Chapter 17

QUALITY ASSURANCE

17.0 QUALITY ASSURANCE PROGRAM

The purpose of this chapter is to provide a description of the Pacific Gas and Electric Company (PG&E) Quality Assurance (QA) Program. The QA Program is applicable to operation of Diablo Canyon Power Plant (DCPP) Unit 1 and Unit 2 and to the Diablo Canyon Independent Spent Fuel Storage Installation (ISFSI). The purpose of the PG&E QA Program is to provide assurance that the design, construction, and operation of DCPP Unit 1 and Unit 2 and the ISFSI are in conformance with applicable regulatory requirements and with the specified design bases.

The following regulatory requirements are applicable to the QA Program described in this chapter:

1. General Design Criterion 1, 1967 – Quality Standards

   DCPP systems and components that are essential to the prevention of accidents which could affect the public health and safety or to mitigate their consequences are required to be designed, fabricated, and erected to quality standards that reflect the importance of the safety function to be performed. Where generally recognized codes or standards on design, materials, fabrication, and inspection are used, they are identified. Where adherence to such codes or standards does not suffice to assure a quality product in keeping with the safety function, they are supplemented or modified as necessary. QA programs, test procedures, and inspection acceptance levels to be used are identified. A showing of sufficiency and applicability of codes, standards, QA programs, test procedures, and inspection acceptance levels used is made.

   The QA Program described in this chapter provides assurance that this criterion is met. Refer to Section 3.2 for a description of classifications used to identify the importance of safety functions performed by specific structures, systems, and components (SSCs).

2. General Design Criterion 5, 1967 – Records Requirements

   Records of the design, fabrication, and construction of essential components of the plant are required to be maintained or controlled by PG&E throughout the life of the reactor.

3. 10 CFR Part 50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

   DCPP is required to include, in its final safety analysis report, information pertaining to the managerial and administrative controls to be used to assure safe operation in accordance with 10 CFR Part 50 Appendix B Criteria I – XVIII.

4. 10 CFR 50.54 [(a) only] – Conditions of Licenses

   DCPP is required to implement the QA program described or referenced in the safety analysis report, which shall include the QA criteria in 10 CFR Part 50 Appendix B.

5. 10 CFR Part 72 Subpart G – Quality Assurance [ISFSI]

   PG&E satisfies the requirement of 10 CFR 72.140(b) of 10 CFR Part 72 Subpart G, to establish a QA program for the ISFSI by crediting the DCPP QA program as allowed by 10 CFR 72.140(d), which includes a provision that a QA program previously approved by the U.S. Nuclear Regulatory Commission (NRC) as satisfying the requirements of 10 CFR Part 50 Appendix B will be accepted as satisfying the requirements of 10 CFR 72.140(b). License Condition 14 of ISFSI License No. SNM-2511 documents NRC determination that the PG&E 10 CFR Part 50 Appendix B QA program (described in this chapter) complies with the requirements of 10 CFR Part 72 Subpart G.

The following sections describe the PG&E QA Program and how the requirements of criteria I - XVIII of 10 CFR Part 50 Appendix B are satisfied.

17.1 ORGANIZATION

PG&E's program to assure the quality and safety of DCPP and the ISFSI is organized in a structured manner with clearly defined levels of authority, assignments of responsibility, and lines of communication. Assignment of responsibility for an item or activity includes responsibility for its quality. Figure 17.1-1 depicts the corporate organizational structure of PG&E. The DCPP operating organization including the position of the Quality Verification (QV) organization in the operating organization is shown in Figure 17.1-2.

PG&E has assumed full responsibility to its employees, stockholders, the general public, and affected governmental regulatory agencies for the establishment and execution of the QA Program prescribed by this chapter and by quality-related program directives and administrative procedures. The work of executing selected portions of the QA Program may be delegated to organizations external to PG&E; however, in all such instances, PG&E retains overall responsibility.

Specific responsibilities pertaining to QA matters are assigned by the QA Program and its implementing procedures and instructions to various individuals throughout PG&E. In each instance, the assignment of a responsibility to an individual includes with it a commensurate delegation of sufficient authority that the person can, in fact, fulfill that responsibility. Unless otherwise specifically prohibited, it is understood that the functions, tasks, and activities necessary to carry out a responsibility may be delegated to and performed by other qualified individuals. All delegations of functions, tasks, activities, and authority shall be documented.

Figure 17.1-2 identifies those individuals and organizational components of PG&E with direct responsibilities related to the quality of the:

- design, maintenance, and operation of DCPP, and
- design, fabrication, construction, testing, operation, maintenance, modification, and decommissioning of ISFSI SSCs that are important to safety.

17.1.1 CORPORATE ORGANIZATION

PG&E is a public utility and the primary operating subsidiary of PG&E Corporation, a holding company. The reporting relationships between the positions described below are provided in the organization chart in Figure 17.1-1.

THE BOARD OF DIRECTORS OF PG&E CORPORATION is responsible for all facets of PG&E's utility business.

THE CEO, AND PRESIDENT, PG&E CORPORATION is accountable to the Board of Directors and establishes the corporate policies, goals, and objectives related to all of PG&E's activities and operations.

THE President and Chief Operating Officer is responsible for and directs the planning, distribution, and development of all the Company's energy resources and nuclear power generation. These functions include such activities as planning and development, engineering, information services, construction, and fossil, nuclear power plant and ISFSI operations. This position through the Director, Applied Technology Services (ATS), is responsible for providing:

- Technical investigations, tests, analyses, examinations, and calibration services in support of DCPP and its ISFSI;
- Developing, evaluating, qualifying, testing, and improving welding, brazing, and heat-treating procedures required by the company; and
- Providing evaluation support of these procedures.

THE VP, NUCLEAR GENERATION and CHIEF NUCLEAR OFFICER (CNO) is responsible for the safe and efficient operation of DCPP. The CNO is responsible for overall ISFSI safety and for taking measures needed to ensure acceptable performance of the ISFSI staff in designing, fabricating, constructing, testing, operating, modifying, decommissioning, and providing technical support to the ISFSI. The CNO satisfies the role of the corporate officer specified by Technical Specification 5.2.1.c, who shall have corporate responsibility for overall DCPP nuclear safety and shall take any measures needed to ensure acceptable performance of the staff in operating, maintaining, and providing technical support to ensure nuclear safety. The CNO oversees the operating organization, the QV organization, and the management review committees described in the following sections. In addition, the CNO is specifically responsible for the following:

- The CNO, or his designee, as specified in station documents, approves and signs official company correspondence to the NRC or its representatives.
- Approving revisions to the QA Program as described in this chapter that constitute a reduction in a commitment made to the NRC.
- Approving revisions to program directives.

17.1.2 OPERATING ORGANIZATION

The reporting relationships between the positions described below are provided in the organization chart in Figure 17.1-2.

17.1.2.1 Vice President Nuclear Generation and CNO

The VP, Nuclear Generation and CNO reports to the President and Chief Operating Officer, is responsible for overall safe operation of DCPP, and has control over onsite activities necessary for the safe operation and maintenance of the plant. The following positions report to the VP Nuclear Generation and CNO:

- Director, Quality Verification (see Section 17.1.3)
- Leader, Employee Concerns Program (see Section 17.1.2.3)
- Director, Nuclear Business Operations is responsible for integrated business planning, business finance, and provides direct support to the VP, Nuclear Generation and CNO. The Manager, Nuclear Supply Chain is matrixed to the Director, Nuclear Business Operations. The Manager, Nuclear Supply Chain is responsible for administration, coordination, planning, and operation of warehousing and procurement of materials in support of DCPP and ISFSI operations and contract services.
- The Sr. Director, Station Director is responsible within those limits established by the plant operating licenses and the policy of the CNO, for the development and implementation of those programs, procedures, and

instructions required for the operation of DCPP. The Station Director has been delegated the necessary authority to approve and direct development and implementation of these programs, procedures, and instructions. The Station Director satisfies the role of the plant manager specified in Technical Specifications 5.1.1 and 5.2.1.b. The following positions report to the Station Director:

- The Director, Operations Services reports to the Station Director and is responsible for safe plant operation, chemistry and environmental operations, and radiological safety. Refer to Section 13.1.2.1 for additional details on the Operations Services organization.

- The Director, Maintenance Services reports to the Station Director and exercises direct supervision over maintenance including the functional areas of electrical maintenance, instrumentation and controls maintenance, mechanical maintenance, and maintenance support.

- The Director, Nuclear Work Management reports to the Station Director and is responsible for the management of DCPP unit outages including planning, organizing, staffing, directing, and controlling the preparation of outages. The Director, Nuclear Work Management is also responsible for the daily work control process and organization.

- Director, Organizational, Performance and Learning Services provides direct supervision over Performance Improvement and is responsible for overall implementation, maintenance, monitoring and evaluation of DCPP personnel training and qualification and for obtaining and maintaining accreditation for training programs specifically identified by the Institute of Nuclear Power Operations (INPO).

- The Senior Director, Nuclear Services is responsible for engineering services, strategic projects, security and emergency services, nuclear fuels management, risk and compliance, and coordination with the Integrated Service Supplier for DCPP and the ISFSI. This position is specifically charged with development, evaluation, qualification, testing, and improvement of nondestructive examination procedures required by PG&E and for evaluation of these types of procedures that are used at DCPP by other organizations. The following positions report to the Senior Director, Nuclear Services.

  - The Director, Engineering Services is responsible for providing day-to-day engineering support for plant operations and for the performance of modifications to the plant. The functional areas reporting to the Director, Engineering Services are mechanical systems engineering; technical support engineering; design engineering; and the instrumentation, controls, and electrical systems engineering.

- The Director, Security and Emergency Services is responsible for implementation of the Security Program which includes the industrial fire group.

- The Director, Risk and Compliance is responsible for nuclear risk and compliance programs, the emergency plan, and regulatory services.

- The Manager, Nuclear Fuels Management is responsible for nuclear fuel purchasing and dry fuel management.

17.1.2.2 Vice President, Power Generation

The VP, Power Generation reports to the President and Chief Operating Officer. Responsibilities include the following support of DCPP:

- Sr. Director, Decommissioning is responsible for DCPP and HBPP decommissioning operations.

- The Director, Geosciences is responsible for geotechnical and seismic engineering services including geo-scientific studies; reports, and calculations (including geology, seismology, vibration ground motion studies, surface faulting, stability of subsurface materials, slope stability, seismic hazards, and seismic fragilities) in support of DCPP and the ISFSI.

17.1.2.3 Leader, Employee Concerns Program

The Leader, Employee Concerns Program, reports to the CNO and is responsible for management of a program, independent of line management, for company and contractor employees to raise concerns dealing with harassment, intimidation, retaliation or discrimination without fear of retaliation.

17.1.3 QUALITY VERIFICATION IN THE ORGANIZATION

The Director, QV is responsible for management of the QA Program and for assuring that the QA Program prescribed in this chapter and in program directives and administrative procedures is effectively implemented by all involved organizations, both internal and external to PG&E. The CEO, and President, PG&E Corporation; the President and Chief Operating Officer, PG&E Utility,; and the CNO, have given the Director, QV the organizational freedom, and delegated the requisite authority to investigate any area or aspect of PG&E's operations as necessary to identify and define problems associated with establishment or execution of the QA Program. They have also delegated to the Director, QV the authority to initiate, recommend, or provide solutions for such problems to whatever management level is necessary, and to verify that effective corrective action is taken in a timely manner. This delegation includes the authority to assess, review, inspect, audit, and monitor the conduct of quality-related

activities performed by or for PG&E to assure compliance with the QA Program and other regulatory requirements.

The Director, QV reports directly to the CNO and has access to the CEO and President, PG&E Corporation; the President and Chief Operating Officer, PG&E Utility; the VP Power Generation; the Senior Director, Station Director; the Senior Director, Nuclear Services; and appropriate directors and managers for any significant quality-related problem or deficiency. He is authorized to prescribe a uniform company-wide method of performing an activity affecting quality by sponsoring or requiring the issuance of procedures when such standardization is considered desirable or essential to the effectiveness of the QA Program. Such uniform methods are contained in program directives and administrative procedures, and compliance with their requirements by all PG&E personnel is mandatory.

The Director, QV will not be responsible for any activities unrelated to responsibilities described in the QA Program that would prevent the required attention to QA matters. Further, the responsibility of the implementation of the QA Program will take precedence over the other non-QA duties.

The Director, QV shall meet the following qualification requirements:

- Management experience through assignments to responsible positions
- Knowledge of QA regulations, policies, practices, and standards
- Experience working in QA or related activity in reactor design, construction, or operation or in a similar highly technological industry
- At the time of initial core loading or assignment to the active position, the Director, QV shall have six years of experience in implementing QA, preferably at an operating nuclear plant, or operations supervisory experience.
- At least one year of these six years of experience shall be nuclear power plant experience in the overall implementation of the QA Program.
- A minimum of one year of this six-year experience requirement shall be related technical or academic training.
- A maximum of four years of this six-year experience requirement may be fulfilled by related technical or academic training.

