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Gregory M. Rueger
Senior Vice President and
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May 8, 1992

PG&E Letter No. DCL-92-117

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

Re: Docket No. 50-275, OL-DPR-80
Docket No. 50-323, OL-DPR-82
Diablo Canyon Units 1 and 2
Reply to Notice of Violation in NRC Inspection Report 50-275/92-09
and 50-323/92-09

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Gentlemen:

NRC Inspection Report 50-275/92-09 and 50-323/92-09, dated April 8, 1992, contained a Notice of Violation citing one Severity Level IV violation regarding the failure to properly track a draft Audit Finding Report and one Severity Level IV violation regarding inadequacies in compensatory actions taken for Nonconformance Report DCO-89-QA-N007, that in turn resulted in PG&E 1989 Audit 89295S being unsatisfactory.

PG&E's response to the Notice of Violation is contained in Enclosure 1. PG&E agrees with the violations as noted, and believes that the corrective actions discussed in Enclosure 1 are adequate to resolve the NRC concerns. Since the occurrence of these events in 1989, PG&E has established measures to compensate for any associated impact, which PG&E believes will demonstrate the acceptability of the generator.

During our review of the Inspection Report, PG&E identified several instances where clarification of NRC observations could provide a more complete understanding of the events in question. These clarifications are contained in Enclosure 2. While these clarifications do not change our response to the violations, PG&E considers the clarifications important to the NRC's perception of the problems.

Sincerely,

Gregory M. Rueger

cc: Dyle G. Acker
Ann P. Hodgdon
Forrest R. Huey
Dennis F. Kirsch
John B. Martin

Steven M. Matthews
Philip J. Morrill
Harry Rood
CPUC
Diablo Distribution

DCO-92-QA-N004

Enclosures

5753S/85K/ALN/2237

9205140268 11 pp.



ENCLOSURE 1

**REPLY TO NOTICE OF VIOLATION IN
NRC INSPECTION REPORT (IR) 50-275/92-09 AND 50-323/92-09**

On April 8, 1992, as part of NRC IR 50-275/92-09 and 50-323/92-09, NRC Region V issued a Notice of Violation (NOV) citing two Severity Level IV violations for Diablo Canyon Power Plant Units 1 and 2.

PG&E had previously met with the NRC in Rockville, Maryland, on February 20, 1992, at which time several issues underlying the NOV were discussed. PG&E initiated Nonconformance Report (NCR) DCO-92-QA-N004 on February 24, 1992, to evaluate these issues. The NRC conducted their inspection March 10 and 11, 1992, and IR 50-275/92-09 and 50-323/92-09 presents the inspection results.

The statements of violation and PG&E's responses follow.

STATEMENT OF VIOLATION A

10 CFR 50, Appendix B, Criterion V, (Instructions, Procedures, and Drawings) prescribes that "Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings...and shall be accomplished in accordance with these instructions, procedures, or drawings."

Procedure QAA-WI-317, Revision 0, dated 11/26/87, titled "External Audit Finding Report Processing," states in paragraph IV.B. that "AFRs that are sent to suppliers shall be tracked in accordance with QAA-WI-302." Procedure QAA-WI-305, Revision 4, dated 01/13/88, titled "External Audit Report Package Format and Content," states in paragraph IV.A.9 that "The audit package shall consist of the...Audit Finding Report.."

An Audit Finding Report, identified pursuant to a supplier audit of Peebles Electric Products on December 11, 1989, identified that "The commercial grade dedication program has not been fully developed for PG&E identified critical parts."

Contrary to the above, as of February 20, 1992, the above audit finding report was not included in the package of the December 11, 1989 audit of Peebles Electric Products, issued by report on April 17, 1990, and was not tracked as required by Procedure QAA-WI-302.

This is a Severity Level IV violation (Supplement 1).

BACKGROUND

PG&E Audit 89295S was conducted on December 11, 1989, to assess whether NEI-Peebles - Electrical Products, Inc. (P-EP) was qualified for placement on PG&E's Qualified Suppliers List (QSL). During the performance of Audit 89295S, three draft Audit Finding Reports (AFRs) were written, the third of which was written to address a potential problem with the specific application



of P-EP's commercial grade dedication activities relative to the generator for PG&E's sixth emergency diesel generator (EDG). Specifically, draft AFR No. 3 stated, "The commercial grade dedication program has not been fully developed for PG&E identified critical parts." The intent of the draft finding was to document the need for further evaluation and documentation of the critical parts, critical characteristics, and testing requirements for items to be supplied by P-EP. Copies of these draft AFRs were given to P-EP by the audit team leader (ATL) at the completion of the audit.

