U. S. NUCLEAR REGULATORY COMMISSION

REGION V

Report No. 50-275/84-30

Docket No. 50-275

Licensee: Pacific Gas and Electric Company
77 Beale Street, Room 1451
San Francisco, California 94106

Facility Name: Diablo Canyon Unit 1

Inspection at: PG&E Corporate Offices, San Francisco, California; and
Diablo Canyon Site, San Luis Obispo County, California

Inspector: for M. L. Padovan, Resident Inspector — Date Signed: 10/31/84

Approved by: P. H. Johnson, Chief
Reactor Projects Section 3 — Date Signed: 10/31/84

Summary:

Inspection from May 20 through October 29, 1984 (Report No. 50-275/84-30)

Area Inspected: Routine inspection of the Quality Assurance Audit Program. This inspection effort required 47 inspector-hours by one resident inspector.

Results: No violations or deviations were identified.

DETAILS

1. Persons Contacted

R. C. Thornberry, Plant Manager
*S. M. Skidmore, Quality Assurance Manager
*J. D. Woessner, Director, Auditing
T. G. de Uriarte, Director, Program Management
*R. T. Twiddy, Director, Quality Services
*G. W. Heggli, Senior Engineer
R. P. Corbett, Senior Engineer
P. C. Burgess, Supervisor, Special Projects
C. M. Seward, Supervisor of Quality Assurance

The inspector also interviewed several other quality assurance personnel.

*Denotes those attending the exit interview on October 29, 1984.

2. Quality Assurance (QA) Audit Program Review

10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants...," requires the licensee to "establish...a quality assurance program which complies with the requirements of this appendix." Specifically, Criterion XVIII, "Audits", requires that "audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program." In a January 22, 1981 letter from P. Crane (PG&E) to R. Tedesco (NRC), the licensee committed to implement certain Regulatory Guides and referenced American National Standards Institute (ANSI) standards in their QA Audit Program. These regulatory guides and ANSI standards were also committed to in Section 17.2 "Quality Assurance Program" of the Diablo Canyon Nuclear Power Plant Final Safety Analysis Report (FSAR). Table 17.2 of the FSAR indicates that the QA Manual complies with the following ANSI standards:

ANSI N18.7-1976, "Administrative Controls and Quality Assurance Program for the Operational Phase of Nuclear Power Plants"

ANSI N45.2-1971, "Quality Assurance Program Requirements for Nuclear Power Plants"

ANSI N45.2.11-1974, "Quality Assurance Requirements for the Design of Nuclear Power Plants"

ANSI N45.2.12-1977, "Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants"

ANSI N45.2.13-1976, "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants"

ANSI N45.2.23-1978, "Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants"

This inspection evaluated PG&E's QA Audit Program against the provisions of the ANSI standards identified in Chapter 17 of the FSAR. The review of the licensee's QA Audit Program addressed the following 14 areas:

- General Requirements
- Planning and Scheduling of Audits
- Audit Procedures
- Personnel
- Audit Plan
- Audit Team
- Notification of Audit
- Performance of Audit
- Audit Reporting
- Response to Audit Results
- Action by Auditing Group
- Followup
- Documentation
- Audit Program Review

In each area, the evaluation (acceptance) criteria and applicable ANSI standards or regulatory requirements were identified. The evaluation criteria were not necessarily quotations from the referenced documents, but reflected the intent of these documents. The licensee's QA Audit Program (as identified in the QA Manual and QA Departmental Procedures) was then evaluated against the evaluation criteria in each area.

a. General Requirements

° 10 CFR 50, Appendix B, Criterion XVIII, Sentence 1 specifies 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. Quality Assurance Manual (QAM), Policy Section XVII met this criterion.

° ANSI N18.7-1976, Section 4.5, Sentence 1 specifies that a comprehensive system of planned and documented audits shall be carried out to verify compliance with all aspects of the administrative controls. Quality Assurance Department Procedure (QADP)-18.1 "Audit Scheduling", Attachment A, Item 32 met this criterion.

° ANSI N45.2.11-1974, Section 11 specifies that a comprehensive system of planned and documented audits shall be carried out to verify compliance with procedures delineating quality assurance actions required during the design process. QADP-18.1, Attachment A, Item 3 met this criterion.

