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PG&E Letter HIL-23-001

ATTN: Document Control Desk
Director, Division of Fuel Management
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Docket No. 72-27, Materials License Number SNM-2514
Humboldt Bay Independent Spent Fuel Storage Installation
Response to NRC Request for Additional Information on Revision 1 to the Humboldt Bay ISFSI Quality Assurance Plan

Reference:

1. PG&E Letter HIL-22-004, Revision 1 to Humboldt Bay ISFSI Quality Assurance Plan, dated July 19, 2022 (ML22200A242)
2. NRC Letter, Humboldt Bay Independent Spent Fuel Storage Installation (ISFSI) Revision 1 to Humboldt Bay ISFSI Quality Assurance Plan, dated December 16, 2022 (ML22340A535)

Dear Commissioners and Staff:

In Reference 1, Pacific Gas and Electric Company (PG&E) submitted Revision 1 of the Humboldt Bay (HB) Independent Spent Fuel Storage Installation (ISFSI) Quality Assurance Plan (QAP) for NRC review and approval. In Reference 2, the NRC provided a request for additional information (RAI) regarding Reference 1. Enclosure 1 provides PG&E's response to the NRC RAI included in Reference 2. Enclosure 2 provides a marked-up version of the updated Revision 1 of the HB ISFSI QAP. Enclosure 3 provides a clean version of the HB ISFSI QAP with revision bars in the left-hand margin where changes were incorporated.

PG&E makes no new or revised regulatory commitments (as defined in NEI 99-04) in this letter.

If you have any questions or require additional information, please contact Mr. Jim Morris at (805) 305-9775.

Sincerely,

Paula Gerfen
Senior Vice President and Chief Nuclear Officer

February 16, 2023
Date

Enclosures

cc: Humboldt Distribution
cc/enc: William C. Allen, NRC Project Manager
Robert J. Lewis, NRC Acting Region IV Administrator

Responses to NRC Request for additional information – Request for Additional Information Humboldt Bay Docket No. 72-0027
HBI-L6, Humboldt Bay ISFSI Quality Assurance Plan, Revision 1

Background

By submittal dated July 19, 2022, Pacific Gas and Electric Company (PG&E) requested approval of HBI-L6, "Humboldt Bay ISFSI Quality Assurance Plan," Revision 1. This request for additional information (RAI) identifies information needed by the U.S. Nuclear Regulatory Commission (NRC) staff in connection with its review of the PG&E Quality Assurance Plan (QAP). The requested information is listed by chapter number and title in the applicant's QAP. NUREG 2215, "Standard Review Plan for Spent Fuel Dry Storage Systems and Facilities," was used by the staff in its review.

Each RAI describes the information needed by the staff for it to complete its review of the submittal and to determine whether the applicant has demonstrated compliance with the regulatory requirements.

Section 12.0 "CONTROL OF MEASURING AND TEST EQUIPMENT"

12.1 State the quality requirements that PG&E intends to impose on Humboldt Bay (HB) Independent Spent Fuel Storage Installation (ISFSI) facility procedures or QA programs related to the control of measuring and test equipment (M&TE) to ensure compliance with Title 10 of the Code of Federal Regulations (10 CFR), Part 72.164, "Control of measuring and test equipment."

Section 3 of Enclosure 1, "Description and Justification for Proposed Changes Included in Revision 1 of the Humboldt Bay Independent Spent Fuel Storage Installation Quality Assurance Plan," states, "HB ISFSI does not currently possess or maintain M&TE. Should this change in the future, then HB ISFSI will provide instructions for their use and maintenance through facility procedures."

Section 12.1, "GENERAL REQUIREMENTS," states, "Proper control, calibration, and adjustments at specified periods to maintain accuracy of M&TE is described in HB ISFSI facility procedures as appropriate. The calibration program shall be compliant with an approved QA Program."

The previously approved NRC-approved HB QAP committed to using Diablo Canyon Power Plant's (DCPP) Radiation Protection organization for controlling M&TE. DCPP has an NRC-approved QAP that meets the requirements of 10 CFR 50, Appendix B, and has been determined to incorporate the proper controls for M&TE. Since PG&E intends to control activities related to M&TE using HB procedures, PG&E needs to delineate the quality requirements that it intends to incorporate into these procedures should they be created and implemented.