Subsequent to completion of Audit 89295S, but prior to issuance of the audit report, P-EP formally responded to the draft AFRs by letter dated January 8, 1990, with the draft AFRs attached. P-EP's response to draft AFR No. 3 indicated that P-EP "will comply with dedication procedures as formulated with PG&E engineers, 12/11/89." The response also indicated that inspection and test results would be retained by P-EP for PG&E review and included some representative dedication procedures. Based on P-EP's response, the ATL concluded that the issue he had raised in draft AFR No. 3 was adequately addressed and could be closed based on the following rationale:

- PG&E had not fully identified the critical parts and critical characteristics at the time of the audit, and thus the AFR drafted during the audit was premature.
- P-EP had a basic dedication program.
- P-EP submitted representative test dedication procedures.
- Subsequent to the audit, but prior to issuance of the final audit report, P-EP and PG&E had reached agreement regarding critical parts and critical characteristics and such information was to be transmitted to P-EP in January 1990 as part of PG&E's Purchase Order.
- PG&E was going to perform an implementation audit in the future, and P-EP's implementation of the dedication program could be verified at that time.

On this basis, the ATL considered draft AFR No. 3 closed. However, contrary to procedure QAA-WI-305, "External Audit Report Package Format and Content," the ATL did not include draft AFR No. 3 in the final audit report. Also, the ATL did not include any reference in the final audit report as to why draft AFR No. 3 was not issued.

REASON FOR THE VIOLATION IF ADMITTED

PG&E agrees that the draft AFR No. 3 in question was not included in the final audit report nor tracked by procedure as described in Violation A.

The Technical Review Group (TRG) investigating this situation as part of DCO-92-QA-N004 has determined that cancellation of draft AFR No. 3 was not handled in accordance with procedure QAA-WI-317. This procedure required that canceled AFRs be so noted in the AFR log with appropriate justification.

Based on recent interviews with the ATL who issued draft AFR No. 3, as well as others associated with the audit, the TRG for DCO-92-QA-N004 determined that



the ATL had closed draft AFR No. 3 based on his judgement and was not influenced in any way by his supervision or by PG&E Engineering.

CORRECTIVE STEPS TAKEN AND RESULTS ACHIEVED

NCR DCO-92-QA-N004 was initiated February 24, 1992, to address this and other anomalies associated with the qualification of P-EP. As a corrective action for the non-issuance of draft AFR No. 3, audits currently being reviewed under temporary procedure PQA-WI-T-4, "Adequacy Evaluations of Supplier Audits" (see discussion of audit review under Violation B), are also being reviewed for consistency of AFR descriptions with checklist results. Results of the reviews show no similar conditions. In addition, a review of the files of audits addressed under Violation B did not yield any unissued draft AFRs.

CORRECTIVE STEPS THAT WILL BE TAKEN TO AVOID FURTHER VIOLATIONS

Procedure PQA-WI-18.8, "Audit Finding Reports" (which replaced QAA-WI-317), has been revised to clarify requirements for documenting, tracking, and canceling draft AFRs. Training on this procedure change will be provided to Procurement Quality Assurance (PQA) auditors and supervisors regarding the procedure change and the reasons for the change.

DATE WHEN FULL COMPLIANCE WILL BE ACHIEVED

The training for PQA auditors and supervisors on the procedure change has commenced and will be completed by May 29, 1992.



STATEMENT OF VIOLATION B

10 CFR 50, Appendix B, Criterion XVI (Corrective Action) requires, in part, that "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition."

Contrary to the above, as of February 22, 1990, PG&E had failed to take appropriate measures to assure correction of deficiencies that had been identified by the licensee involving inadequate auditing of suppliers of safety related equipment. In particular, corrective actions associated with a licensee Nonconformance Report (NCR 89-N007), issued on July 7, 1989, were not implemented for Audit 89295S, performed on December 11, 1989. This failure resulted in the placing of a safety related electrical generator purchase order with a supplier whose quality assurance program did not conform to the requirements of the procurement documents.

This is a Severity Level IV violation (Supplement 1).

BACKGROUND

As indicated in the response to Violation A, Audit 89295S was conducted December 11, 1989, to assess whether P-EP was qualified for placement on PG&E's QSL. As a result of the audit, P-EP was qualified to supply a generator for the sixth EDG. However, PG&E's subsequent implementation Audit 90197S of P-EP in August 1990 found significant deficiencies in P-EP's implementation of its QA program, in contrast with the results of Audit 89295S.