° ANSI N45.2.13-1976, Section 12 specifies that periodic or random audits shall be performed to verify compliance with procurement activities described in this standard. The scope of planned auditing activity may cover individual operations, events, processes, or the complete quality assurance program. When deemed necessary by the purchaser, audits of subtier

suppliers are to be carried out to assure that their quality assurance programs on procurement adequately translate the necessary requisites of the governing procurement documents to the items or services involved. The audits are to be conducted in accordance with established methods. QADP-18.1, Attachment A, Item 4; and QAM, Procedure 11.1, "Quality Assurance Department Audits", Item 3.1 met these criteria.

No violations or deviations were identified.

b. Planning and Scheduling Audits

- ANSI N45.2.12-1977, Section 3.4 specifies that the audit system, including both internal and external audits, shall be planned, documented and conducted to assure coverage of the applicable quality assurance program and overall coordination and scheduling of audit activities. The audit system is to be periodically reviewed, and revised as necessary, to assure that coverage and schedule reflect current activites. QAM, Policy Section VIII "Identification and Control of Items," Item (2); and QADP-18.1 "Audit Scheduling," Items 3.3.1, 3.3.2 and 4.2 met these criteria.

- ANSI N45.2.12-1977, Section 3.5 specifies that auditing shall be initiated as early in the life of the activity as practicable, consistent with the schedule of accomplishing the activity, to assure timely implementation of quality assurance requirements. In any case, auditing is to be initiated early enough to assure effective quality assurance during the design, procurement and contracting activities. QADP-18.1, Item 3.1.1 met these criteria.

- ANSI N18.7-1976, Section 4.5, Sentence 2 specifies that audits of selected aspects of operational phase activities shall be performed with a frequency commensurate with their safety significance, and in such a manner as to ensure that an audit of all safety-related functions is completed within a period of 2 years. Regulatory Guide 1.33*, dated February 1978, specifies that "the following program elements should be audited at the indicated frequencies: (1) the results of actions taken to correct deficiencies that affect nuclear safety and occur in facility equipment, structures, systems, or methods of operation - at least once per 6 months, (2) the conformance of facility operation to provisions contained within the technical specifications and applicable license conditions - at least once per 12 months, (3) the performance, training, and qualifications of the facility staff - at least once per 12 months." QADP-18.1, Attachment A met these criteria.

- ANSI N45.2-1971, Section 19, Paragraph 5 and ANSI N45.2.11-1974, Section 11.5 specify that regularly scheduled audits should be supplemented by audits for one or more of the following conditions: (1) when it is necessary to assess the

capability of a contractor's quality assurance program, prior to awarding a contract or purchase order, (2) when significant changes are made in functional areas of the quality assurance program, such as significant reorganization or procedure revisions**, (3) when it is suspected that the quality of the item is in jeopardy due to deficiencies in the quality assurance program**, (4) when a systematic, independent assessment of program effectiveness is considered necessary**, and (5) when necessary to verify implementation of required corrective action.** QADP-18.1, Items 3.1.2.b.1, 3.1.3.a, 3.1.3.b, 3.1.3.c, and 3.1.3.d met these criteria.

*NOTE: Regulatory Guide 1.144, January 1979, Regulatory Position C.3.a states that (a) for internal audits of operational phase activites, Regulatory Guide 1.33 shall be followed.

**NOTE: Double-asterisked criteria for performance of supplemental audits are indicated by Regulatory Guide 1.144 as having "...sufficient safety importance to be treated..." as mandatory.

No violations or deviations were identified.

c. Audit Procedures

10 CFR 50, Appendix B, Criterion XVIII, Sentence 2 specifies that the audits shall be performed in accordance with the written procedures or checklists. QADP-18.2 "Quality Assurance Audits," Item 3.3.1.c met this criterion.

No violations or deviations were identified.

d. Personnel

- 10 CFR 50, Appendix B, Criterion XVIII, Sentence 2 specifies that audits shall be performed by appropriately trained personnel not having direct responsibilities in the areas being audited. QADP-18.1, Item 3.2.1.b met this criterion.

- ANSI N45.2.12-1977, Section 2.1 specifies that in the case of internal audits, personnel having direct responsibility for performing the activities being audited shall not be involved in the selection of the audit team. QADP-18.1, Item 3.2.1 (auditors assigned by QA Supervisor) met this criterion.

- ANSI N45.2.11-1974, Section 11.1, Sentence 3 specifies that the personnel performing audits (of design activities) shall be of a level of competency, and have sufficient authority and organizational freedom, to make the audit process meaningful and effective. QAM, Policy Section 1, "Organization," Item (3), met this criterion.