This information is needed to determine compliance with 10 CFR 72.164.

PG&E Response to RAI

Measuring and Test Equipment (M&TE) shall be calibrated, controlled and periodically adjusted by qualified personnel using qualified procedures in accordance with applicable codes, standards, and requirements.

M&TE required to support Humboldt Bay (HB) Independent Spent Fuel Storage Installation (ISFSI) quality activities are identified in HB ISFSI work control documents. During long-term storage at the HB ISFSI, proper control, calibration, and adjustments of M&TE are performed by Diablo Canyon Power Plant (DCPP) organizations or by contractor personnel in accordance with an approved Quality Assurance (QA) Program.

PG&E has revised Section 12.1 to replace “DCPP Radiation Protection organization” with “DCPP organizations or by contractor personnel” to ensure that DCPP organizations and contractor personnel that use M&TE to perform HB ISFSI quality activities are required to satisfy the M&TE requirements in Section 12.1 in accordance with an approved QA Program.

Enclosure 2 provides a marked-up version of the updated Revision 1 of the HB ISFSI QA Plan. Enclosure 3 provides a clean version of the HB ISFSI QA Plan with revision bars in the left-hand margin where changes were incorporated.

HBI-L6
HUMBOLDT BAY ISFSI QUALITY ASSURANCE PLAN
Revision 1
(marked up version)

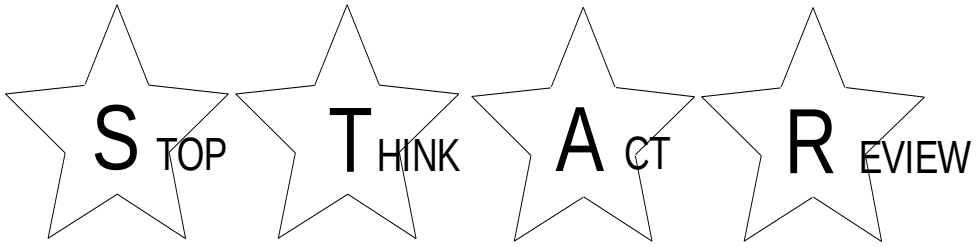
HBI-L6

HUMBOLDT BAY ISFSI QUALITY ASSURANCE PLAN

Rev. ~~0~~1

QUALITY ~~RELATED~~

Humboldt Bay ISFSI



APPROVAL
Approved By: _____ / _____ / _____ (Print Name) (Signature) (Date)
Effective Date:

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INTRODUCTION

Pacific Gas and Electric (PG&E) has established and is implementing a Quality Assurance Program for Humboldt Bay Independent Spent Fuel Storage Installation (HB ISFSI) that satisfies the requirements of 10 CFR 72 Subpart G and 10 CFR 71 Subpart H for the procurement, maintenance, repair and use of radioactive materials transport packages.

The HB ISFSI QA Program prescribes the quality requirements and controls that govern the Important to Safety (ITS) operations and maintenance activities for the long-term storage of the Humboldt Bay spent nuclear fuel and Greater Than Class C (GTCC) waste. Required HB ISFSI QA Program changes to support the HB ISFSI unloading campaign for transfer of spent fuel and GTCC to the Department of Energy (DOE) will accompany changes to the HB ISFSI License and Technical Specification for the specific activities.

The HB ISFSI QA Program consists of the HB ISFSI QA Plan (QAP) and implementing procedures and instructions. The HB ISFSI QA Program applies to the ITS Structures Systems and Components (SSCs) in Appendix A and administrative programs in Appendix B of the HB ISFSI QAP.

The HB ISFSI QAP describes the organizational structure; levels of authority; lines of communication; and the functional responsibilities for implementing quality requirements, establishing and maintaining the QA Program, and assessing the performance of activities subject to the HB ISFSI QAP.

Implementation of the HB ISFSI QAP requirements is performed in a graded approach commensurate with any items or activities importance to safety. The HB ISFSI QAP is implemented through the use of approved procedures (i.e. policies, procedures, manuals, instructions, or other documents) that provide written guidance for the control of ITS items and activities.