The TRG investigating this situation as a part of DCO-92-QA-N004 has determined the root cause was less-than-adequate audit planning, with contributory causes including:

- Inadequate time allotted for the audit.
- Less-than-adequate supervisory direction and communication.
- In 1989, the Supplier Audit Section of PG&E's QA Department was undergoing transitional changes to implement certain aggressive corrective actions of NCR DCO-89-QA-N007, coupled with the QA Department reorganization begun in December 1989 and finalized in April 1990. This was a major contributory cause to the less-than-adequate audit planning.



REASON FOR THE VIOLATION IF ADMITTED

PG&E agrees with the violation.

Audit 89295S was conducted while the corrective actions for DCO-89-QA-N007 were being implemented. DCO-89-QA-N007 was initiated in July 1989 to address inadequate supplier audits. Corrective actions for DCO-89-QA-N007 were begun in August 1989, but were not fully implemented until December 1990. As a result, Audit 89295S, conducted in December 1989, did not totally benefit from the DCO-89-QA-N007 corrective actions. The TRG for DCO-92-QA-N004 determined that DCO-89-QA-N007 focused on audits completed during the period from August 1986 - August 1989. DCO-89-QA-N007 had concentrated primarily on identifying and correcting past deficiencies and had not included an action to check supplier audits conducted during the August 1989 - December 1990 time-frame (or "window"), when DCO-89-QA-N007 corrective actions were being implemented, and thus contributed to PG&E's delay in recognizing the deficiencies of Audit 89295S until August 1990.

While PG&E agrees that Audit 89295S was inadequate, we are confident that the DCO-89-QA-N007 corrective actions would have precluded the discrepancies of Audit 89295S had those corrective actions been fully implemented in December 1989.

CORRECTIVE STEPS TAKEN AND RESULTS ACHIEVED

P-EP was re-audited on August 15-17, 1990 (Audit 90197S). As a result of significant findings identified during the audit, P-EP was removed from PG&E's QSL, to be later reinstated with compensatory measures for a one-time purchase.

PG&E participated with P-EP in their audit of Peebles Electric Machines-Scotland (PEM) on October 8-12, 1990. This audit was prompted by the significant findings identified during audit 90197S of P-EP in August 1990.

An Engineering Evaluation was initiated in August 1990 to address the impact of the findings identified during Audit 90197S of P-EP. The evaluation was later expanded to address the findings identified during the October 1990 joint P-EP/PG&E audit of PEM.

DCO-92-QA-N004 was initiated February 24, 1992, based on questions raised at the February 20, 1992, meeting with the NRC and to address these audit inconsistencies. The TRG acknowledged that an earlier Quality Evaluation (Q0008302, dated January 16, 1991) had addressed these audit inconsistencies, had concluded that similar causal factors resulted in the inconsistencies, and had concluded that the situation was an isolated case. However, the TRG concluded on March 8, 1992, that, based on its determination of the root cause and contributory causes, criteria should be developed to evaluate the acceptability of other supplier audits performed, and thus the acceptability of items procured during the December 1989 time-frame. As a result, temporary procedure PQA-WI-T-4 was developed to establish criteria for adequacy evaluations of supplier audits conducted during that time-frame (window). The window selected was August 1989 through December 1990 on the basis that the DCO-89-QA-N007 corrective actions began to be implemented in August 1989 and



were not fully implemented until December 1990 and that DCO-89-QA-N007 did not fully take into consideration the audits being conducted during the window.

The review of audits used a two-tier review approach, consisting of an initial review by a Review Team (RT) and a second review by a Review Committee (RC). This approach resulted in each audit report being reviewed twice by different reviewers.

- The RT consisted of auditors from within PQA. Use of the PQA auditors was considered essential for the initial review because of their expertise in supplier auditing. The RT was selected such that no RT member had prior responsibility as an audit member or approving supervisor for the audits assigned for review.
- The RC was selected by the TRG for DCO-92-QA-N004 and consisted of four senior members: two from PQA, one from Nuclear Safety Assessment and Regulatory Affairs, and one from Nuclear Engineering and Construction Services - Quality Engineering.

By using this two-tier approach in conjunction with the diversity of RC members, we achieved a check and balance in the results of the reviews, while maintaining the necessary independence to reach objective conclusions.