The Director, QV responsibilities include:

- Regularly assessing and reporting on the status, adequacy, and effectiveness of PG&E's QA Program to the CNO and other affected PG&E management and nuclear oversight committees.

- Identifying, preparing, and submitting for approval such changes to the QA Program prescribed herein as are necessary to maintain the QA Program up to date and in conformance with current regulatory requirements and PG&E commitments to the NRC.

- Reviewing all regulatory submittals as they pertain to the QA Program; Director, QV concurrence is required prior to submittal.

- Assessing and assuring that the QA Program is effectively implemented at DCPP and the ISFSI.

- Assuring timely and effective corrective actions through audits, regular assessments, and quality assessment status reports.

- Providing recommendations on solutions to quality problems and for performing monitoring, assessments, independent quality control (QC) inspections, reviews, and audits for the areas covered by the QA Program including supplier quality.

- QA associated with the HBPP.

- The Director, QV has the authority and responsibility to stop work should there be a serious breach of any part of the QA Program, or of technical or regulatory requirements wherein public health or safety could be involved. If stopping work would involve changing a nuclear generating unit's power level or separating such a unit from the PG&E system, the concurrence of the CNO, or the Station Director is required.

- Through the conduct of assessments, audits, reviews, monitors, and independent QC inspections, the Director, QV is responsible for quality overview of DCPP operating characteristics, operations, modifications, maintenance, and surveillance; and ISFSI design, fabrication, construction, testing, operation, modification, decommissioning, and related activities to verify independently that these activities are performed correctly and that human errors are reduced as much as practicable.

17.1.4 MANAGEMENT REVIEW COMMITTEES

The following committees function at the managerial level within PG&E to provide review of DCPP and ISFSI design, maintenance, and operation activities.

Administrative procedures or charters for the committees provide detailed responsibilities and functions, as well as membership, authority, and reporting requirements. The reporting relationships of the committee are identified in the organization chart on Figure 17.1-2.

17.1.4.1 Nuclear Safety Oversight Committee

The Nuclear Safety Oversight Committee (NSOC) reports to the CNO and implements the independent review function. NSOC functions, responsibilities, and meeting requirements are described in Section 17.2.3.

The mission of the NSOC is to provide an integral part of the DCPP oversight process by independently assessing the nuclear safety and performance of the station and advising the CNO on issues that could affect station performance and/or nuclear safety. The scope includes facility operations, the adequacy and implementation of all DCPP nuclear safety policies and programs, and any issues related to nuclear, radiological, industrial, and environmental safety. Based on this assessment, the NSOC will provide comments and/or recommendations to the CNO that are directed at ensuring overall excellence in Operations and overall station performance.

17.1.4.2 Plant Staff Review Committee

The Plant Staff Review Committee (PSRC) reports to the CNO and is responsible to advise the Station Director on matters related to nuclear safety. The PSRC is responsible for providing timely and continuing monitoring of operating activities to assist the Station Director in keeping aware of general DCPP and ISFSI conditions and to verify that day-to-day operating activities are conducted safely and in accordance with applicable administrative controls. The PSRC performs periodic reviews of DCPP and ISFSI operations and of plans for future activities. In addition, the PSRC performs special reviews, investigations or analyses, and screens subjects of special concern. PSRC functions, responsibilities, and meeting requirements are described in Section 17.2.4.

17.1.5 ORGANIZATIONAL PROTOCOLS

Verification of conformance to established requirements (except designs) is accomplished by (1) individuals or groups within QV who do not have direct responsibility for performing the work being verified or (2) individuals or groups trained and qualified in QA concepts and practices and independent of the organization responsible for performing the task. The persons and organizations performing QA and QC functions have direct access to management levels that assure the ability to: (a) identify quality problems; (b) initiate, recommend, or provide solutions through designated channels; and (c) verify implementation of solutions. They are sufficiently free from direct pressures for cost and schedule, and have the authority and responsibility to stop unsatisfactory work and control further processing, delivery, and/or installation of nonconforming material. (The organizational positions with stop work authority are identified in the implementing procedures.) QV is required to review and document concurrence with all procedures and instructions that define methods for implementing the QA Program.

Each organization that supports DCPP and the ISFSI documents and maintains current a written description of its internal organization. This documentation describes the business unit or department structure, levels of authority, lines of communication, and assignments of responsibility. Such documentation takes the form of organization charts supported by written job descriptions or other narrative material in sufficient detail that the duties and authority of each individual whose work affects quality is clear. Interfaces between organizations are described in administrative procedures or other documents controlled in accordance with the appropriate requirements of Section 17.6.

The individuals assigned to the positions having a particular responsibility in program directives and administrative procedures (as described above) are the only individuals who are authorized to perform these activities. However, circumstances may arise where it is considered either necessary or desirable to have such activities, or some portion of them, performed by someone else. In such cases, the assigning organization retains responsibility and shall verify that the procedures and instructions to be followed in performing the work are adequate for controlling the work and meet applicable requirements. In such circumstances, the detailed procedures and instructions to be followed in performing the work are reviewed and approved by the person assigned responsibility for the work prior to the commencement of work. The purpose of such review and approval is to verify that such procedures and instructions reflect an acceptable method of performing the work and are in compliance with the requirements of the QA Program. All instances in which authority is to be delegated or support services are to be provided are documented.

17.1.6 SUPPLIER ORGANIZATIONS

Suppliers to DCPP and the ISFSI are required to conform to the PG&E QA Program or to their own program approved by PG&E. Supplier QA Programs are required to comply with the applicable portions of both 10 CFR Part 50, Appendix B, and 10 CFR Part 72, Subpart G, and the applicable regulatory documents and industry standards identified in Table 17.1-1. The quality program is defined in the contract or similar procurement document. Suppliers to PG&E are required to document their internal organizational arrangements to the extent necessary for PG&E to assure the supplier is capable of effectively managing, directing, and executing the requirements of the procurement documents. The authority and responsibility of persons and organizations who perform activities that might affect the quality of the procured items or services shall be clearly established. The Suppliers' organizational structure, levels of authority, and functional assignments of responsibility shall be such that:

(1) The QA function of formally verifying conformance to the technical and quality requirements of the procurement documents is accomplished by qualified personnel who are independent of those who performed or directly supervised the work.

(2) Personnel who perform QA functions have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend,

or provide solutions; to verify implementation of those solutions; and to control further processing of the items or services until proper dispositioning has occurred.

17.2 QUALITY ASSURANCE PROGRAM

17.2.1 PROGRAM APPLICABILITY

The quality of the:

- safety-related aspects of the design, construction, and operation of DCPP, and
- important-to-safety aspects related to the design, fabrication, construction, testing, operation, maintenance, modification, and decommissioning of the ISFSI SSCs

shall be assured through the QA Program prescribed by this chapter and by quality-related program directives and administrative procedures. The QA Program requirements, as a minimum, apply to those DCPP SSCs classified as PG&E Design Class I in Section 3.2. The QA Program requirements apply to ISFSI SSCs classified as important to safety in ISFSI UFSAR, Section 4.5. The applicable QA criteria are executed to an extent that is commensurate with the importance to safety.

The QA Program applies to the following:

(1) DCPP design, construction, and operation of SSCs that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. The SSCs that serve these functions are classified as PG&E Design Class I. In addition, certain QA Program requirements apply to the nonsafety-related programs discussed below to provide additional assurance that these objectives are satisfied.

(2) The design, construction, and operation of those portions of DCPP SSCs whose function is not required as above but whose failure could reduce the functioning of the above DCPP features to an unacceptable level or could incapacitate control room occupants. Certain of these SSCs are conservatively designated as PG&E Design Class I. Other nonsafety-related SSCs with seismic qualification requirements are subject to the seismic configuration control program listed below. Seismically Induced System Interaction Program requirements are governed by quality-related procedures.

(3) Activities affecting the above DCPP features.

(4) Geotechnical and seismic engineering services performed by Geosciences in support of DCPP and the ISFSI. The Geosciences organization performs these activities in accordance with the DCPP QA Program described in Chapter 17.

(5) Technical investigations, tests, analyses, examinations, calibration services performed at ATS in support of nuclear generation. This includes responsibility for the Nuclear Weld Control Manual. The ATS organization maintains QA Program administrative controls independent from DCPP. These administrative controls are specific to the ATS organization, are reviewed and approved by the Director, QV and comply with the requirements listed in Chapter 17.

(6) Managerial and administrative controls to ensure safe operation of the ISFSI, both prior to issuance of a license and throughout the life of the licensed activity.

(7) Activities that provide confidence that ISFSI SSCs will perform satisfactorily in service, including activities that determine that physical characteristics and quality of materials or components adhere to predetermined requirements.

In addition, the QA Program includes requirements that apply to the following DCPP and ISFSI nonsafety-related programs:

	Program	DCPP	ISFSI
(1)	Fire Protection	X	
(2)	Emergency Preparedness	X	X
(3)	Security	X	X
(4)	Radiation Protection	X	X
(5)	Radiological Monitoring and Controls Program	X	
(6)	ISFSI Radiological Environmental Monitoring		X
(7)	Environmental Monitoring	X	
(8)	Radioactive Waste Management	X	X
(9)	Fitness for Duty (FFD)	X	
(10)	Regulatory Guide 1.97, Category 2 and 3 Instrumentation	X	
(11)	Seismic Configuration Control	X	
(12)	Anticipated Transient Without Scram Mitigation	X	

Program	DCPP	ISFSI
System Actuation Circuitry (AMSAC) Equipment (13) Diverse and Flexible Coping Strategy (FLEX) Equipment including the Spent Fuel Pool Level Instrumentation	X	

17.2.2 PROGRAM CONTROL

The status and adequacy of this QA Program shall be regularly monitored, and it shall be revised as necessary to improve its effectiveness or to reflect changing conditions.

The Director, QV is responsible for the preparation, issue, interpretation, and control of this QA Program, and for concurring with changes to quality-related program directives and administrative procedures that propose a change to the QA Program as it is described in a commitment to a regulatory agency. The Director, QV is responsible to assure the requirements set forth in this QA Program, quality-related program directives, and administrative procedures are in compliance with current regulatory requirements and PG&E commitments to the NRC as shown in Table 17.1-1. Proposed changes to program directives are also approved by the CNO.

The QA Program documents, including any changes, supplements, or appendices, are issued and maintained as controlled documents. Changes to the QA Program as described herein that do not reduce commitments shall be included in the periodic updates required by 10 CFR 50.71(e). Proposed changes to this QA Program that reduce commitments are reviewed and concurred with in writing by the Director, QV and are approved by the CNO or his designee, prior to being submitted to and approved by the NRC in accordance with 10 CFR 50.54 prior to issue for use.

Implementation of the QA Program is accomplished through separately issued procedures, instructions, and drawings. Each VP, director, and manager is responsible for the establishment and implementation of detailed procedures and instructions prescribing the activities for which he is responsible. Such documents are derived from the requirements and reflect the responsibilities specified in the QA Program. Activities affecting quality are accomplished in accordance with these instructions, procedures, and drawings. All personnel are instructed that compliance with those requirements, and the requirements of the QA Program, is mandatory.

Questions or disputes involving interpretations of QA Program requirements, or of the commitments and requirements upon which it is based, are referred to the Director, QV for resolution. Questions or disputes involving the responsibilities defined in this chapter and program directives are referred to the CNO. Questions or disputes involving other quality matters are resolved by referring the matter in a timely manner to successively higher levels of management until, if necessary, the matter reaches that level which has direct authority over all contesting parties.

Personnel who perform functions addressed by the QA Program are responsible for the quality of their work. They are indoctrinated, trained, and appropriately qualified to assure that they have achieved and maintained suitable proficiency to perform those functions. Qualifications of such personnel are in accordance with applicable codes, standards, and regulatory requirements.

The Director, QV or his designated representative, regularly reports to the CNO, responsible company management, and NSOC on the effectiveness of the QA Program as it relates to DCPP and ISFSI design, maintenance, and operation of DCPP and the ISFSI. Such reports are based on the results of audits, reviews, inspections, tests, and other observations of activities as prescribed by the QA Program.

Annually, the Director, QV reports to the CNO on the effectiveness of the QA Program and results of the Audit Program. The report includes an evaluation of compliance with current regulatory requirements and commitments to the NRC.

17.2.3 INDEPENDENT REVIEW AND AUDIT PROGRAM

The QA Program includes an independent review function, implemented by NSOC (refer to Section 17.1.4). This function provides an independent review of DCPP and ISFSI changes, tests, and procedures, which constitute a change to the DCPP facility or ISFSI as described in the DCPP UFSAR or ISFSI UFSAR. In addition, the independent review function will verify that reportable events are investigated in a timely manner and corrected in a manner that reduces the probability of recurrence of such events; and detect trends that may not appear to a day-to-day observer.

The individuals assigned responsibility for independent reviews shall be qualified in specific disciplines. These individuals shall collectively have the experience and competence required to review activities in the following areas:

(1) DCPP and ISFSI operations

(2) Nuclear engineering

(3) Chemistry and radiochemistry

(4) Metallurgy

(5) Nondestructive testing

(6) Instrument and control

(7) Radiological safety

(8) Mechanical and electrical engineering

(9) Administrative controls

(10) QA practices

(11) Other appropriate fields

NSOC shall report to and advise the CNO, on those areas of responsibility specified in the sections below.