The requirements and commitments contained in the HB ISFSI QAP are mandatory and must be implemented, enforced, and adhered to by all individuals and organizations performing activities affecting quality. Workers are encouraged to actively participate in the continued improvement and implementation of the HB ISFSI QAP. Any necessary changes should be promptly communicated and implemented.

1.0 ORGANIZATION

1.1 GENERAL REQUIREMENTS

PG&E personnel are responsible for the operation and maintenance of the HB ISFSI and packaging and transportation of radioactive material. Assignment of the responsibility for an item or activity includes responsibility for its quality.

1.2 DELEGATION OF AUTHORITY

Specific responsibilities pertaining to quality assurance matters are assigned by the HB ISFSI QAP and its implementing procedures and instructions to various individuals throughout PG&E. The work of executing selected portions of the HB ISFSI QAP may be delegated to organizations external to PG&E; however, in all such instances, PG&E retains overall responsibility. 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.

Delegations of functions, tasks, activities, and authority shall be documented. Individuals may fulfill more than one function unless prevented by the need to maintain independence as specified in the HB ISFSI QAP.

1.3 ORGANIZATIONAL RESPONSIBILITIES

PG&E has assumed full responsibility for the establishment and execution of the HB ISFSI QAP, administrative programs and implementing procedures, prescribed herein. The HB ISFSI QAP describes the organizational structure for key personnel, functional responsibilities, levels of authority, line of communication, and interfaces of persons and organizations performing activities governed by the HB ISFSI QAP. Generic titles are used for the functions and responsibilities. Differences (if any) between actual titles used in the organization are traceable to the HB ISFSI QAP titles by the use of administrative procedures.

The ~~SENIOR VICE PRESIDENT, GENERATION AND~~ CHIEF NUCLEAR OFFICER (CNO) establishes the corporate policies, goals and objectives related to PG&E's nuclear power generation assets, activities and operation. The CNO, or designee, as specified in writing, approves and signs official company correspondence to the U.S. Nuclear Regulatory Commission (NRC) or its representatives pertaining to the HB ISFSI.

The CNO approves revisions to the QA Program for nuclear generation assets, activities and operation as described herein that require prior NRC approval.

The SENIOR LEADER responsible for HB ISFSI reports to the CNO and has overall responsibility for the safe storage of nuclear fuel and for taking measures to ensure acceptable performance of HB ISFSI operations and project execution.

The DIRECTOR - NUCLEAR QUALITY VERIFICATION (Quality Director) reports to the CNO for HB ISFSI quality activities, and has access to the President, the HB ISFSI Director, and appropriate managers for any significant quality problem or deficiency related to the HB ISFSI. The Quality Director has the organizational freedom and requisite authority to assess, review, inspect, audit, and monitor the conduct of quality activities to assure compliance with the HB ISFSI QAP and other regulatory requirements.

The Quality Director is responsible for assuring that the HB ISFSI QAP and its implementing procedures are effectively implemented and complied with by all involved organizations, both internal and external to PG&E. The Quality Director is also responsible for maintaining and submitting for approval changes to the HB ISFSI QAP, and the review of all regulatory submittals as they pertain to the HB ISFSI QAP and his/her concurrence is required prior to submittal.

The NUCLEAR QUALITY VERIFICATION ORGANIZATION (Quality Organization) reports to the Quality Director and include the quality assurance, supplier quality and independent quality control inspection functions. These individuals or groups do not have direct responsibility for performing the work being verified; are trained and qualified in QA concepts and practices; are independent of the organization responsible for performing the task and have direct access to the management levels necessary to perform this function.

The Quality Organization is sufficiently free from direct pressures for cost and schedule that assures the ability to: (a) identify quality problems; (b) initiate, recommend, or provide solutions through designated channels; and (c) verify implementation of solutions.

Individuals within the Quality Organization have the authority to stop unsatisfactory work and control further processing, delivery, or installation of nonconforming material. Organizational positions with stop work authority are identified in the implementing procedures.

The HB ISFSI DIRECTOR is responsible for the conduct of activities related to the HB ISFSI. This includes responsibility for operation, maintenance, training, security, and emergency preparedness. The day-to-day responsibilities are delegated to and executed by the HB ISFSI management team. Specific responsibilities are described in administrative procedures.