The total population of audits considered for this review consisted of 121 audits (excluding Audit 89295S) that were performed or issued during the window. Since the ultimate purpose of the review was to assure unacceptable items were not procured during the window, it was recognized that some audits would not be relevant to the review. Accordingly, the audit population to be reviewed was reduced to 74 by eliminating some audits based on the applicability of any one of the following criteria:

- Audits previously evaluated as part of DCO-89-QA-N007.
- Audits replaced by requalification activities subsequent to the "window."
- Initial qualification audits from which the supplier was not placed on the QSL.
- Audits that removed suppliers from the QSL with appropriate evaluations of past purchases.
- Implementation audits not used for qualification of suppliers.

All 74 audits received a detailed review by the RT, followed by a review of RT results by the RC. As detailed in procedure PQA-WI-T-4, the reviews included:

- Review of audit checklists to determine if the summary documentation addresses each criterion adequately, including sufficient objective evidence to support the conclusion.
- Determination if the AFRs identified in the audit report are consistent with the results documented within the audit checklists.
- Determination if the audit sufficiently evaluates the suppliers' QA program for the identified criteria.



- Determination if the audits exhibited attributes of Audit 89295S of P-EP, namely: (a) audit scope changes; (b) less-than-adequate audit duration or audit team size; and (c) less-than-adequate notification time of the need to perform an audit.

Reviews by the RT and RC have been completed for the 74 audits. Although the TRG has not completed their analysis of the results, the following preliminary observations are presented for information:

- 9 out of the 74 audits were found unsatisfactory.
- 7 of the 9 unsatisfactory audits occurred between October 1989 to February 1990.
- No unsatisfactory audits after August 1990 were identified.

The results demonstrate that some unsatisfactory audits did occur in the window, with most of them occurring at about the same time-frame as the December 1989 Audit 89295S performed at P-EP. The results demonstrate that the DCO-89-QA-N007 corrective actions, while not fully implemented until December 1990, were producing the planned effect; namely, no unsatisfactory audits were found in the window after August 1990.

The nine audits determined to be unsatisfactory were judged so because they lacked sufficient documented objective evidence to support the auditors' conclusions regarding significant requirements. In other words, a reviewer - using only the documentation contained in the audit checklists - could not be certain that the suppliers' quality programs contained an important programmatic element, or whether the element was being adequately implemented. Based on the audit reviews conducted for NCR DCO-89-QA-N007, our experience indicates that, in cases like these nine audits, we only have documentation or oversight problems on the part of the auditors, and not unqualifiable suppliers or deficient products. However, this will be confirmed for these nine audits via the use of applicable third-party audits or by reauditing the supplier. Any significant deficiencies identified in these nine suppliers' quality programs will be evaluated for impact upon their qualification status and upon past purchases in accordance with existing PG&E procedures. These followup actions will be tracked and resolved as part of the corrective actions for DCO-92-QA-N004.

CORRECTIVE STEPS THAT HAVE BEEN, OR WILL BE, TAKEN TO AVOID FURTHER VIOLATIONS

While it is agreed that Audit 89295S was inadequate, PG&E is confident that the DCO-89-QA-N007 corrective actions would have precluded these inadequacies had the corrective actions been fully implemented in December 1989. Since these corrective actions have been in place since December 1990, no further actions are deemed necessary other than emphasizing the value of audit planning and imparting lessons learned from the nine unsatisfactory audits.

These corrective actions are considered sufficient to preclude further violations.



DATE WHEN FULL COMPLIANCE WILL BE ACHIEVED

An assessment of the need for reauditing any of the nine suppliers, and for contacting the suppliers and establishing a schedule for any reaudits, will be completed by May 29, 1992. The training for auditors and supervisors in the importance of audit planning and the lessons learned from the unsatisfactory audits will be completed by May 29, 1992.



ENCLOSURE 2

ADDITIONAL COMMENTS TO
NRC INSPECTION REPORT (IR) 50-275/92-09 AND 50-323/92-09

During our review of the IR, PG&E identified several instances where clarification of NRC observations could provide a more complete understanding of the events in question. While these clarifications do not change our response to the violations, PG&E considers the clarifications important to the NRC's perception of the problems. Three items are noted below.

1. Results of PG&E Audit 89214S of PEM

- Page 3 of the IR, first bullet, states in part:

PG&E conducted an audit of PEM during August 1989 in an attempt to requalify PEM as a qualified supplier. As a result of problems found, the audit was deemed not sufficient to requalify PEM and was not listed on the QSL.