Composition – Membership shall include a chairman and a minimum of four members, of whom no more than a minority are members of the onsite operating organization. The NSOC Chair shall have a minimum of 6 years of professional level managerial experience in the power field and NSOC members shall have a minimum of 5 years of professional level experience in the power field.

The NSOC Chair and all members shall have qualifications that meet or exceed the requirements and recommendations of Section 4.7 of ANSI/ANS 3.1-1978.

An individual may possess competence in more than one specialty area.

Consultants: Consultants shall be used as determined by the NSOC Chair to provide expert advice to NSOC.

Meeting Frequency: NSOC shall meet at least twice a year.

Quorum: A quorum of NSOC is necessary for the performance of the NSOC function required by the QA Program. A quorum shall be a majority (one-half or more) of the members, but no fewer than four (including the Chair). No more than a minority of the quorum shall have line responsibility for operation of the plant.

Review: NSOC shall review:

(1) The evaluations for: (a) changes to procedures, equipment, or systems, and (b) tests or experiments completed under the provision of 10 CFR 50.59 or 10 CFR 72.48, to verify that such actions did not require prior NRC approval

(2) Proposed changes to procedures, equipment, or systems, that require prior NRC approval in accordance with 10 CFR 50.59 or 10 CFR 72.48

(3) Proposed tests or experiments that require prior NRC approval in accordance with 10 CFR 50.59 or 10 CFR 72.48

(4) Proposed changes to DCPP Technical Specifications or Operating License

(5) Proposed changes to the ISFSI Technical Specifications or licenses

(6) Violations of codes, regulations, orders, Technical Specifications, license requirements, or of internal procedures or instructions having nuclear safety significance

(7) Significant operating abnormalities or deviations from normal and expected performance of DCPP and ISFSI equipment that affect nuclear safety

(8) All reportable events

(9) All recognized indications of an unanticipated deficiency in some aspect of DCPP design or operation of safety-related SSCs that could affect nuclear safety

(10) All recognized indications of an unanticipated deficiency in some aspect of ISFSI design or operation of important-to-safety SSCs that could affect nuclear safety

(11) Meeting minutes of the PSRC.

(12) Any other matter involving safe operation of DCPP or ISFSI.

NSOC may delegate reviews of selected topics such as changes processed under 10 CFR 50.59 and 10 CFR 72.48 to specialists or subgroups. NSOC shall review summaries of delegated activities.

Records - A report documenting the scope and conclusions of each NSOC meeting shall be prepared, approved, and forwarded to the CNO.

The QA Program also includes an audit function implemented by the QV organization. (Refer to Section 17.18 for audit frequencies.) Distribution of audit reports shall include responsible management of both the audited and auditing organizations. The audit report shall be approved within thirty days after the post audit conference.

17.2.4 PLANT STAFF REVIEW COMMITTEE

A PSRC has been established for DCPP and the ISFSI. The PSRC satisfies applicable requirements of ANSI N18.7-1976, and its activities are controlled as described below:

PSRC Function - The PSRC shall function to advise the Station Director on all matters related to nuclear safety.

Composition - The PSRC shall be composed of a minimum of 8 senior management individuals, including the chairman. PSRC membership shall include one or more individuals knowledgeable in the following areas: operations, maintenance, radiation protection, engineering, and performance improvement. The PSRC Chairman and regular PSRC members shall be appointed in writing by the Station Director. The qualifications of each PSRC member shall meet or exceed the requirements and recommendations of Section 4.7 of ANSI/ANS 3.1-1978. To maintain QA and independent review independence, the Director, QV shall not be a member of the PSRC, however, PSRC meeting notifications and review material shall be provided to the Director, QV.

Alternates - The Station Director shall designate in writing other regular members who may serve as the Acting Chairman of PSRC meetings. All alternates to regular members shall be appointed in writing by the Station Director. Alternates may be designated for specific PSRC members and shall have expertise and qualifications in the same general area as the regular PSRC member they represent. No more than two alternates shall participate as voting members in PSRC activities at any one time.

Meeting Frequency - The PSRC shall meet at least twice per calendar year and as convened by the PSRC Chairman or his designated alternate.

Quorum - The minimum quorum of the PSRC necessary for performance of the PSRC responsibility and authority provisions of this QA Program shall be a majority (more than one-half) of the members of the PSRC. For purposes of the quorum, this majority shall include the Chairman or the acting chairman, and no more than two alternate members.

The PSRC shall be responsible for:

(1) Reviewing the documents listed below to verify that proposed actions do not require prior NRC approval or require a change to the Technical Specifications and recommending approval or disapproval in writing to the appropriate approval authority

(a) Evaluations of proposed procedures and procedure changes completed under the provisions of 10 CFR 50.59 or 10 CFR 72.48

(b) Evaluations of proposed tests or experiments completed under the provisions of 10 CFR 50.59 or 10 CFR 72.48

(c) Evaluations of proposed changes or modifications to plant structures, systems, or equipment completed under the provisions of 10 CFR 50.59 or 10 CFR 72.48

(d) Evaluations of proposed changes to the following plans and programs completed under the provisions of 10 CFR 50.59, 10 CFR 72.48, or other applicable regulations:

1. Security Plan
2. Emergency Plan
3. Fire Protection Program

(2) Reviewing all proposed changes to the DCPP Technical Specifications and ISFSI Technical Specifications and advising the Station Director on their acceptability

(3) Investigating all violations of the DCPP Technical Specifications and the applicable ISFSI Technical Specifications including the preparation and forwarding of reports covering evaluation and recommendations to prevent recurrence to the CNO. The assessment shall include an assessment of the safety significance of each violation

(4) Reviewing all reportable events and advising the Station Director on the acceptability of proposed corrective actions, and forwarding of reports covering evaluation and recommendations to prevent recurrence to the CNO.

(5) Reviewing significant DCPP and ISFSI operating experience or events that may indicate the existence of a nuclear safety hazard, and advising the Station Director on an appropriate course of action

(6) Reviewing the Security Plan and implementing procedures and submitting results and recommended changes to the Station Director

(7) Reviewing the Emergency Plan and implementing procedures and submitting results and recommended changes to the Station Director

(8) Reviewing any accidental, unplanned, or uncontrolled radioactive release including the preparation and forwarding of reports covering evaluation, recommendations, and disposition of the corrective action to prevent recurrence to the CNO

(9) Recommending in writing to the appropriate approval authority, approval or disapproval of the items considered under paragraphs (1) and (2), above

(10) Rendering determinations in writing with regard to whether each item considered under paragraphs (1) through (4), above, require prior NRC approval

(11) Providing written notification within 24 hours to the CNO, of disagreement between the PSRC and the Station Director; however, the Station Director shall have responsibility for resolution of such disagreements

(12) Reviewing, prior to approval, new procedures used to handle heavy loads in exclusion areas and changes directly related to methods and routes used to handle heavy loads in exclusion areas.

Records - The PSRC shall maintain written minutes of each PSRC meeting that, at a minimum, document the results of all PSRC activities performed under the responsibility and authority provisions of this QA Program section. Copies shall be provided to the CNO, and to NSOC.

17.2.5 Selection and Training of Nuclear Power Plant Personnel

Staffing, training, and qualification is the single most important variable which can be controlled to achieve the nuclear generation goals of maximizing plant safety, efficiency, and reliability. Therefore, it is the policy of nuclear generation that personnel at all levels shall be qualified for the positions they fill and receive the necessary training and retraining to enable them to perform at the highest level of efficiency. Nuclear generation personnel shall meet or exceed the minimum qualifications of ANSI/ANS 3.1 1978, for comparable positions, with the following exceptions [Reference 2]:

(a) The radiation protection manager shall meet or exceed the minimum qualifications of Regulatory Guide 1.8, Revision 2, April 1987, for radiation protection manager.
(b) The operations manager shall meet or exceed the minimum qualifications as specified in Technical Specification 5.2.2.e.
(c) The licensed Reactor Operators and Senior Reactor Operators shall meet or exceed the minimum qualifications of ANSI/ANS 3.1-1993 as endorsed by Regulatory Guide 1.8, Revision 3, May 2000 with the exceptions clarified in the current revision to the Operator Licensing Examination Standards for Power Reactors, NUREG-1021, Section ES-202 [Reference 1].
(d) For the purpose of 10 CFR 55.4, a licensed SRO and a licensed RO are those individuals who, in addition to meeting the requirements specified in (c), perform the functions described in 10 CFR 50.54(m).

.

NOTE: These exceptions are also listed in Table 17.1-1, Current Regulatory Requirements and PG&E Commitments Pertaining to the Quality Assurance Program, where all pertinent commitments are captured.

17.3 DESIGN CONTROL

Design activities shall be performed in an orderly, planned, and controlled manner directed to achieving the DCPP and ISFSI designs that best serve the needs of PG&E and its customers without posing an undue risk to the health and safety of the public or to the environment.

Design activities shall be controlled to assure that design, technical, and quality requirements are correctly translated into design documents and that changes to design and design documents are properly controlled. Design control procedures shall address responsibilities for all phases of design including:

(1) Responsibilities

(2) Interface control

(3) Design input

(4) Design performance

(5) Design verification

(6) Design change

Systematic methods shall be established and documented for communicating needed design information across the external and internal design interfaces, including changes to the design information, as work progresses. The interfaces between the DCPP engineering organization and other organizations, either internal or external to PG&E, performing work affecting quality of design shall be identified and documented. This identification shall include those organizations providing criteria, designs, specifications, technical direction, and technical information and shall be in sufficient detail to cover each SSC and the corresponding design activity.

Provisions for design input shall define the technical objectives for SSCs being designed or analyzed. For the SSC being designed, or for the design services being provided (for example, design verification), design input requirements shall be determined, documented, reviewed, approved, and controlled.

Required design analyses (such as physics, stress, thermal, hydraulic, and accident analysis; material compatibility; accessibility for inservice inspection, maintenance, and repair; and ALARA considerations) shall be performed in a planned, controlled, and correct manner. PG&E procedures shall identify the review and approval responsibilities for design analyses.

The preparation and control of design documents (such as specifications, drawings, reports, and installation procedures) shall be performed in a manner to assure design inputs are correctly translated into design documents (for example, a documented check to verify the dimensional accuracy and completeness of design drawings and specifications).

PG&E shall provide for reviewing, confirming, or substantiating the design to assure that the design meets the specified design inputs. Design verification shall be performed by competent individuals or groups other than those who performed the original design, but who may be from the same department. Individuals performing the verification shall not meet any of the following four criteria:

(1) Have immediate supervisory responsibility for the individual performing the design. In exceptional circumstances, the designer's immediate supervisor can perform the verification provided:

  (a) The supervisor is the only technically qualified individual

  (b) The need is individually documented and approved in advance by the supervisor's management; and

  (c) QA audits cover frequency and effectiveness of use of supervisors as design verifiers to guard against abuse

(2) Have specified a singular design approach

(3) Have ruled out certain design considerations

(4) Have established the design inputs for the particular design aspect being verified

The results of the design verification efforts shall be documented with the identification of the verifier clearly provided. Design verification methods may include, but not be limited to, the following: design reviews, use of alternate calculations, and qualification testing. The design verification method shall be identified and documented. The design verification shall be completed prior to relying upon the SSC to perform its function. Procedures shall assure that verified computer codes are certified for use and that their applicability is specified.

Proposed changes or modifications to ISFSI or DCPP SSCs that affect nuclear safety shall be designed by a qualified individual or organization, and reviewed by a qualified individual/group other than the individual/group who prepared the change or modification, but who may be from the same organization. These reviews shall include a determination as to whether additional cross-discipline reviews are necessary. If deemed necessary, they shall be performed by review personnel of the appropriate discipline(s). These reviews shall also determine whether an evaluation per 10 CFR 50.59 or 10 CFR 72.48 is

necessary. If necessary, one shall be prepared and presented to the PSRC for review prior to approval.

Each DCPP and ISFSI change or modification shall be approved by the Station Director or his designee, as specified in administrative procedures, prior to implementation.

Procedures for implementing design changes, including field changes, shall assure that the impact of the change is carefully considered, required actions documented, and information concerning the change transmitted to all affected persons and organizations. These changes shall be subjected to design control measures commensurate with those applied to the original design. Design changes shall be reviewed and approved by the same organization or group that was responsible for the original design.

Document control measures shall be established for design documents that reflect the commitments of the DCPP UFSAR and the ISFSI UFSAR. These design documents shall include, but are not limited to, specifications, calculations, computer programs, system descriptions, the DCPP UFSAR and ISFSI UFSAR when used as a design document, and drawings including flow diagrams, piping and instrument diagrams, control logic diagrams, electrical single line diagrams, structural drawings for major facilities, site arrangements, and equipment locations.

Nonconforming activities such as procedure violations, deviations, or errors and deficiencies in approved design documents, including design methods (such as computer codes), shall be controlled as described in Sections 17.15 and 17.16.