- ANSI N45.2.23-1978, Section 2.2, in Sentences 1 and 2 specifies that the responsible auditing organization shall establish audit personnel qualifications, and shall specify requirements for the use of technical specialists for auditing of the quality assurance programs. This standard also states that personnel selected for quality assurance auditing assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. QADP-17.1 "Auditor Qualification," Items 3.1, 3.2 and 3.3, met these criteria.

No violations or deviations were identified.

e. Audit Plan

- ANSI N45.2.12-1977, Section 4.2.1, specifies that an individual audit plan, describing the audit to be performed, shall be developed and documented by the auditing organization. It further states that this plan shall identify the audit scope, the requirements, the activities to be audited, organizations to be notified, the applicable documents, the schedule, and written procedures or checklists. QADP-18.2, Item 3.3.1.a. met these criteria.

- ANSI N18.7-1976, Section 5.2.7.2 (by reference to ANSI N45.2.11-1974) and ANSI N45.2.11-1974, Section 11.4, Sentences 1 and 3 specify that audits (of design activities) shall include an evaluation of design quality assurance policies, practices, procedures and instructions; the effectiveness of implementation; and actions taken to correct deficiencies in the program. These references also state that an audit plan shall be developed, and should identify 1) the functional areas to be audited, 2) the extent of audit within these areas to determine effectiveness, 3) the names and assignments of those who will perform the audit, 4) the scheduling arrangements, and 5) the methods of reporting findings and recommendations. QADP-18.2, Items 1.1.1, 3.3.6.b.5, 3.3.3.1.a, and 3.3.4.h; and QAM, Procedure 11.1, Items 2.1.7.d and 3.6.8 met these criteria.

- ANSI N18.7-1976, Section 4.5, Paragraph 2, Sentence 1 specifies that audits shall include, as a minimum, verification of compliance with, and effectiveness of implementation of, internal rules; procedures (for example, operating, design, procurement, maintenance, modification, refueling, surveillance, test, security, radiation control procedures, and the emergency plan); regulations and license provisions; programs for training; retraining; qualification and performance of the operating staff; corrective actions taken following abnormal occurrences; and observation of performance of operating, refueling, maintenance and modification activities, including associated record keeping.

The specified activities were generally prescribed in Attachment A of QADP 18.1. However, verification of compliance with operating procedures and license conditions was not specified in the licensee's QA Program. Additionally, the QAM and QADP's do not address the performance of the operating staff and operating activities. It is recognized that "Activity Audits," performed by onsite QA personnel, do review operating activities, but the QA Program does not presently address QA Activity Audits. In response to the inspector's findings, the licensee agreed to incorporate these QA Activity Audits into the QA Program. This will be followed as an open item (84-30-01).

No violations or deviations were identified.

f. Audit Team

° ANSI N45.2.12-1977, Section 4.2.2 specifies that one or more auditors comprise (sic) an audit team, and that lead auditor shall be appointed team leader. His responsibilities include orienting the team, coordinating the audit process, establishing the pace of the audit, assuring communications within the team and with the organization being audited, participating in the audit performance, and coordinating the preparation and issuance of reports. This standard states that in selecting personnel for auditing assignments, consideration is to be given to special abilities, specialized technical training, prior pertinent experience, personal characteristics and education.

QADP-18.2, Item 2.6 met these criteria. However, for clarity, the responsibilities of the lead auditor (as described above) should be better identified in QADP-18.2, Item 2.6 and QADP-18.1, Item 3.2.1.a. Similarly, criteria for selection of auditing personnel could be better defined in Item 3.2.1.a. The licensee stated that these clarifications will be considered in the next revisions to these procedures.

° ANSI N45.2.12-1977, Section 4.2.3 specifies that the team leader shall assure that the audit team is prepared prior to initiation of the audit. Pertinent policies, procedures, standards, instructions, codes, regulatory requirements and prior audit reports are to be made available for information and review by the auditors. Each auditor is to be provided with the audit plan. The procedures or checklists are to be prepared to assure orderly accomplishment of the audit. During the familiarization phase of the audit, particular attention is to be directed toward an understanding of internal and external organization, the contractual interfaces, and the responsibilities of the organization to be audited.

QADP-18.2, Attachment A met these criteria. The Audit Plan Form (Attachment A of QADP-18.2) is presently distributed to the Auditors solely through a "cc:" on the form. As discussed

with the licensee, a statement in the body of the procedure, that each auditor shall be provided with a copy of the audit plan, will strengthen the procedure. The licensee agreed to consider adding this statement in the next procedure revision.