The chronology of pertinent events was as follows:

- PEM's listing on the QSL was based on a December 1986 audit (Audit 86255S).
- PEM was removed from the QSL in January 1990 as a result of NCR DCO-89-QA-N007, which concluded that qualification Audit 86255S was inadequate due to lack of objective evidence.
- The August 1989 Audit 89214S of PEM was a preplanned followup to the July 1989 Audit 89180S of P-EP, and did not result in the removal of PEM from the QSL. Audit 89214S of PEM could have been used to reinstate PEM on the QSL; however, it was determined that, because PEM was a sub-supplier to P-EP, PEM was not required to be on the QSL.

2. References to QA Specification SP-D-Pebbles

- Page 3 of the IR, 4th double bullet, states:

The audit was based upon a draft procurement specification (SP-D-Pebbles/Rev. 3) which was not issued until later, on February 6, 1991.

QA Specification SP-D-Pebbles, Revision 3, was an approved QA specification and was issued on October 11, 1989.

- Page 3 of the IR, 5th double bullet, states:

The audit was conducted even prior to the issuance of specification SP-D-Pebbles/Rev. 2 on February 22, 1990. The audit report was finally issued on April 17, 1990.



This statement incorrectly references the specification revision and issue date. The audit was conducted after the issuance of SP-D-Peebles, Revision 3, dated October 11, 1989. (SP-D-Peebles, Revision 2, was dated August 22, 1989.) The date referred to (February 22, 1990) is the date of issuance of the purchase order ZS-1539-AB-9, Revision 2.

3. Houston Light & Power Audit Results

- Page 14 of the IR, first paragraph of Item b, states in part:

As a result of the inadequate 1989 audit, a safety-related purchase order was placed with P-EP in February 1990, which did not meet 10 CFR 50, Appendix B, quality assurance program requirements, as specified in the purchase order documents. This deficiency was not identified until receipt of an audit from Houston Light & Power in July 1990 (disqualifying P-EP for safety-related procurement), and a similarly disqualifying PG&E audit performed in August 1990.

As indicated under Item 1, "Purpose of Draft AFR No. 3," PG&E did not recognize that significant deficiencies existed in P-EP's program until Audit 90197S was conducted. The Houston Light & Power (HL&P) audit was conducted July 25 through 27, 1990. PG&E received HL&P's audit report on September 6, 1990, approximately two weeks after completion of PG&E Audit 90197S, which was conducted August 15 through 17, 1990. PG&E Audit 90197S was the basis of disqualification of P-EP, not the HL&P audit as stated in the IR.



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 RUEGER, G.M. Pacific Gas & Electric Co.
 RECIP. NAME RECIPIENT AFFILIATION
 Document Control Branch (Document Control Desk)

SUBJECT: Responds to NRC ltr re violations noted in Insp Repts
 50-275/92-09 & 50-323/92-09. Corrective actions:
 NCR DCO-92-QA-N004 was initiated 920224, to address anomalies
 associated w/qualification of P-EP.

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Pacific Gas and Electric Company

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Gregory M. Rueger
Senior Vice President and
General Manager
Nuclear Power Generation

May 8, 1992

PG&E Letter No. DCL-92-117



U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

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Gregory M. Rueger

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DCO-92-QA-N004

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ENCLOSURE 1

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On this basis, the ATL considered draft AFR No. 3 closed. However, contrary to procedure QAA-WI-305, "External Audit Report Package Format and Content," the ATL did not include draft AFR No. 3 in the final audit report. Also, the ATL did not include any reference in the final audit report as to why draft AFR No. 3 was not issued.

REASON FOR THE VIOLATION IF ADMITTED

PG&E agrees that the draft AFR No. 3 in question was not included in the final audit report nor tracked by procedure as described in Violation A.

The Technical Review Group (TRG) investigating this situation as part of DCO-92-QA-N004 has determined that cancellation of draft AFR No. 3 was not handled in accordance with procedure QAA-WI-317. This procedure required that canceled AFRs be so noted in the AFR log with appropriate justification.

Based on recent interviews with the ATL who issued draft AFR No. 3, as well as others associated with the audit, the TRG for DCO-92-QA-N004 determined that



the ATL had closed draft AFR No. 3 based on his judgement and was not influenced in any way by his supervision or by PG&E Engineering.