17.4 PROCUREMENT DOCUMENT CONTROL

The procurement documents shall include those requirements necessary to assure that the items and services to be provided will be of the desired quality.

The procurement documents shall also include provisions for the following, as appropriate:

(1) Basic Technical Requirements - These include drawings, specifications, codes, and industrial standards with applicable revision data; test and inspection requirements; and special instructions and requirements, such as for designing, fabricating, cleaning, erecting, packaging, handling, shipping, and, if applicable, extended storage in the field.

(2) QA Requirements - These include the requirements for the supplier to have an acceptable QA Program; provisions for access to the supplier's facilities and records for source inspection and audit when the need for such inspection and audit has been determined; and provisions for extending applicable QA Program and other requirements of procurement documents to subcontractors and suppliers, including PG&E's access to facilities and records.

(3) Documentation Requirements - These shall include records to be prepared, maintained, submitted or made available for review and instructions on record retention and disposition.

The procedures that implement procurement document control shall describe the organizational responsibilities for procurement planning; preparation, review, approval and control of procurement documents; supplier selection; bid evaluations; and review and evaluation of supplier QA Programs prior to initiation of activities affected by the program.

Procedures shall be established to review the adequacy of technical and QA requirements stated in procurement documents; determine that requirements are correctly stated, inspectable, and controllable; assure adequate acceptance and rejection criteria; and provide for the preparation, review, and approval of procurement documents in accordance with QA Program requirements. The review and documented concurrence of the adequacy of QA requirements stated in procurement documents shall be performed by independent personnel trained and qualified in applicable QA practices and concepts.

Changes to procurement documents shall be subject to the same control as the original document.

17.5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities affecting quality shall be prescribed by and accomplished in accordance with documented procedures, instructions, and drawings.

The VP in charge of each PG&E organizational unit that performs activities affecting quality is responsible for the establishment and implementation of instructions, procedures, and/or drawings prescribing such activities. Standard guidelines for the format, content, and review and approval processes shall be established and set forth in a procedure or instruction issued by that organizational unit.

The method of performing activities affecting quality shall be prescribed in documented instructions, procedures, and/or drawings of a type appropriate to the circumstances. This may include shop drawings, process specifications, job descriptions, planning sheets, travelers, QA manuals, checklists, or any other written or pictorial form provided that the activity is described in sufficient detail such that competent personnel could be expected to satisfactorily perform the work functions without direct supervision.

Within the constraints, limitations, or other conditions as may be imposed by the specific DCPP Technical Specifications and other license requirements or commitments, procedures prescribing a preplanned method of conducting the following aspects of DCPP operations shall be established in accordance with the applicable regulations, codes, standards, and specifications: preoperational tests, systems operations, general DCPP activities, startup, shutdown, power operations and load changing, process monitoring, fuel handling, maintenance, modifications, radiation control, calibrations and tests, chemical-radiochemical control, abnormal or alarm conditions, emergency plan, tests and inspections, emergencies, and significant events.

Within the constraints, limitations, or other conditions as may be imposed by the ISFSI Technical Specifications and other license requirements or commitments, procedures prescribing a preplanned method of conducting the activities and programs specified shall be established in accordance with the applicable regulations, codes, standards, and specifications.

In addition to the above, DCPP and ISFSI procedures and programs shall be established and controlled as described below.

(1) Written procedures shall be established, implemented, and maintained covering the activities referenced in the ISFSI Technical Specifications.

(2) Written procedures shall be established, implemented, and maintained covering the activities referenced in DCPP Technical Specification 5.4.1.

(3) Each procedure required by paragraphs (1) and (2) above, and changes thereto, and all proposed tests or experiments that affect nuclear safety shall be reviewed and approved prior to implementation in accordance with

the review and approval requirements below. Each procedure required by paragraphs (1) and (2) above, as modified by Table 17.1-1, shall also be reviewed periodically as set forth in administrative procedures.

These procedure review and approval requirements apply when approving DCPP and ISFSI programs and procedures, or changes to DCPP and ISFSI programs and procedures. They also apply when approving or changing corporate procedures and procedures used by support organizations if they could have an immediate effect on DCPP and ISFSI operations or the operational status of safety-related DCPP SSCs or ISFSI SSCs that are important to safety. They do not apply to editorial or typographical changes.

(4) Each procedure or program required by paragraphs (1) and (2) above, and other procedures, tests, and experiments that affect nuclear safety or the treatment of radwaste, and changes thereto, shall be prepared by a qualified individual/group. Each procedure, program, test, or experiment, and changes thereto, shall be reviewed by an individual/group other than the individual/group who prepared the proposed document or change, but who may be from the same organization as the individual/group who prepared it, and shall be approved, prior to implementation, by the Station Director or his designee, as identified in administrative procedures.

(5) A responsible organization shall be assigned for each program or procedure required by paragraphs (1) and (2) above. The responsible organization shall assign reviews of proposed procedures, programs, and changes to qualified personnel of the appropriate discipline(s).

(6) Individuals responsible for the above reviews shall be knowledgeable in the document's subject area, shall meet or exceed the qualification requirements of Section 4.7.2 of ANSI/ANS 3.1-1978, and shall be designated as qualified reviewers by the Station Director or his designee for DCPP and ISFSI procedures.

(7) The reviews specified in paragraph (3) above shall include a determination as to whether additional cross-discipline reviews are necessary. If deemed necessary, they shall be performed by review personnel of the appropriate discipline(s).

(8) The reviews specified in paragraph (3) above shall also determine whether an evaluation per 10 CFR 50.59 or 10 CFR 72.48 is necessary. If necessary, one shall be prepared and presented to the PSRC for review prior to approval.

(9) Temporary changes to procedures required by paragraph (1) above may be made provided:

(a) The intent of the original procedure is not altered

(b) Administrative controls for approval and timely notification or training of personnel affected by the temporary change have been implemented; and

(c) The change is documented, reviewed as described above, and approved by the appropriate approval authority within 14 days of implementation.

(10) Temporary changes to procedures required by paragraph (2) above may be made provided all of the following criteria are met:

(a) The intent of the original procedure is not altered

(b) The change is approved by at least two exempt staff members who meet applicable qualification requirements of ANSI/ANS 3.1-1978, and are knowledgeable in the subject area of the procedure. For changes to procedures listed below, at least one approver shall hold a Senior Reactor Operators license. (Refer to the second exception for Regulatory Guide 1.33, Revision 2, in Table 17.1-1.)

1. All Operations Section procedures

2. Surveillance Test Procedures

3. Emergency Plan Implementing Procedures

4. Any other procedure if the proposed change affects equipment or system operating status

If the approving Senior Reactor Operator is not the Shift Foreman of the affected unit, that individual shall determine whether the Shift Foreman should be notified of the change immediately, and shall notify him/her if appropriate.

(c) The change is documented, reviewed as described above, and approved by the appropriate approval authority within 14 days of implementation.

17.6 DOCUMENT CONTROL

Documents and changes to documents that prescribe or verify activities affecting quality shall be controlled in a manner that precludes the use of inappropriate or outdated documents. As a minimum, controlled documents include: design documents, including documents related to computer codes; procurement documents; instructions and procedures for such activities as fabrication, construction, modification, installation, test, operation, maintenance, and inspection; as-built documents; QA and QC manuals and quality-affecting procedures; DCPP UFSAR; ISFSI UFSAR; and nonconformance reports.

The organization responsible for establishing instructions, procedures, drawings, and/or other documents prescribing activities affecting quality is also responsible to develop and implement systematic methods for the control of such documents in accordance with the requirements herein. In those instances where such documents directly involve organizational interfaces, that organization with ultimate responsibility for the issuance of the documents is responsible for establishing the methods for their control.

Procedures and instructions shall assure that documents, including changes, are prepared; reviewed by a qualified individual other than the person who generated the document; approved for release by authorized personnel; distributed to the location where the activity is performed prior to commencing work; and used in performing the activity. Procedures and instructions shall require the development of as-built drawings and the removal or appropriate identification of obsolete or superseded documents.

Procedures and instructions that define methods for implementing the QA Program requirements shall be reviewed and concurred with by the QV organization, for compliance and alignment with the QA Program. Revisions to these documents shall also be reviewed and concurred with by QV if they propose a change to the QA Program as it is described in a commitment to a regulatory agency.

The controls shall identify those responsible for preparing, reviewing, approving, and issuing documents to be used. They shall also define the coordination and control of interfacing documents and shall require the establishment of current and updated distribution lists.

A document control system shall be established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents. Master lists, when utilized as an element of the document control system, shall be updated and distributed to predetermined responsible personnel.

17.7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

Supplier activities in providing purchased material, equipment, and services shall be monitored as planned and necessary to assure such items and services meet procurement document requirements.

Procedures shall describe each organization's responsibilities for the control of purchased material, equipment, and services, including the interfaces between all affected organizations.

All materials, equipment, and services shall meet the specified technical and quality requirements. Verification that a supplier can meet the specified technical and quality requirements shall be by one or a combination of the following:

(1) Evaluation of the supplier's history

(2) Evaluation of current supplier quality records

(3) Evaluation of the supplier's facilities, personnel, and implementation of a QA Program

Such evaluations shall be documented. Suppliers whose QA Programs have been found by the QV organization, to satisfy specified quality requirements shall be listed on the PG&E Qualified Suppliers List, which is controlled by QV.

Suppliers of commercial grade calibration services may be qualified based on their accreditation by a nationally-recognized accrediting body, as an alternative to qualification by supplier audit, commercial grade survey, or in-process surveillance.

A documented review of the suppliers' accreditation by the purchaser may be used as the qualification method, as described in PG&E commitments to Regulatory Guides 1.123, Revision 1, and 1.144, January 1979, which are documented in Table 17.1-1. This review shall include, at a minimum, all of the following:

(1) The accreditation is to ANSI/ISO/IEC 17025

(2) The accrediting body is either the National Voluntary Laboratory Accreditation Program (NVLAP) or an accrediting body recognized by NVLAP through a Mutual Recognition Agreement (MRA).

(3) The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.

A QV plan shall be established and documented that applies to each procurement and identifies the manner by which PG&E intends (with appropriate QV organization

involvement) to assure the quality of the material, equipment, or service as defined in the procurement documents and to accept those items or services from the supplier.

The QV plan shall identify inspection, audit, and/or surveillance activities to be performed including the characteristics or processes to be witnessed, inspected, or verified; the method of surveillance; and the extent of documentation required. The timing and sequence of the activities shall be planned to identify any system or product deficiencies before subsequent activities may preclude their disclosure.

The QV plan shall also be based on consideration of:

(1) Importance to DCPP and ISFSI safety

(2) Complexity of inspectable characteristics

(3) Uniqueness of the item or service

Supplier performance and compliance with procurement documents may be monitored by either source verification, receiving inspection, or a combination of the two. Source verification activities may consist of inspections, audits, surveillance, or a combination thereof and are conducted at the supplier's facility. When source verification activities are specified in the QV plan, the timing and sequence of these activities are to be delineated.

Receiving inspection activities, as required by the QV plan, shall be coordinated with source verification activities performed prior to shipments. If sampling is performed, it shall be in accordance with procedures and/or recognized standards. Receipt inspection shall include a review which verifies that supplier quality records required by procurement documents are acceptable and that items are properly identified and traceable to appropriate documentation.

Records of QV activities shall be traceable to the materials, equipment, or services to which they apply. Documentation of acceptance in accordance with the procurement QV plan shall be available at the site prior to installation or acceptance for use. Documentary evidence that procurement document requirements have been met shall clearly reflect each requirement. Supplier's Certificates of Conformance are periodically evaluated by audits and independent inspections or tests to assure they are valid and the results documented.

When spare or replacement parts are procured, supplier selection and QV activities shall be planned and implemented to verify compliance with requirements meeting or exceeding those of the original.

17.8 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

Materials, parts, and components shall be identified and controlled in a manner to preclude the use of incorrect or defective items.

All materials, parts, and components, including partially fabricated subassemblies, batches, lots, and consumables, shall be identified in a manner that each can be related to its applicable drawing, specification, or other technical documentation at any stage from initial receipt through fabrication, installation, repair, or modification. Controls and implementing procedures shall ensure that only correct and accepted items are used during all stages and describe the responsibilities of the involved organizations.

Physical identification of items shall be used whenever possible and practical. Controls may, however, be through physical separation, procedure, or other appropriate means. Identification may be either on the item or on records traceable to the item.

Identification marking, where employed, shall be clear, unambiguous, and indelible and its application shall not impair the function of the identified item or any other item. When an item is subdivided, the identifying marking shall be transferred to each resulting part. Markings shall not be rendered illegible by treatment, process, assembly, installation, or coating unless other means of identification and determining acceptability are provided.

Verification activities, such as inspection, shall be performed to ensure that the provisions of this policy and related implementing procedures are followed for items prior to release for fabrication, assembly, shipping, installation, and use.

When required by code, standard, or specification, traceability of materials, parts, or components to specific inspection or test records shall be provided for and verified.