No violations or deviations were identified.

g. Notification of Audit

ANSI N45.2.12-1977, Section 4.2.4 specifies that involved organizations shall be notified of a scheduled audit a reasonable time before the audit is to be performed. It states that this notification should be in writing, and should include such information as the scope and schedule of the audit, and the name of the audit team leader. With prior agreement of the parties involved, unannounced audits may be performed. QADP-18.2, Item 3.3.2.a met these criteria.

No violations or deviations were identified.

h. Performance of Audits

- ANSI N45-2.12-1977, Section 4.3.1 specifies that a brief pre-audit conference shall be conducted with cognizant organization management. The purpose of the conference shall be to confirm the audit scope, present the audit plan, introduce auditors, meet counterparts, discuss audit sequence and plans for the post-audit conference, and establish channels of communication. QADP-18.2, Item 3.3.3.a. was found to meet these criteria.

- ANSI N45.2.12-1977, Section 4.3.2 (except 4.3.2.1 and 4.3.2.4) specifies that objective evidence shall be examined for compliance with quality assurance program requirements: (1) selected elements of the quality assurance program shall be audited to the depth necessary to determine whether or not they are being implemented effectively, (2) nonconformances or quality assurance program deficiencies should be acknowledged by a member of the audited organization, (3) conditions requiring immediate corrective action shall be reported immediately to management of the audited organization, and (4) specific attention* will be given to corrective action on program deficiencies identified during previous audits. QADP-18.2, Items 3.3.4.b, c, f, g, and e met these criteria.

  ANSI N45.2.12-1977, Section 4.3.3 specifies that at the conclusion of the audit process, a post-audit conference shall be held with management of the audited organization to present audit findings and clarify misunderstandings. QADP-18.2, Item 3.3.5.a met this criterion.

  * NOTE: As modified by Regulatory Position 4.b of Regulatory Guide 1.144, which also notes that, "...corrective action on program deficiencies identified during previous audits is

construed to mean corrective action on program deficiencies in the area that is being audited."

No violations or deviations were identified.

i. Audit Reporting

- 10CFR50, Appendix B, Criterion XVIII, Sentence 3 and ANSI N45.2-1971, Section 19, Sentence 3 specify that audit results shall be documented and reviewed by management having responsibility in the area audited. QAM Section XVIII indicated that the General Office Nuclear Plant Review and Audit Committee (GONPRAC) shall review audit reports. Additionally, the licensee indicated that the audit reports are distributed to managers in the areas audited. However, there was no clear requirement in the QA Program specifying that audits be reviewed by management of the audited area. In discussions with the inspector, the licensee indicated that the QA program will be revised to require appropriate management review of audit results. This will be followed as an open item (84-30-02).

- ANSI N45.2.12-1977, Section 4.4 specifies that an audit report, which shall be signed by the audit team leader, shall provide: (1) a description of the audit scope, (2) identification of the auditors, (3) persons contacted during pre-audit, audit and post-audit activities, (4) a summary of audit results, including an evaluation statement regarding the effectiveness of the quality assurance program elements which were audited, (5) a descripton of each quality assurance program deficiency in sufficient detail to assure that corrective action can be effectively carried out by the audited organization, (6) recommendations for correcting program deficiencies or improving the quality assurance program, as appropriate, and (7) for distribution of the report to responsible management of both the audited and auditing organizations. The audit report is to be issued within thirty days after the post-audit conference. QADP-18.2, Item 3.3.6.b.1, 2, 3, 4, 5, 6, and 3.3.6.b met these criteria.

No violations or deviations were identified.

j. Response to Audit Results

- ANSI N18.7-1976, Section 4.5, Paragraph 2, Sentence 2 specifies that written reports of audits shall be reviewed by the independent review body, and by appropriate members of management, including those having responsibility in the area audited. Audit reports are to be reviewed by GONPRAC as specified in QAM Policy Section XVIII. However, as discussed in paragraph 2.i above, the addition of clarifying statements to the QAM is necessary to ensure that management responsible for the audited areas will review the audit reports.

- ANSI N45.2.12-1977, Section 4.5.1, Sentences 1, 2, and 3 specify that management of the audited organization or activity shall investigate adverse audit findings, schedule corrective action (including measures to prevent recurrence), and respond as requested by the audit report, giving results of the review and investigation. The response is to clearly state the corrective action taken or planned. In the event that corrective action cannot be completed within thirty days, the audited organization's response is to include a scheduled date for the corrective action to be completed.