CORRECTIVE STEPS TAKEN AND RESULTS ACHIEVED

NCR DCO-92-QA-N004 was initiated February 24, 1992, to address this and other anomalies associated with the qualification of P-EP. As a corrective action for the non-issuance of draft AFR No. 3, audits currently being reviewed under temporary procedure PQA-WI-T-4, "Adequacy Evaluations of Supplier Audits" (see discussion of audit review under Violation B), are also being reviewed for consistency of AFR descriptions with checklist results. Results of the reviews show no similar conditions. In addition, a review of the files of audits addressed under Violation B did not yield any unissued draft AFRs.

CORRECTIVE STEPS THAT WILL BE TAKEN TO AVOID FURTHER VIOLATIONS

Procedure PQA-WI-18.8, "Audit Finding Reports" (which replaced QAA-WI-317), has been revised to clarify requirements for documenting, tracking, and canceling draft AFRs. Training on this procedure change will be provided to Procurement Quality Assurance (PQA) auditors and supervisors regarding the procedure change and the reasons for the change.

DATE WHEN FULL COMPLIANCE WILL BE ACHIEVED

The training for PQA auditors and supervisors on the procedure change has commenced and will be completed by May 29, 1992.



STATEMENT OF VIOLATION B

10 CFR 50, Appendix B, Criterion XVI (Corrective Action) requires, in part, that "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition."

Contrary to the above, as of February 22, 1990, PG&E had failed to take appropriate measures to assure correction of deficiencies that had been identified by the licensee involving inadequate auditing of suppliers of safety related equipment. In particular, corrective actions associated with a licensee Nonconformance Report (NCR 89-N007), issued on July 7, 1989, were not implemented for Audit 89295S, performed on December 11, 1989. This failure resulted in the placing of a safety related electrical generator purchase order with a supplier whose quality assurance program did not conform to the requirements of the procurement documents.

This is a Severity Level IV violation (Supplement 1).

BACKGROUND

As indicated in the response to Violation A, Audit 89295S was conducted December 11, 1989, to assess whether P-EP was qualified for placement on PG&E's QSL. As a result of the audit, P-EP was qualified to supply a generator for the sixth EDG. However, PG&E's subsequent implementation Audit 90197S of P-EP in August 1990 found significant deficiencies in P-EP's implementation of its QA program, in contrast with the results of Audit 89295S.

The TRG investigating this situation as a part of DCO-92-QA-N004 has determined the root cause was less-than-adequate audit planning, with contributory causes including:

- Inadequate time allotted for the audit.
- Less-than-adequate supervisory direction and communication.
- In 1989, the Supplier Audit Section of PG&E's QA Department was undergoing transitional changes to implement certain aggressive corrective actions of NCR DCO-89-QA-N007, coupled with the QA Department reorganization begun in December 1989 and finalized in April 1990. This was a major contributory cause to the less-than-adequate audit planning.



REASON FOR THE VIOLATION IF ADMITTED

PG&E agrees with the violation.

Audit 89295S was conducted while the corrective actions for DCO-89-QA-N007 were being implemented. DCO-89-QA-N007 was initiated in July 1989 to address inadequate supplier audits. Corrective actions for DCO-89-QA-N007 were begun in August 1989, but were not fully implemented until December 1990. As a result, Audit 89295S, conducted in December 1989, did not totally benefit from the DCO-89-QA-N007 corrective actions. The TRG for DCO-92-QA-N004 determined that DCO-89-QA-N007 focused on audits completed during the period from August 1986 - August 1989. DCO-89-QA-N007 had concentrated primarily on identifying and correcting past deficiencies and had not included an action to check supplier audits conducted during the August 1989 - December 1990 time-frame (or "window"), when DCO-89-QA-N007 corrective actions were being implemented, and thus contributed to PG&E's delay in recognizing the deficiencies of Audit 89295S until August 1990.

While PG&E agrees that Audit 89295S was inadequate, we are confident that the DCO-89-QA-N007 corrective actions would have precluded the discrepancies of Audit 89295S had those corrective actions been fully implemented in December 1989.

CORRECTIVE STEPS TAKEN AND RESULTS ACHIEVED

P-EP was re-audited on August 15-17, 1990 (Audit 90197S). As a result of significant findings identified during the audit, P-EP was removed from PG&E's QSL, to be later reinstated with compensatory measures for a one-time purchase.

PG&E participated with P-EP in their audit of Peebles Electric Machines-Scotland (PEM) on October 8-12, 1990. This audit was prompted by the significant findings identified during audit 90197S of P-EP in August 1990.

An Engineering Evaluation was initiated in August 1990 to address the impact of the findings identified during Audit 90197S of P-EP. The evaluation was later expanded to address the findings identified during the October 1990 joint P-EP/PG&E audit of PEM.

