and objectivity of audit conduct, and provides further rationale for the acceptability of our current practice.

Within the Plant Support Executive Summary of the subject Inspection Report, is the statement that "...the inspectors questioned the independence of the audit process." While the EP inspection was being conducted and during discussions relative to the pre-audit interviews, no questions were raised relative to "independence of the audit process". The requirements of ANSI/ASME N45.2.12-1977 relative to independence are basically twofold. Section 2.1 requires that auditors be independent of any direct responsibility for performance of the activity they audit. Also, Section 3.3.1 requires a management policy establishing organizational independence and authority of the auditors. This policy is established in audit procedures which are approved by department management. No issues were expressed relative to these requirements and further review within RG&E has not identified any deficiencies with independence of the audit process.

Relative to the pre-audit discussions, an explanation of our process for audit preparations may provide clarification. Planning for internal audits begins with a review of audit planning guides, applicable industry information, recent Technical Specification amendments, contacting auditee supervision for audit plan input and discussing audit area information and performance with other knowledgeable quality group personnel. The pre-audit discussions with the audited

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organization occur 2 to 6 weeks prior to the audit entrance meeting and are in addition to other aspects of audit plan preparation. The information gained during the preparation is used to assemble the audit checklist questions and the formal Audit Plan. If the audited organization has identified additional concerns, the audit team leader determines whether additional time and resources are needed. This may result in providing additional technical specialists or other resource reallocation.

The use of the pre-audit discussions originated with a Process Improvement Team in 1994. The intention was to get additional input to the planning process while allowing the audited organization to be more responsive to the audit and enhance cooperation during the audit. The audit process by itself is sufficiently comprehensive and probing to provide assurance of uncovering programmatic issues; identification of issues of concern to the audited organization provides us an enhancement that adds further value to the audit, while meeting program requirements.

In Section 4.1.7 of the report, the inspectors questioned whether having pre-audit information provided with identified weaknesses could "...raise questions about the capability of the audit team to identify program problems independently." The capability of the audit program to identify problems is assessed via the annual Audit Program Effectiveness evaluation, biennial audits directed by the NSARB, as well as, through assessment by outside entities, including the NRC. Since this is a crucial role of Quality Assurance, the results of these evaluations are closely reviewed by RG&E management. The capability of the individual auditors is closely controlled via strict training and experience requirements, as well as, normal supervisory work reviews. No evidence has been observed which would indicate either the process, or individual auditors, are failing to identify problems.

Also in Section 4.1.7, the inspectors questioned "... the audit team's capability of remaining objective in reaching its conclusions if an issue has already been characterized as a problem...". While no evidence of this occurring has been observed (by RG&E or the NRC Inspectors), should it occur, it would tend to bias the team to consider the audited area to be more problematic than it was. This would seem to be a conservative result, but one which is not expected due to the experience and training of the audit personnel. The ability to stay unbiased and focused is an important aspect of auditor training and performance evaluation.

We appreciate the NRC input in this area and hope this serves to clarify the inspectors' questions.

Very truly yours,

Thomas A. Marlow for

Robert C. Mecredy

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xc: Mr. Guy Vissing (Mail Stop 14C7)
Project Directorate I-1
Washington, D.C. 20555

U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

Ginna Senior Resident Inspector

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