17.9 SPECIAL PROCESSES

Special processes shall be controlled and performed by qualified personnel using qualified procedures or instructions in accordance with applicable codes, standards, specifications, criteria, or other special requirements.

A special process is an activity in which the quality of the result is highly dependent upon either process variables or the skill and performance of the person doing the work, and the specified quality is difficult to verify by inspection and test after the process is completed.

Special processes include, but are not limited to:

(1) Welding

(2) Heat treating

(3) Nondestructive examination

(4) Chemical cleaning

(5) Others as specified in design and procurement documents (examples are certain protective coating applications and concrete batch plant operations, which are controlled by specifications on a case-by-case basis)

The implementing instructions shall contain the criteria for assuring proper process control and shall be qualified and controlled to assure compliance with applicable codes, standards, QA procedures, and design specifications. Substantiating records of qualifications and controls shall be maintained.

17.10 INSPECTION

A comprehensive program of inspection of items and activities affecting quality shall be conducted to verify conformance with established requirements. Procedures shall describe the organizational responsibilities necessary to carry out the inspection program.

The objective of the inspection program shall be to verify the quality of the items and activities and conformance to the applicable documented instructions, procedures, and drawings for accomplishing activities affecting quality. The inspection program, including information relative to individual inspections to be performed, shall be developed based on a review of the design drawings, specifications, and other controlled documents that prescribe items and activities affecting quality. Inspections shall be performed utilizing appropriate inspection procedures and instructions together with the necessary drawings, specifications, and other controlled documents. The inspections shall be documented and evaluated.

Inspection procedures, instructions, or checklists shall provide for the following: identification of characteristics and activities to be inspected; a description of the method of inspection; identification of the individuals or groups responsible for performing the inspection operation; acceptance and rejection criteria; identification of required procedures, drawings, and specifications, including revisions; recording the name of the inspector or data recorder and the results of the inspection operation; and specifying necessary measuring and test equipment (M&TE) including accuracy requirements. The inspection program shall include, but not be limited to, those inspections required by applicable codes, standards, specifications, and DCPP and ISFSI Technical Specifications. The inspection program shall also require both of the following during the operational phase of DCPP:

(1) Inspection of modifications, repairs, and replacements, where required to assure a suitable level of confidence that an item will perform its intended function, shall verify conformance to the original design requirements or appropriately approved equivalents

(2) Verification of the cleanness of those portions of plant safety-related systems that have been subject to potential contamination during maintenance and modification activities through an inspection performed immediately prior to closure of the portion of the system

The inspection program shall require inspection of ISFSI modifications, repairs, and replacements to be in accordance with existing design requirements.

The inspection program shall require inspection and/or test of items for each work operation where such is necessary to assure quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of process shall be required. Both inspection and process monitoring shall be required when control is

inadequate without both. Both inspection and process control shall be performed when required by applicable code, standard, or specification.

Mandatory QC inspection hold points shall be identified in the inspection program. When required, the specific hold points shall be indicated in the drawings, procedures, or instructions that prescribe the work activity. Work shall not proceed beyond such hold points without the documented consent of the QV organization.

When the inspection program permits or requires a sample of a large group of items that are amenable to statistical analysis, the sampling procedures to be used shall be based on recognized standard practices.

Inspections to verify the quality of work shall be performed by qualified individuals other than those who performed or directly supervised the activity being inspected. During the inspection, such persons shall not report directly to the immediate supervisors who are responsible for the work being inspected.

Personnel performing inspections shall be qualified in accordance with applicable regulations, codes, standards, and specifications.

Inspection records shall contain the following where applicable: a description of the type of observation, the date and results of the inspection, information related to conditions adverse to quality, inspector or data recorder identification, evidence as to the acceptability of the results, and action taken to resolve any discrepancies noted.

17.11 TEST CONTROL

A program of testing shall be conducted as necessary to demonstrate that SSCs will perform satisfactorily in service. This program shall ensure that the necessary testing is identified and performed at the appropriate time in accordance with written test procedures that incorporate or reference the requirements and acceptance limits contained in the applicable design documents.

The program shall cover all required tests, including tests prior to installation, preoperational tests, and operational tests.

The procedures that implement testing shall provide for meeting appropriate prerequisites for the test (for example, environmental conditions, specification of instrumentation, and completeness of tested item), sufficient instruction for the performance of the test, specification of any witness or hold points, acceptance and rejection criteria and limits, and the documentation of the test. The procedures shall provide for evaluation and documentation of the test results and data and their acceptability as determined by a qualified person or group.

Test records shall contain the following where applicable: a description of the type of observation, the date and results of the test, information related to conditions adverse to quality, inspector or data recorder identification, evidence as to the acceptability of the results, and action taken to resolve any discrepancies noted.

17.12 CONTROL OF MEASURING AND TEST EQUIPMENT

Organizational responsibilities shall be delineated for establishing, implementing, and assuring the effectiveness of the calibration program for M&TE. This program shall include the generation, review, and documented concurrence of calibration procedures; the calibration of M&TE; and the maintenance and use of calibration standards.

M&TE, including reference standards, used to determine the acceptability of items or activities shall be strictly maintained within prescribed accuracy limits.

M&TE, including reference standards, shall be of suitable range, type, and accuracy to verify conformance with requirements.

Procedures for control of M&TE shall provide for the identification (labeling, codes, or alternate documented control system), recall, and calibration (including documented precalibration checks) of the M&TE. The calibration procedures shall delineate any necessary environmental controls, limits, or compensations in excess of those which may be inherent to the general program.

The calibrations shall utilize documented valid relationships to nationally recognized standards or accepted values of natural physical constants. Where national standards do not exist, the basis for the calibration shall be documented. Calibration of M&TE shall be against standards that have an accuracy of at least four times the required accuracy of the equipment being calibrated or, when this is not practical, have an accuracy that assures the equipment being calibrated will be within required tolerance and that the basis of acceptance is documented and authorized by responsible management of the PG&E organization performing that activity.

Calibrating standards shall have greater accuracy than standards being calibrated. Calibrating standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by responsible management.

The calibration intervals, whether calendar- or usage-based, shall be predetermined and documented. Indication of expiration, if feasible, will be displayed on or with the M&TE. Significant environmental or usage restrictions will be indicated on or with the equipment or be factored into the documented system used to control the issuance of the M&TE. Special calibration shall be required whenever the accuracy of the equipment is suspect.

Records shall be maintained to show that established schedules and procedures for the calibration of the M&TE have been followed. M&TE shall be identified and traceable to the calibration test data. Records of the usage of the M&TE shall be maintained to facilitate corrective action in the event of the discovery of a deficiency concerning the calibration or use of M&TE, so that measures may be taken and documented to determine the validity of previous inspections performed and of the acceptability of items inspected or tested since the previous calibration of the deficient M&TE.

17.13 HANDLING, STORAGE, AND SHIPPING

Material and equipment shall be handled, stored, and shipped in accordance with design and procurement requirements in a manner that will prevent damage, deterioration, or loss.

Special coverings, equipment, and protective environments shall be specified and provided where necessary for the protection of particular items from damage or deterioration. When such special protective features are required, their existence shall be verified and monitored as necessary to assure they continue to serve their intended function.

Special handling tools and equipment shall be provided where necessary to ensure items can be handled safely and without damage. Special handling tools and equipment shall be controlled and maintained in a manner such that they will be ready and fit to serve their intended function when needed. Such control shall include periodic inspection and testing to verify that special handling tools and equipment have been properly maintained.

Special attention shall be given to marking and labeling items during packaging, shipment, and storage. Such additional marking or labeling shall be provided as is necessary to ensure that items can be properly maintained and preserved. This shall include indication of the presence of special environments or the need for special control. Provisions shall be described for the storage of chemicals, reagents (including control of shelf life), lubricants, and other consumable materials.

Special handling, preservation, storage, cleaning, packaging, and shipping requirements are established and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions.

17.14 INSPECTION, TEST, AND OPERATING STATUS

The inspection, test, and/or operating status of material, equipment, and operating systems shall be readily apparent and verifiable.

The procedures used to indicate status shall provide means for assuring that required inspections and tests are performed in the prescribed sequence; acceptability is indicated; and nonconforming items are clearly identified throughout fabrication, installation, test, maintenance, repairs, and modification to prevent inadvertent use or operation. Items accepted and released are identified to indicate their inspection status prior to forwarding them to a controlled storage area or releasing them for installation or further work. Deviations from the prescribed sequence shall be subject to the same level of control as the generation of the original sequence to prevent the bypassing or omission of a required test or inspection.

Identification of status may be by such means as, but not limited to, tags, stamps, markings, labels, or travelers. In some instances, records traceable to the item may be used. The procedures implementing control of inspection, test, and operating status shall clearly delineate authority for the application, change, or removal of a status identifier.

17.15 CONTROL OF NONCONFORMING CONDITIONS

Items and activities that do not conform to requirements shall be controlled in a manner that will prevent their inadvertent use or installation. Technical decisions as to the disposition of each nonconforming condition shall be made by personnel with assigned authority in the relevant disciplines. The control, review, and disposition of nonconforming conditions shall be accomplished and documented in accordance with approved written procedures and instructions.

Nonconforming conditions shall be documented and affected organizations notified of such conditions. Further processing of the nonconforming conditions and other items affected by them shall be controlled in a manner to prevent their inadvertent use or installation pending a decision on their disposition.

The responsibility and authority for the disposition of nonconforming conditions shall be established and set forth in the applicable procedures and instructions for their control. The rework or repair of nonconforming items and the disposition of operational nonconforming conditions shall be accomplished in accordance with written procedures and instructions. Dispositions involving design changes shall be approved by the organization with the authority for design.

The acceptability of rework or repair of materials, parts, components, systems, or structures shall be verified by reinspecting and retesting the item as originally inspected and tested, or by a method that is at least equal to the original inspection or testing method. Reworked and repaired items shall be reinspected in accordance with applicable procedures and instructions. The acceptability of nonconforming items that have been dispositioned "repair" or "accept-as-is" shall be documented. Such documentation shall include a description of the change, waiver, or deviation that has been accepted in order to record the change and, if applicable, denote the as-built condition.

Corrective action for conditions adverse to quality shall be processed in accordance with Section 17.16.

In cases where required documentary evidence that items have passed required inspections and tests is not available, the associated materials or equipment shall be considered nonconforming. Until suitable documentary evidence is available to show that the material or equipment is in conformance, affected systems shall be considered to be inoperable and reliance shall not be placed on such systems to fulfill their intended safety functions.

Nonconforming conditions that require reporting to the NRC shall be reviewed by NSOC. Such review shall include the results of any investigations made and the recommendations resulting from such investigations to preclude or reduce the probability of recurrence of the event or circumstance.

17.16 CORRECTIVE ACTION

Each individual condition adverse to quality shall be identified, controlled, and evaluated, and a disposition shall be determined for the remedial action and corrective action as soon as practicable. These activities shall be performed consistent with Section 17.15, Control of Nonconforming Conditions.

Systematic review and evaluation of all conditions adverse to quality shall be conducted and documented. Conditions adverse to quality shall include, but not be limited to: engineering, design, and drafting errors; equipment failures and malfunctions; abnormal occurrences; deficiencies; deviations; and defective material, equipment, and services.

The review and evaluation shall include identification of quality trends, repetitive occurrences, and significant conditions adverse to quality. The quality trends and other significant review findings shall be analyzed and appropriate corrective action determined. Findings and actual or recommended corrective action shall be reported to management by the responsible organization for review and assessment.

Significant conditions adverse to quality shall be investigated to the extent necessary to assess the root causes and to determine the corrective action required to prevent recurrence of the same or similar conditions. The corrective action required for significant conditions adverse to quality shall be accomplished in a timely manner. Significant conditions adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to management.

Significant conditions adverse to quality that are related to DCPP or ISFSI operations or maintenance shall be reported to NSOC. Completion of corrective actions for significant conditions adverse to quality shall be reviewed and verified by personnel having no direct responsibility for either the disposition or the corrective action taken.

Follow-up reviews shall be conducted to verify that the corrective action was properly implemented, performed in a timely manner, and that it was effective in correcting the identified condition.

Significant conditions adverse to quality shall be evaluated for reportability to the NRC in accordance with 10 CFR Part 21, 10 CFR 50.72, 10 CFR 50.73, 10 CFR 50.9, 10 CFR 72.74, and 10 CFR 72.75, the DCPP and ISFSI Technical Specifications, and other applicable regulations and shall be reported as required.

17.17 QUALITY ASSURANCE RECORDS

Sufficient records shall be maintained to furnish evidence of both the quality of items and activities affecting quality and to meet applicable code, standard, and regulatory requirements. The records include all documents referred to or described in the QA Program or required by implementing procedures such as operating logs, maintenance and modification procedures, related inspection results, and reportable occurrences; and other records required by the DCPP and ISFSI Technical Specifications and the Code of Federal Regulations. In addition to the records of the results of reviews, designs, fabrication, installation, inspections, calibrations, tests, maintenance, surveillances, audits, personnel qualification, special process qualification, and material analyses for PG&E quality-related activities and ISFSI SSCs that are important to safety, those of vendors, suppliers, subcontractors, and contractors shall also be maintained.