DCO-92-QA-N004 was initiated February 24, 1992, based on questions raised at the February 20, 1992, meeting with the NRC and to address these audit inconsistencies. The TRG acknowledged that an earlier Quality Evaluation (Q0008302, dated January 16, 1991) had addressed these audit inconsistencies, had concluded that similar causal factors resulted in the inconsistencies, and had concluded that the situation was an isolated case. However, the TRG concluded on March 8, 1992, that, based on its determination of the root cause and contributory causes, criteria should be developed to evaluate the acceptability of other supplier audits performed, and thus the acceptability of items procured during the December 1989 time-frame. As a result, temporary procedure PQA-WI-T-4 was developed to establish criteria for adequacy evaluations of supplier audits conducted during that time-frame (window). The window selected was August 1989 through December 1990 on the basis that the DCO-89-QA-N007 corrective actions began to be implemented in August 1989 and



were not fully implemented until December 1990 and that DCO-89-QA-N007 did not fully take into consideration the audits being conducted during the window.

The review of audits used a two-tier review approach, consisting of an initial review by a Review Team (RT) and a second review by a Review Committee (RC). This approach resulted in each audit report being reviewed twice by different reviewers.

- The RT consisted of auditors from within PQA. Use of the PQA auditors was considered essential for the initial review because of their expertise in supplier auditing. The RT was selected such that no RT member had prior responsibility as an audit member or approving supervisor for the audits assigned for review.
- The RC was selected by the TRG for DCO-92-QA-N004 and consisted of four senior members: two from PQA, one from Nuclear Safety Assessment and Regulatory Affairs, and one from Nuclear Engineering and Construction Services - Quality Engineering.

By using this two-tier approach in conjunction with the diversity of RC members, we achieved a check and balance in the results of the reviews, while maintaining the necessary independence to reach objective conclusions.

The total population of audits considered for this review consisted of 121 audits (excluding Audit 89295S) that were performed or issued during the window. Since the ultimate purpose of the review was to assure unacceptable items were not procured during the window, it was recognized that some audits would not be relevant to the review. Accordingly, the audit population to be reviewed was reduced to 74 by eliminating some audits based on the applicability of any one of the following criteria:

- Audits previously evaluated as part of DCO-89-QA-N007.
- Audits replaced by requalification activities subsequent to the "window."
- Initial qualification audits from which the supplier was not placed on the QSL.
- Audits that removed suppliers from the QSL with appropriate evaluations of past purchases.
- Implementation audits not used for qualification of suppliers.

All 74 audits received a detailed review by the RT, followed by a review of RT results by the RC. As detailed in procedure PQA-WI-T-4, the reviews included:

- Review of audit checklists to determine if the summary documentation addresses each criterion adequately, including sufficient objective evidence to support the conclusion.
- Determination if the AFRs identified in the audit report are consistent with the results documented within the audit checklists.
- Determination if the audit sufficiently evaluates the suppliers' QA program for the identified criteria.



- Determination if the audits exhibited attributes of Audit 89295S of P-EP, namely: (a) audit scope changes; (b) less-than-adequate audit duration or audit team size; and (c) less-than-adequate notification time of the need to perform an audit.

Reviews by the RT and RC have been completed for the 74 audits. Although the TRG has not completed their analysis of the results, the following preliminary observations are presented for information:

- 9 out of the 74 audits were found unsatisfactory.
- 7 of the 9 unsatisfactory audits occurred between October 1989 to February 1990.
- No unsatisfactory audits after August 1990 were identified.

The results demonstrate that some unsatisfactory audits did occur in the window, with most of them occurring at about the same time-frame as the December 1989 Audit 89295S performed at P-EP. The results demonstrate that the DCO-89-QA-N007 corrective actions, while not fully implemented until December 1990, were producing the planned effect; namely, no unsatisfactory audits were found in the window after August 1990.

The nine audits determined to be unsatisfactory were judged so because they lacked sufficient documented objective evidence to support the auditors' conclusions regarding significant requirements. In other words, a reviewer - using only the documentation contained in the audit checklists - could not be certain that the suppliers' quality programs contained an important programmatic element, or whether the element was being adequately implemented. Based on the audit reviews conducted for NCR DCO-89-QA-N007, our experience indicates that, in cases like these nine audits, we only have documentation or oversight problems on the part of the auditors, and not unqualifiable suppliers or deficient products. However, this will be confirmed for these nine audits via the use of applicable third-party audits or by reauditing the supplier. Any significant deficiencies identified in these nine suppliers' quality programs will be evaluated for impact upon their qualification status and upon past purchases in accordance with existing PG&E procedures. These followup actions will be tracked and resolved as part of the corrective actions for DCO-92-QA-N004.