  The "Instructions for Completing Audit Finding Report" on the reverse side of Attachemnt A to QAM Procedure 11.1 generally satisfied the evaluation criteria. However, the instructions indicated that the "responsible organization" is to take the required action. Procedure 11.1 could be strengthened by indicating that management of the responsible organization is to take the necessary action. The licensee indicated that this observation would be considered during the next revision to the QAM.

No violations or deviations were identified.

k. Action by Audited Group

- ANSI N45.2-1971, Section 19, Paragraph 1, Sentence 4 specifies that responsible management shall take necessary action to correct the deficiencies revealed by the audit. QAM Procedure 11.1, Item 2.2.4. met this criterion.

- ANSI N45.2.12-1977, Section 4.5.1, Sentence 4 specifies that the audited organization shall provide a follow-up report stating the corrective action taken and the date corrective action was completed. The audited organization is also take appropriate action to assure that corrective action is accomplished as scheduled. Provisions to accomplish corrective action are indicated in QAM Procedure 11.2, "Quality Problem Status Reports," Item 2.2.4. However, the requirement for a follow-up report delineating the completed corrective action was not included in the QAM. Instead, the audited organizations respond to audit findings directly on the Audit Finding Report. The licensee noted that changes are being made to the QAM to improve this situation. This will be followed as an open item (84-30-03).

- ANSI N45.2.12-1977, Section 4.3.2.4 specifies that when a nonconformance, or quality assurance program deficiency, is identified as a result of an audit, further investigation shall be conducted by the audited organiazation to identify the cause and effect, and to determine the extent of the corrective action required. QAM Procedure 11.1, Items 2.2.3 and 2.2.5 met this criterion.

No violations or deviations were identified.

l. Follow-up

- 10 CFR 50, Appendix B, Criterion XVIII, Sentence 4 specifies that follow-up action, including reaudit of deficient areas, shall be taken where indicated. QAM Procedure 11.1, Items 2.1.7.c and d met this criterion.

- ANSI N45.2.11-1974, Section 11.7 specifies that appropriate corrective action and timely follow-up action, including reaudit of deficient areas, shall be taken where indicated by the audit findings. QAM Procedure 11.1, Items 3.1.2.c.6 and 3.1.3 met this criterion.

- ANSI N45.2.12-1978, Section 4.5.2 specifies that when necessary, follow-up actions shall be performed by the audit team leader or management of the auditing organization to: (1) obtain the written response when required by the audit report, (2) evaluate the adequacy of the response, (3) assure that corrective action is identified and scheduled for each adverse finding, and (4) confirm that corrective action is accomplished as scheduled. QAM Procedure 11.1, Item 2.1.7 met these criteria.

No violations or deviations were identified.

m. Documentation

- ANSI N45.2.12-1977, Section 5.2 specifies that records shall be generated and retained for all audits. Records are to include the audit system plan, individual audit plans, audit reports, written replies, and the record of completion of corrective actions. QADP-16.3, Item 4.4.1; QADP-18.1, Item 4.2; and QADP-18.2, Items 4.1 and 4.2 met this criterion.

- ANSI N45.2.12-1977, Section 5.3 specifies that records shall include documentary evidence of the qualifications and training of auditors, and shall be retained for the same period of time as required for the audit report with which the auditors are associated. QADP-17.2, Attachment A, Page 2 of 3 met this criterion.

No violations or deviations were identified.

n. Audit Program Review

ANSI N18.7-1976, Section 4.5, Paragraph 4 specifies that a periodic review of the audit program shall be performed by the independent review body, or by a management representative, at least semiannually, to assure that audits are being accomplished in accordance with the requirements of the technical specifications and of this Standard. Additionally, Section 4.1, paragraphs 1, 2, and 6 specify that audit programs shall be periodically reviewed for effectiveness by management of the owner organization. QADP-18.1, Attachment A, Page 3 of 3, Item 40 specified that an independent

review of the Audit Program will be performed every 6 months. However, the QADP did not indicate that the review is to be performed by the independent review body (GONPRAC), or by a management representative, and in actuality, the QA Audit organization was compiling the information, which was then independently reviewed. In discussions with the inspector, the licensee indicated that the QADP would be revised to specify the proper review body, and that the quality of the semiannual review of the QA Audit program would be enhanced. These items will be followed as an open item (84-30-04).

No violations or deviations were identified.

3. Exit Meeting

On October 29, 1984, the inspection scope and findings were summarized with the licensee representatives denoted in paragraph 1 of this report.