A management control system for the collection, storage, and maintenance of completed QA records shall be maintained. This records management program shall be designed and implemented to assure that the QA records are complete, readily retrievable when needed, and protected from damage or destruction during storage by fire, flooding, theft, environmental conditions, or other causes.

QA records stored electronically will follow the guidance for electronic records management given in the Nuclear Information and Records Management Association (NIRMA) technical guidelines, TG 11-1998, “Authentication of Records;” TG 15-1998, “Management of Electronic Records;” TG 16-1998, “Software Configuration Management and Quality Assurance;” and TG 21-1998, “Electronic Records Protection and Restoration.” QA records will be stored on electronic media (that is, optical disk, magnetic tape, network array, etc.) meeting the requirements of the NIRMA guidelines. Alternately, records stored on optical disks may meet the requirements of Generic Letter 88-18, October 1988, “Plant Record Storage on Optical Disk.” The information systems organization will determine the appropriate electronic media. Regardless of the electronic media selected, the process must be capable of producing legible, accurate, and complete records during the required retention period.

Backup copies of in-process electronic media records will be maintained in multiple, physically-independent electronic locations. Backup copies of QA records in electronic media will be maintained in multiple, physically-independent electronic locations until such time as images of these records are created, copied, and verified on two copies of an appropriate electronic storage medium. The two copies will then be stored in separate physical locations. File legibility verification will be completed on all QA records stored on electronic media by either visually verifying the file legibility or by electronically verifying exact binary file transfer.

Periodic media inspections to monitor image degradation will be conducted in accordance with the NIRMA guidelines or media manufacturers’ recommendations. These periodic inspections shall be documented.

QA records stored on electronic media will be refreshed or copied on to new media and subsequently verified if the projected lifetime of the original media does not exceed the retention period of the records stored on those media. These requirements meet the intent of Generic Letter 88-18, October 1988.

Detailed records for items or activities shall be specified by instructions, procedures, drawings, or specification or other documents that prescribe the item or activity and shall be generated by the organization responsible for the item or activity including PG&E and non-PG&E organizations. Each department generating QA records is responsible for transmitting those records to the records processing organization for archival purposes.

All records shall be assigned a retention period in conformance with Title 10, Code of Federal Regulations, other applicable codes, standards, and specifications.

17.17.1 DCPP LIFETIME RECORDS

The following records are retained for the duration of the unit Operating License:

(1) Records and drawing changes reflecting unit design modifications made to systems and equipment described in the UFSAR

(2) Records of new and irradiated fuel inventory, fuel transfers, and assembly burnup histories

(3) Records of radiation exposure for all individuals entering radiation control areas

(4) Records of gaseous and liquid radioactive material released to the environs

(5) Records of transient or operational cycles for those unit components identified in Table 5.2-4.

(6) Records of reactor tests and experiments

(7) Records of training and qualification for current members of the unit staff

(8) Records of in-service inspection performed pursuant to 10 CFR 50.55a

(9) Records of QA activities required by Chapter 17

(10) Records of reviews performed for changes made to procedures or equipment or to tests and experiments pursuant to 10 CFR 50.59

(11) Records of PSRC and NSOC meetings

(12) Records of the Independent Review and Audit Program

(13) Records of analyses required by the Radiological Environmental Monitoring Program (Regulatory Guide 4.15, Revision 1)

(14) Records of service lives of all hydraulic and mechanical snubbers required by the UFSAR including the date at which the service life commences and associated installation and maintenance records

(15) Records of secondary water sampling and water quality

(16) Records of reviews performed for changes made to the Offsite Dose Calculation Manual

(17) Records of reviews performed for changes made to the Process Control Program

17.17.2 DCPP NONPERMANENT RECORDS

The following records are retained for at least five years:

(1) Records and logs of unit operation covering time interval at each power level

(2) Records and logs of principal maintenance activities, inspections, repair, and replacement of principal items of equipment related to nuclear safety

(3) All reportable events

(4) Records of surveillance activities, inspections, and calibrations required by the Technical Specifications

(5) Records of changes made to procedures required by Technical Specification 5.4.1

(6) Records of radioactive shipments

(7) Records of sealed source and fission detector leak tests and results

(8) Records of annual physical inventory of all sealed source material of record

17.17.3 DIABLO CANYON ISFSI RECORDS

Important-to-safety records shall be classified as lifetime or nonpermanent. The following records shall be maintained as required for the ISFSI:

(1) Radiation protection program and survey records

(2) Records associated with reporting defects and noncompliance

(3) Records important to decommissioning

(4) Records of changes to the physical security plan made without prior NRC approval

(5) Records of changes, tests and experiments, and of changes to procedures described in the ISFSI UFSAR pursuant to 10 CFR 72.48

(6) Records showing receipt, inventory, location, disposal, acquisition, and transfer of spent fuel

(7) A copy of the current inventory of spent fuel in storage at the ISFSI

(8) A copy of the current material control and accounting procedures

(9) Other records required by license conditions or by NRC rules, regulations or orders

(10) Records of the occurrence and severity of important natural phenomena that affect ISFSI design

(11) QA records (including records pertaining to the design, fabrication, erection, testing, maintenance, and use of SSCs important to safety; and results of reviews, inspections, tests, audits, monitoring of work performance, and material analyses)

(12) A copy of the current physical security plan, plus any superseded portions of the plan

(13) A copy of the current safeguards contingency plan procedures, plus any superseded portions of the procedures

(14) Operating records, including maintenance, alterations or additions made

(15) Records of off-normal occurrences and events

(16) Environmental survey records

(17) Records of employee qualifications and certifications

(18) Record copies of:

- ISFSI FSAR Updates
- Reports of accidental criticality or loss of special nuclear material
- Material status reports
- Nuclear material transfer reports
- Reports of pre-operational test acceptance criteria and results
- Procedures
- Environmental Report
- Emergency Plan

(19) Construction Records; and

(20) Records of events associated with radioactive releases.

Facilities for the temporary or permanent storage of completed QA records shall be established in predetermined locations as necessary to meet the requirements of codes, standards, and regulatory agencies. Such facilities shall be constructed and maintained so as to protect the contents from possible damage or destruction.

17.18 AUDITS

The adequacy and effectiveness of the QA Program shall be continually monitored through a comprehensive system of internal and supplier audits. The audit system implemented by the QV organization includes all aspects of the QA Program. The audit system shall:

(1) Verify, through examination and evaluation of objective evidence, that this QA Program has been implemented as required

(2) Identify any deficiencies or nonconformances in the QA Program

(3) Verify the correction of any identified deficiencies or nonconformances

(4) Assess the adequacy and effectiveness of the QA Program

A comprehensive plan for the audit system shall be established and documented. Audit frequencies are determined by a performance-based evaluation plan. This plan uses assessment indicators to identify and schedule audits based on performance results and importance of the activity relative to safety. The plan shall identify the scope of individual audits that are to be performed, the aspects of this QA Program covered by each audit, and the schedule for performing audits. The audit system plan shall be reviewed at least semiannually, and revised as necessary, to assure that coverage and schedule reflect current activities, and that audits of DCPP operational phase activities and ISFSI activities are being accomplished in accordance with applicable requirements. Other associated activities included as part of the audit program are: indoctrination and training programs; the qualification and verification of implementation of QA programs of contractors and suppliers; interface control among the applicant and the principal contractors; audits by contractors and suppliers; corrective action, calibration, and nonconformance control systems; DCPP UFSAR and ISFSI UFSAR commitments; and activities associated with computer codes.

Auditors shall be independent of direct responsibility for the performance of the activities that they audit, have experience or training commensurate with the scope and complexity of their audit responsibility, and be qualified in accordance with applicable standards.

Auditing shall be initiated as early in the life of an activity as is practicable and consistent with the schedule for accomplishing the activity. In any case, auditing shall be initiated early enough to assure that the QA Program is effectively implemented throughout each activity. Individual audits shall be regularly scheduled on the basis of the status and importance of the activities that they address.

For audits, other than those with scheduled frequency mandated by regulation (such as the Safeguards Contingency Plans or the Security Program), a grace period not to exceed 25 percent of the audit interval may be utilized when the urgency of other priorities makes meeting the specified schedule dates impractical. For audit activities deferred by using a grace period,

the next scheduled due date shall be based on the original schedule due date. When an audit interval extension greater than one month is used, the next audit for that particular audit area will be scheduled from the original anniversary month rather than from the month of the extended audit.

A maximum extension not to exceed 25 percent of the audit interval shall also apply to supplier audits and evaluations except that a total combined time interval for any three consecutive survey or audit intervals shall not exceed 3.25 times the specified survey or audit interval.
Audit reports shall be prepared, signed by the Audit Team Leader, and issued to responsible management of both the audited and auditing organizations.

Audits are regularly scheduled on a formal audit schedule prepared by the QV organization. The audit schedule is reviewed regularly by the Director, QV and the schedule is revised as necessary to assure adequate coverage as commensurate with activities and past performance. Audits are performed in accordance with approved audit plans. Such audits may be augmented by other QV assessments and independent inspections. Additional audits may be performed as requested by NSOC, the CNO, the VP Nuclear Generation, or the Director, QV.

The following areas shall be audited at least once per 24 months, or more frequently as performance dictates:

(1) The conformance of DCPP and ISFSI operation to provisions contained within the applicable Technical Specifications and applicable licenses

(2) The performance, training, and qualifications of the entire DCPP and ISFSI staff

(3) The results of actions taken to correct deficiencies occurring in DCPP and ISFSI equipment, structures, systems, or method of operation that affect nuclear safety

(4) The performance of activities required by the QA Program to meet the criteria of Appendix B of 10 CFR Part 50

(5) The Radiological Environmental Monitoring Program, implementing procedures, and program results

(6) The Offsite Dose Calculation Procedure and its implementing procedures

(7) The Process Control Program and implementing procedures for processing and packaging radioactive wastes

(8) The Nonradiological Environmental Monitoring Program

(9) A representative sample of routine DCPP and ISFSI procedures that are used more frequently than every two years. This audit is to ensure the acceptability of the procedures and to verify that the procedures review and revision program is being implemented effectively.

(10) The performance of activities required to be audited by ANS-3.2/ANSI N18.7-1976, Section 4.5.

(11) Review of design documents and process to ensure compliance with Section 17.3 (i.e., use of supervisors as design verifiers). In addition, QV shall sample and review specifications and design drawings to assure that the documents are prepared, reviewed, and approved in accordance with PG&E procedures and that the documents contain the necessary QA requirements, acceptance requirements, and quality documentation requirements.

(12) QV shall audit the departments that qualify personnel and procedures to assure that the process qualification activity, records, and personnel meet the applicable requirements. They shall also audit the organizations implementing special processes to provide assurance that the processes are carried out in accordance with approved procedures by qualified personnel using qualified equipment and that required records are properly maintained.

(13) The performance of activities required by the QA Program for the Radioactive Effluent Controls Program.

(14) The Radiation Protection Program, in accordance with 10 CFR Part 20.

(15) The FFD Program in accordance with 10 CFR 26.41.

(16) Each element of the Physical Security Protection Program in accordance with 10 CFR 73.55(m)(1). However, changes to personnel, procedures, equipment, or facilities that potentially could adversely affect security shall be audited within 12 months of the change.

(17) Each element of the of the Safeguards Contingency Plan in accordance with 10 CFR Part 73 Appendix C and 10 CFR 50.54(p)(3). However, changes to personnel, procedures, equipment, or facilities that potentially could adversely affect security shall be audited within 12 months of the change.

(18) Review of the Security Training and Qualification Program in accordance with 10 CFR Part 73 Appendix B Section I.

(19) The Access Authorization Program in accordance with 10 CFR 73.56(n)(1)

(20) The Cyber Security Program in accordance with 10 CFR 73.54(g). Review the cyber security program as a component of the physical security program in accordance with the requirements of §73.55(m), including the periodicity requirements.

(21) The Emergency Preparedness Program in accordance with 10 CFR 50.54(t). However, changes to personnel, procedures, equipment, or facilities that potentially could adversely affect emergency preparedness shall be audited within 12 months of the change.

(22) The Fire Protection and Loss Prevention Program. Each audit shall include the annual, biennial, and triennial topical areas described in Generic Letter 82-21, October 1982, as well as the NFPA 805 Monitoring Program as identified in Amendment 225 to Facility Operating License No. DPR-80 (Unit 1) and Amendment 227 to Facility Operating License No. DPR-82 (Unit 2), and shall utilize qualified independent licensee personnel or an outside fire protection consultant. An outside fire protection consultant shall be utilized at least every third year. Performance based scheduling for this audit (at least once per 24 months, or more frequently as performance dictates) is applied under the provision of NRC Administrative Letter 95-06, December 1995.

The following activities shall be audited at least once per 12 months unless specified otherwise. However, if the audit frequencies required by the governing regulations are changed, audit frequencies shall at least meet the revised minimum requirements.

(1) If a contractor's or vendor's Access Authorization Program is accepted, that contractor's or vendor's Access Authorization Program shall be audited in accordance with 10 CFR 73.56(n)(2) - at least once every 12 months.