CORRECTIVE STEPS THAT HAVE BEEN, OR WILL BE, TAKEN TO AVOID FURTHER VIOLATIONS

While it is agreed that Audit 89295S was inadequate, PG&E is confident that the DCO-89-QA-N007 corrective actions would have precluded these inadequacies had the corrective actions been fully implemented in December 1989. Since these corrective actions have been in place since December 1990, no further actions are deemed necessary other than emphasizing the value of audit planning and imparting lessons learned from the nine unsatisfactory audits.

These corrective actions are considered sufficient to preclude further violations.



DATE WHEN FULL COMPLIANCE WILL BE ACHIEVED

An assessment of the need for reauditing any of the nine suppliers, and for contacting the suppliers and establishing a schedule for any reaudits, will be completed by May 29, 1992. The training for auditors and supervisors in the importance of audit planning and the lessons learned from the unsatisfactory audits will be completed by May 29, 1992.



ENCLOSURE 2

ADDITIONAL COMMENTS TO
NRC INSPECTION REPORT (IR) 50-275/92-09 AND 50-323/92-09

During our review of the IR, PG&E identified several instances where clarification of NRC observations could provide a more complete understanding of the events in question. While these clarifications do not change our response to the violations, PG&E considers the clarifications important to the NRC's perception of the problems. Three items are noted below.

1. Results of PG&E Audit 89214S of PEM

- Page 3 of the IR, first bullet, states in part:

PG&E conducted an audit of PEM during August 1989 in an attempt to requalify PEM as a qualified supplier. As a result of problems found, the audit was deemed not sufficient to requalify PEM and was not listed on the QSL.

The chronology of pertinent events was as follows:

- PEM's listing on the QSL was based on a December 1986 audit (Audit 86255S).
- PEM was removed from the QSL in January 1990 as a result of NCR DC0-89-QA-N007, which concluded that qualification Audit 86255S was inadequate due to lack of objective evidence.
- The August 1989 Audit 89214S of PEM was a preplanned followup to the July 1989 Audit 89180S of P-EP, and did not result in the removal of PEM from the QSL. Audit 89214S of PEM could have been used to reinstate PEM on the QSL; however, it was determined that, because PEM was a sub-supplier to P-EP, PEM was not required to be on the QSL.

2. References to QA Specification SP-D-Peebles

- Page 3 of the IR, 4th double bullet, states:

The audit was based upon a draft procurement specification (SP-D-Peebles/Rev. 3) which was not issued until later, on February 6, 1991.

QA Specification SP-D-Peebles, Revision 3, was an approved QA specification and was issued on October 11, 1989.

- Page 3 of the IR, 5th double bullet, states:

The audit was conducted even prior to the issuance of specification SP-D-Peebles/Rev. 2 on February 22, 1990. The audit report was finally issued on April 17, 1990.



This statement incorrectly references the specification revision and issue date. The audit was conducted after the issuance of SP-D-Peebles, Revision 3, dated October 11, 1989. (SP-D-Peebles, Revision 2, was dated August 22, 1989.) The date referred to (February 22, 1990) is the date of issuance of the purchase order ZS-1539-AB-9, Revision 2.

3. Houston Light & Power Audit Results

- Page 14 of the IR, first paragraph of Item b, states in part:

As a result of the inadequate 1989 audit, a safety-related purchase order was placed with P-EP in February 1990, which did not meet 10 CFR 50, Appendix B, quality assurance program requirements, as specified in the purchase order documents. This deficiency was not identified until receipt of an audit from Houston Light & Power in July 1990 (disqualifying P-EP for safety-related procurement), and a similarly disqualifying PG&E audit performed in August 1990.

As indicated under Item 1, "Purpose of Draft AFR No. 3," PG&E did not recognize that significant deficiencies existed in P-EP's program until Audit 90197S was conducted. The Houston Light & Power (HL&P) audit was conducted July 25 through 27, 1990. PG&E received HL&P's audit report on September 6, 1990, approximately two weeks after completion of PG&E Audit 90197S, which was conducted August 15 through 17, 1990. PG&E Audit 90197S was the basis of disqualification of P-EP, not the HL&P audit as stated in the IR.