(2) FFD services that are provided by contractor/vendor personnel who are offsite or are not under the direct daily supervision or observation of DCPP personnel and Health and Human Services (HHS)-certified laboratories must be audited on a nominal 12-month frequency in accordance with 10 CFR 26.41.

Management of the audited organization shall review the audit report and respond to any quality problem reports, investigate any significant findings to identify their cause and determine the extent of corrective action required, including action to prevent recurrence. They shall schedule such corrective action and also take appropriate action to assure it is accomplished as scheduled. They shall respond to QV regarding each significant finding stating the root cause, immediate action taken, and the corrective action taken or planned to prevent recurrence. Such responses may be documented directly within electronic databases used for the corrective action program.

The QV organization shall review the written responses to all audit findings, evaluate the adequacy of each response, assure that corrective action to prevent recurrence is identified and taken for each significant finding, and confirm that corrective action is accomplished as scheduled.

Audit records shall be generated and retained by QV for all audits.

17.19 REFERENCES

1. License Amendment 187/189, dated May 26, 2006

2. License Amendment 237/239, dated September 11, 2020

TABLE 17.1-1

CURRENT REGULATORY REQUIREMENTS AND PG&E COMMITMENTS PERTAINING TO THE QUALITY ASSURANCE PROGRAM

The Quality Assurance Program for DCPP and the Diablo Canyon Independent Spent Fuel Storage Installation (ISFSI) described in Chapter 17 of the UFSAR, program directives, and administrative procedures complies with the requirements set forth in the Code of Federal Regulations. In addition, it complies with the regulatory documents and industry standards listed below. Changes to this list are not made without the review and concurrence of the Director, Quality Verification (QV).

Reg. Guides	Date (Rev)	Standard No.	Rev.	Title/Subject	Exceptions
1.8	2/79 (Proposed Rev. 2)	ANSI/ANS 3.1	1978	Personnel Selection and Training	Except that for the Quality Verification Director, the one year of qualifying nuclear power plant experience in the overall implementation of the Quality Assurance program can be obtained outside the Quality Assurance organizations. Except certain personnel are trained and qualified to the Institute of Nuclear Power Operations (INPO) criteria as described in Chapter 13. Except that a retraining and replacement training program for the plant staff meets or exceeds the requirements and recommendations of Section 5.5 of ANSI N18.1-1971 and 10 CFR Part 55. This exception is based on the NRC letter to PG&E, dated July 19, 1989, issuing License Amendments No. 43 and 42. Except that the Radiation Protection Manager's qualifications shall meet or exceed the qualifications of Regulatory Guide 1.8, Revision 2, April 1987, for the Radiation Protection Manager.

Reg. Guides	Date (Rev)	Standard No.	Rev.	Title/Subject	Exceptions
1.8, cont.					Except that the person serving as the manager responsible for the independent review and audit program shall have a minimum of 6 years of professional level managerial experience in the power field. This exception is based on NRC letter to PG&E dated February 6, 1992, issuing Licensing Amendment No. 68/67. Except that the Operations Manager shall meet the requirements of the Technical Specifications. Except that the licensed reactor operators and senior reactor operators shall meet or exceed the minimum qualifications of ANSI/ANS 3.1-1993 as endorsed by Regulatory Guide 1.8, Revision 3, May 2000 with the exceptions clarified in the current revision to the Operator Licensing Examination Standards for Power Reactors, NUREG-1021, Section ES-202. This exception is based on NRC letter to PG&E dated May 26, 2006, issuing License Amendment Nos. 187/189.
(S.G.) 26	3/72	--	--	Quality Group Classifications and Standards	It is recognized that during the design and construction of DCPP Unit 1 and Unit 2, significant industry and regulatory changes were made in establishing common methods of classification, (e.g., Safety Guide 26, March 1972). Safety Guide 26 differs in detail from the methods of classification used for DCPP and is not the DCPP Licensing Basis. A comparison of the PG&E Quality/code classes to Safety Guide 26, March 1972, is provided in Table 3.2-4. Refer to UFSAR Section 3.2 for more details. This Safety Guide does not apply to the Diablo Canyon ISFSI.

Reg. Guides	Date (Rev)	Standard No.	Rev.	Title/Subject	Exceptions
(S.G.) 28	6/72	ANSI N45.2	1971	Quality Assurance Program Requirements (Design and Construction)	
(S.G.) 29	6/72	--	--	Seismic Design Classification	It is recognized that during the design and construction of DCPP Unit 1 and Unit 2, significant industry and regulatory changes were made in establishing common methods of classification (e.g., Safety Guide 29, June 1972). Safety Guide 29 differs in detail from the methods of classification used for DCPP and is not the DCPP Licensing Basis. A comparison of the PG&E Quality/Code classes to Safety Guide 29, June 1972, is provided in Table 3.2-4. Refer to UFSAR Section 3.2 for more details.
1.30 (S.G.) 30	8/72	ANSI N45.2.4	1972	Quality Assurance Requirements for the Installation, Inspection, and Testing of Instrumentation and Electric Equipment	The evaluation of (data sheet) acceptability is indicated on the results and data sheets by the approval signature (paragraph 2.4). No visual examination for contact corrosion is made on breaker and starter contacts unless there is evidence of water damage or condensation. Contact resistance tests are made on breakers rated at 4 kV and above. No contact resistance test is made on lower voltage breakers or starters (paragraph 3[4]). No system test incorporates a noise measurement. If the system under test meets the test criteria, then noise is not a problem (paragraph 6.2.2).
1.33 (Note 1)	2/78 (Rev 2)	ANSI N18.7	1976	Quality Assurance Program Requirements (Operation)	Except that PG&E will not perform biennial review of all DCPP and Diablo Canyon ISFSI procedures, except under the conditions described in Note 1 (see note at end of table).

Reg. Guides	Date (Rev)	Standard No.	Rev.	Title/Subject	Exceptions
1.33, cont.					Except that for temporary changes to procedures, PG&E will require a review by an individual who holds a Senior Reactor Operators license only if the procedure is one of the types listed in Section 17.5 (10) of this UFSAR. Furthermore, this individual need not be the supervisor in charge of the shift. Except that audit frequencies specified in Regulatory Guide 1.33, Revision 2, need not be met. Audits shall be performed at the frequencies specified in Section 17.18 of this UFSAR. Except that audits and reviews of the Emergency Preparedness Program shall be performed in accordance with 10 CFR 50.54(t). Except that a grace period of up to 90 days will be allowed for audit scheduling, except where the schedule is mandated by regulation. The next schedule due date shall be based on the original schedule due date but shall not exceed the original due date plus 90 days. Except that when purchasing commercial-grade calibration services from certain accredited calibration laboratories, the procurement documents are not required to impose a quality assurance program consistent with ANSI N45.2-1971. Alternative requirements described in UFSAR, Section 17.7 for Regulatory Guide 1.123, Revision 1 may be implemented in lieu of imposing a quality assurance program consistent with ANSI N45.2-1971.

Reg. Guides	Date (Rev)	Standard No.	Rev.	Title/Subject	Exceptions
1.37	3/73	ANSI N45.2.1	1973	Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants	Not applicable to the Diablo Canyon ISFSI.
1.38	5/77 (Rev 2)	ANSI N45.2.2	1972	Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Water-Cooled Nuclear Power Plants	Warehouse personnel will normally visually scrutinize incoming shipments for damage of the types listed in Section 5.2.1 of ANSI N45.2.2 - 1972; this activity is not necessarily performed prior to unloading. Separate documentation of the shipping damage is not necessary. Release of the transport agent after unloading and the signing for receipt of the shipment provides adequate documentation of completion of the shipping damage inspection. Any damage noted will be documented and dispositioned. Persons performing this visual scrutiny are not considered to be performing an inspection function as defined under Regulatory Guide 1.74, February 1974; therefore, they do not require certification as an inspector under Regulatory Guide 1.58, Revision 1.
1.39	9/77 (Rev 2)	ANSI N45.2.3	1973	Housekeeping Requirements for Water-Cooled Nuclear Power Plants	Housekeeping zones established at the power plants differ from those described in the standard; however, PG&E is in compliance with the intent of the standard.

Reg. Guides	Date (Rev)	Standard No.	Rev.	Title/Subject	Exceptions
1.58	9/80 (Rev 1)	ANSI N45.2.6	1978	Qualification of Nuclear Power Plant Inspection, Examination, and Testing Personnel	ANSI N45.2.6 applies to individuals conducting independent QC inspections, examinations, and tests. ANSI/ANS 3.1-1978 applies to personnel conducting inspections and tests of items or activities for which they are responsible (e.g., plant surveillance tests, maintenance tests, etc.). Except that inspector/examiner reevaluation due dates may be extended a maximum of 90 days. The next reevaluation due date shall be based on the original scheduled due date but shall not exceed the original due date plus 90 days. NDE personnel shall be qualified and certified in accordance with CP-189-1995. ISI ultrasonic examiners shall meet the additional requirements of ASME Section XI, Appendix VIII, 2001 Edition with no Addenda.
1.64	6/76 (Rev 2)	ANSI N45.2.11	1974	Quality Assurance Requirements for the Design of Nuclear Power Plants	Except PG&E will allow the designer's immediate supervisor to perform design verification in exceptional circumstances and with the controls as described in NUREG-0800, Revision 2, July 1981.
1.74	2/74	ANSI N45.2.10	1973	Quality Assurance Terms and Definitions	

Reg. Guides	Date (Rev)	Standard No.	Rev.	Title/Subject	Exceptions
1.88	10/76 (Rev 2)	ANSI N45.2.9	1974	Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records	Except PG&E will comply with the 2-hour rating of Section 5.6 of ANSI N45.2.9 issued July 15, 1979. Except PG&E will also meet the intent of the guidelines for the storage of QA records in electronic media as, endorsed by Generic Letter 88-18, “Plant Record Storage on Optical Disks,” issued October 20, 1988, and Regulatory Issues Summary 2000-18, “Guidance on Managing Quality Assurance Records in Electronic Media,” issued October 23, 2000. Note: PG&E will maintain records of spent fuel and high-level radioactive waste in storage in accordance with ANSI N45.2.9-1974 rather than 10 CFR 72.72(d). Refer to ISFSI UFSAR, Section 9.4.2.
1.94	4/76 (Rev 1)	ANSI N45.2.5	1974	Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants	Except PG&E will not require manufacturer's certification for material suitability as inferred in ANSI N45.2.5-1974, Sections 3.1 and 3.2, when PG&E procures: (a) material from a supplier that has a QA program that meets the relevant requirements of 10CFR50, Appendix B, and the supplier is included in ASME Section III (NCA-3800/NCA-4000) or on the PG&E Qualified Suppler List; or (b) material as a “Commercial-Grade” item and dedicates it in accordance with PG&E's Commercial-Grade Dedication Program. Not applicable to the Diablo Canyon ISFSI.

TABLE 17.1-1

Reg. Guides	Date (Rev)	Standard No.	Rev.	Title/Subject	Exceptions
1.97	5/83 (Rev 3)	ANSI/ANS 4.5	1980	Instrumentation for Light-Water-Cooled Nuclear Power Plants To Assess Plant And Environs Conditions During And Following An Accident	This Regulatory Guide is not applicable to the Diablo Canyon ISFSI.
1.116	5/77 (Rev 0-R)	ANSI N45.2.8	1975	Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems	
1.123 (Note 2)	7/77 (Rev 1)	ANSI N45.2.13	1976	Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants	In addition to ANSI N45.2.13-1976, Section 10.3.3, PG&E will accept items and services which are complex or involve special processes, environmental qualification, or critical characteristics which are difficult to verify upon receipt by suppliers' Certificate of Conformance if and only if the supplier has been evaluated and qualified utilizing Performance Based Supplier Audit techniques. See Note 2 for Reg Guide 1.123, Revision 1
1.144 (Note 3)	1/79	ANSI N45.2.12	1977	Auditing of Quality Assurance Programs for Nuclear Power Plants	Except the scheduled date for triennial vendor audits and annual supplier evaluations may be extended a maximum of 90 days. The next scheduled due date shall be based on the original scheduled due date but shall not exceed the original due date plus 90 days.

Reg. Guides	Date (Rev)	Standard No.	Rev.	Title/Subject	Exceptions
1.144, cont.					Except that the corrective action program stipulated in the QA Program may be used instead of the requirements of Section 4.5.1 as long as the appropriate time limits are applied to significant conditions adverse to quality. Also, no additional documentation is necessary if needed corrective actions are taken and verified prior to audit report issuance. See Note 3 for Reg Guide 1.144, January 1979
1.146	8/80	ANSI N45.2.23	1978	Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants	Except that auditor recertification due dates may be extended a maximum of 90 days. The next recertification due date shall be based on the original scheduled due date but shall not exceed the original due date plus 90 days. Except that in lieu of the requirements of 2.3.4 of ANSI N45.2-1978, the prospective lead auditor shall have participated in at least one nuclear quality assurance audit within the year preceding the individual's effective date of qualification.
4.15	2/79 (Rev 1)	--	--	Quality Assurance for Radiological Monitoring Programs (Normal Operations) - Effluent Streams and the Environment	Record retention requirements are stated in Chapter 17, Section 17.17. This Regulatory Guide does not apply to the Diablo Canyon ISFSI.

Reg. Guides	Date (Rev)	Standard No.	Rev.	Title/Subject	Exceptions
		NFPA 805	2001 Edition	Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants	The fire protection program for DCPP satisfies the requirements of GDC 3 (1971) by complying with NFPA 805, "Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants," 2001 Edition in accordance with 10 CFR 50.48(c) as stipulated by Operating License Condition 2.C(5) and 2.C(4) for Units 1 and 2, respectively. Due to the absence of combustible materials within the Diablo Canyon ISFSI, other than the fuel in the onsite transporter, and based upon an analysis of a transporter fuel tank fire, it is concluded that a fire protection program is not required for the Diablo Canyon ISFSI. Thus, this BTP is not applicable.
---	--	NCIG-01	2	Visual Weld Acceptance Criteria for Structural Welding at Nuclear Power Plants	
---	--	NCIG-02	2	Sampling Plan for Visual Reinspection of Welds	
---	--	NCIG-03	1	Training Manual for Inspection of Structural Weld at Nuclear Power Plants Using the Acceptance Criteria of NCIG-01	

Note 1 (Regulatory Guide 1.33, Revision 2):

These controls replace the biennial procedure review requirement found in Section 5.2.15 of ANSI N18.7-1976:

1. All applicable DCPP and Diablo Canyon ISFSI procedures (shall)* be reviewed following an unusual incident, such as an accident, unexpected transient, significant operator error, or equipment malfunction, and following any modification to a system, as specified by Section 5.2 of ANSI N18.7-1976/ANS 3.2, which is endorsed by Regulatory Guide 1.33, Revision 2.

2. Non-routine procedures (e.g., emergency operating procedures, procedures which implement the emergency plan, and other procedures whose usage may be dictated by an event) (shall)* be reviewed at least every two years and revised as appropriate.

3. Routine DCPP and Diablo Canyon ISFSI procedures that have not been used for two years (shall)* be reviewed before use to determine if changes are necessary or desirable.

* The word should has been changed to shall denoting a regulatory commitment.

Note 2(Regulatory Guide 1.123, Revision 1):

The requirements of ANSI N45.2.13-1976, Section 3.2, "Content of the Procurement Documents," Subsection 3.2.3, "Quality Assurance Program Requirements" are accepted with the following exception:

When purchasing commercial-grade services from calibration laboratories accredited by a nationally-recognized accrediting body, the procurement documents are not required to impose a quality assurance program consistent with ANSI N45.2-1971. Nationally-recognized accrediting bodies include the NVLAP administered by the NIST and other accrediting bodies recognized by NVLAP via a MRA. In such cases, accreditation may be accepted in lieu of the Purchaser imposing a QA Program consistent with ANSI N45.2-1971, provided all the following are met:

(1) The accreditation is to ANSI/ISO/IEC 17025.

(2) The accrediting body is either NVLAP or other Accreditation Bureau (AB) accepted as signatory (full member) to the International Laboratory Accreditation Cooperation (ILAC) through a Mutual Recognition Arrangement (MRA); e.g., American Association for Laboratory Accreditation (A2LA), ACLASS Accreditation Service (ACLASS), Laboratory Accreditation Bureau (LAB), International Accreditation Service (IAS), or similar.

(3) The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.

(4) The purchase documents impose additional technical and administrative requirements, as necessary, to satisfy DCPP QA Program and technical requirements, including the requirement that the calibration/certificate report include identification of the laboratory equipment/standard used.

(5) The purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.

Note 3 (Reg. Guide 1.144):

The following interpretation is added with respect to Regulatory Guide 1.144, Section C.3.b(2):

When purchasing commercial-grade calibration services from calibration laboratories accredited by a nationally-recognized body, the accreditation process and accrediting body may be credited with carrying out a portion of the Purchaser's duties of verifying acceptability and effective implementation of the calibration service supplier's quality assurance program.

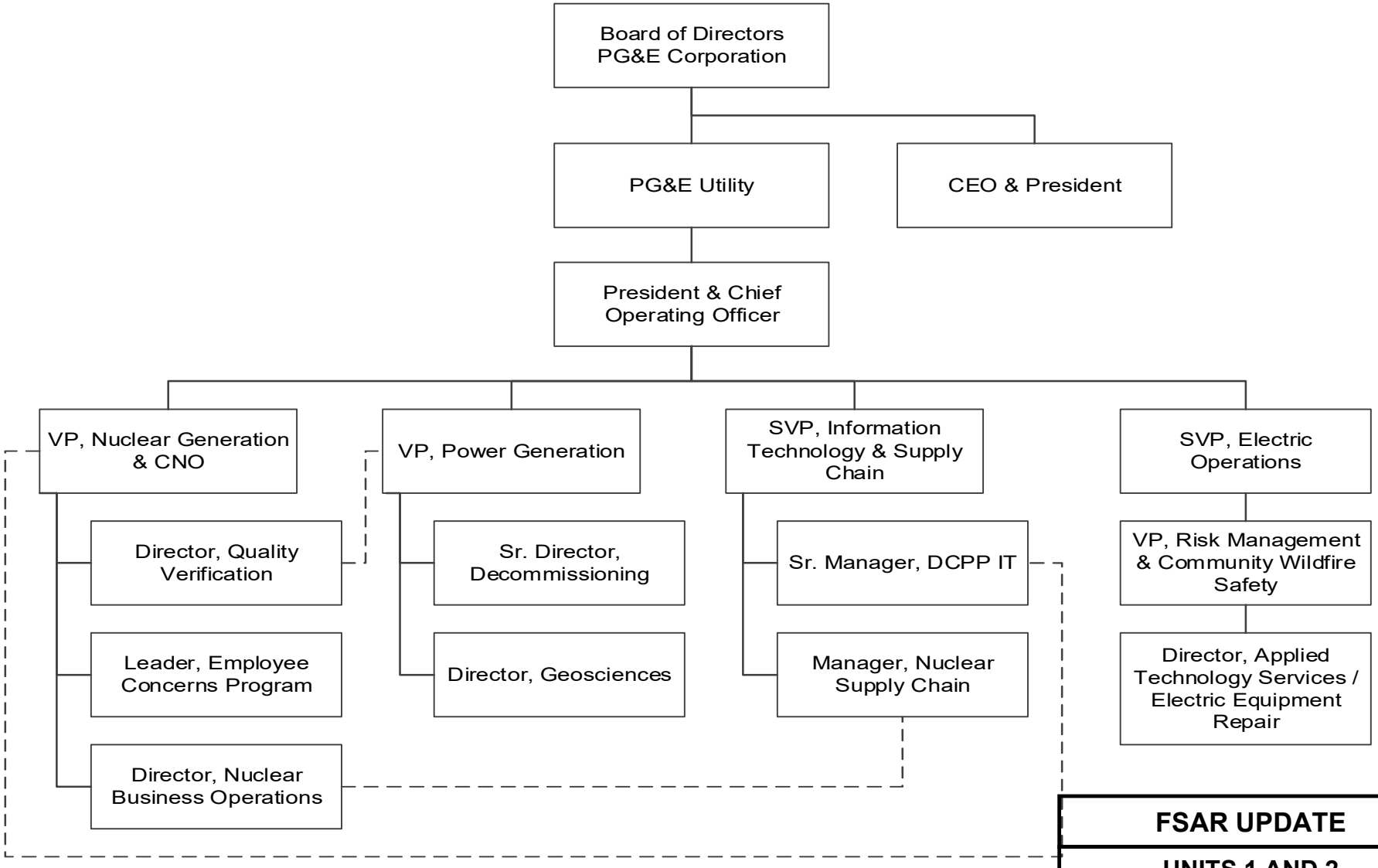
Nationally-recognized accrediting bodies include the National Voluntary Laboratory Accreditation Program (NVLAP) administered by the National Institute of Standards and Technology (NIST) and other accrediting bodies recognized by NVLAP via a Mutual Recognition Agreement (MRA)

In lieu of performing an audit, accepting an audit by another licensee, or performing a commercial-grade supplier survey, a documented review of the suppliers' accreditation shall be performed by the Purchaser. This review shall include, at a minimum, verification of all the following:

(1) The accreditation is to ANSI/ISO/IEC 17025

(2) The accrediting body is either NVLAP or other Accreditation Bureau (AB) accepted as signatory (full member) to the International Laboratory Accreditation Cooperation (ILAC) through a Mutual Recognition Arrangement (MRA) e.g., American Association for Laboratory Accreditation (A2LA), ACLASS Accreditation Service (ACLASS), Laboratory, Accreditation Bureau (LAB), International Accreditation Service (IAS) or similar.

(3) The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.

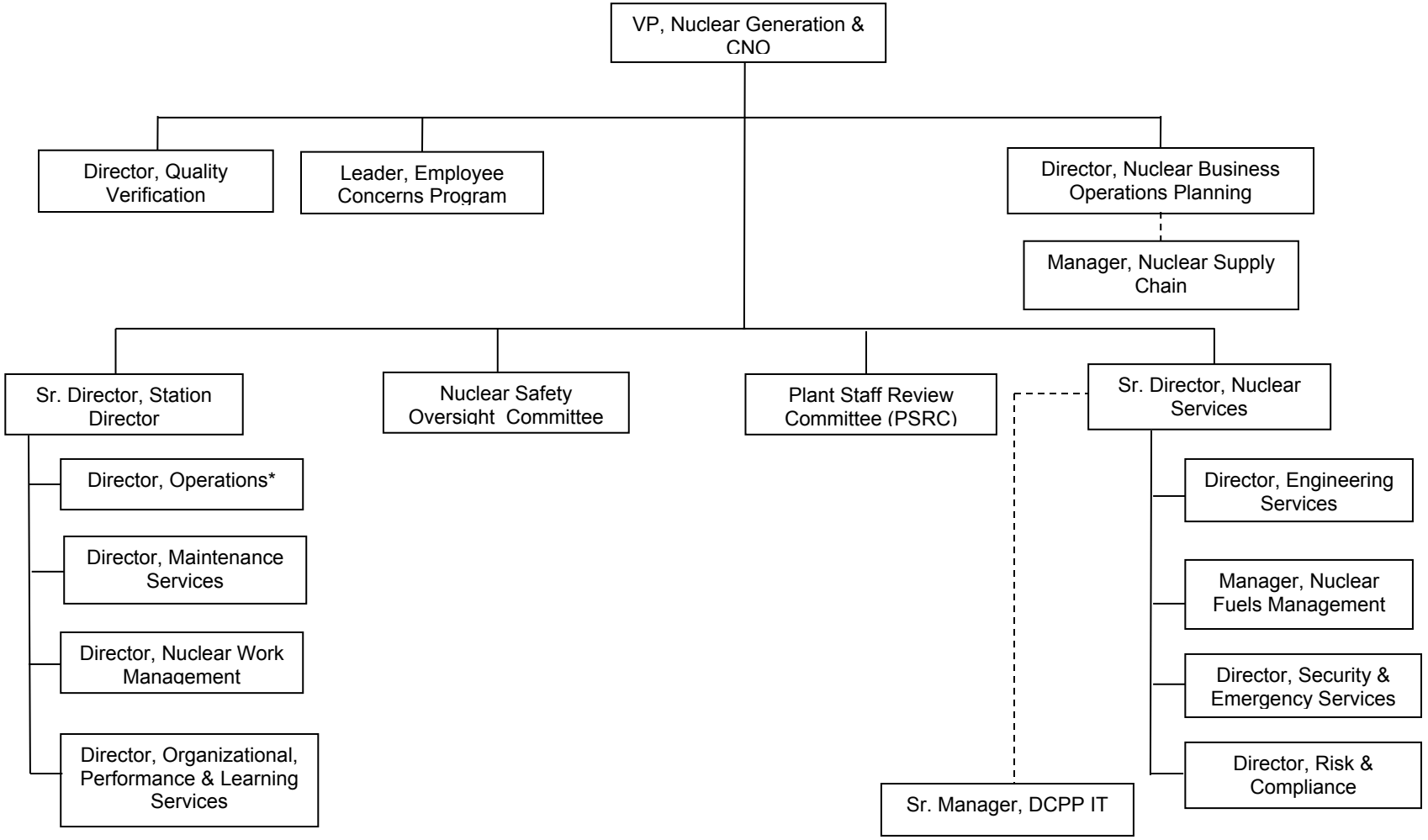


FSAR UPDATE

UNITS 1 AND 2
DIABLO CANYON SITE

FIGURE 17.1-1
PACIFIC GAS AND ELECTRIC COMPANY UTILITY ORGANIZATION

Revision 26 September 2021



*Refer to Figure 13.1-5 for Operations organization chart

--- Matrixed to Corporate

FSAR UPDATE

UNITS 1 AND 2
DIABLO CANYON SITE

FIGURE 17.1-2
NUCLEAR QUALITY AND THE OPERATING ORGANIZATION