The HB ISFSI Director is also responsible for the development of programs, procedures, and instructions required for HB ISFSI within the requirements and/or limits established in the HB ISFSI QAP; HB ISFSI Technical Specifications; and administrative guidelines established in the HB ISFSI Final Safety Analysis Report (FSAR).

The HB ISFSI Director shall delegate these responsibilities to other members of the HB ISFSI management team during his/her absence.

The ISFSI MANAGER is responsible for the operation and maintenance of the HB ISFSI, maintenance of the Physical Security Plan and interfacing with outside agencies.

The Diablo Canyon Power Plant (DCPP) RADIATION PROTECTION MANAGER is responsible for implementing the HB ISFSI radiation protection program for the protection of the workers and members of the public.

The SENIOR LEADER of DCPP Engineering is the Design Authority for HB ISFSI and is responsible for technical aspects of the engineering and design of HB ISFSI SSC including, performance of modifications; configuration control and design bases defense and management; quality classification of

SSC; and the specification of technical and quality requirements for the purchase of services, materials, and equipment.

SUPPLIERS that provide ITS SSCs or services are required to comply with the HB ISFSI QAP or to a QA Program approved by PG&E. Supplier QA Programs are required to meet or exceed the applicable portions of 10 CFR 72, Subpart G. The Quality Program requirements are defined in the contract or similar procurement document.

Suppliers to PG&E are required to document their internal organization, 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.

2.0 QUALITY ASSURANCE PROGRAM

2.1 GENERAL REQUIREMENTS

The Quality Assurance Program for the HB ISFSI is established to satisfy the requirements of 10 CFR 72 Subpart G and 10 CFR 71 Subpart H for the procurement, maintenance, repair and use of radioactive materials transport packages.

The HB ISFSI Quality Assurance Program is documented in approved procedures (i.e., policies, procedures, manuals, instructions, or other documents).

2.2 PROGRAM APPLICABILITY

The HB ISFSI QA Program prescribes the quality requirements and controls that govern the ITS operations and maintenance activities for the long-term storage of the Humboldt Bay spent nuclear fuel and Greater than Class C waste. The quality requirements are identified in the HB ISFSI QAP and the quality controls are identified in implementing procedures.

The ITS SSCs in Appendix A are subject to the HB ISFSI QAP requirements described herein. The ITS SSCs in Appendix A are assigned quality classification/category commensurate with the SSCs' importance to safety.

Select HB ISFSI QAP requirements are applicable to the administrative programs in Appendix B as identified in implementing procedure.

HB ISFSI ITS support activities performed by PG&E or contractor personnel are in accordance with an approved QA Program.

The effectiveness of the implementation of the HB ISFSI QAP shall be assured through Quality programs and documentation as specified in implementing procedures.

2.3 GRADED APPROACH

A graded approach is used to establish the controls applied to ITS SSCs in Appendix A. The level of quality applied to administrative programs in Appendix B is commensurate with the activity's importance to safety. In some cases, additional quality requirements for the administrative programs may apply based on other regulatory requirements (e.g., 10CFR20 for Radiation Protection; NRC Security Orders).

The graded approach also applies to the level of quality oversight for quality activities.

2.4 PROGRAM CONTROL

The status and adequacy of the HB ISFSI QAP and implementing procedures shall be regularly monitored and revised, as necessary, to improve its effectiveness or reflect changing conditions.

Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of quality assurance program they are executing.

The HB ISFSI QAP, including any changes, supplements, or appendices are issued and maintained as controlled documents.

Implementation of the HB ISFSI QAP is accomplished through separately issued procedures, instructions, and drawings. Each organization is responsible for the establishment and implementation of detailed procedures and instructions prescribing the quality activities for which they are responsible. Such documents are derived from the requirements and reflect the responsibilities specified in the HB ISFSI QAP. Each organization is responsible for identifying, assessing, and correcting conditions adverse to quality as described in Section 16.0.

2.5 RESOLUTION OF DIFFERENCES

Questions or disputes involving interpretations of HB ISFSI QAP requirements and commitments are referred to the Quality Director for resolution. Questions or disputes involving the responsibilities defined in the HB ISFSI QAP are referred to the ~~Vice President, Nuclear Generation and~~ 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 the management level which has direct authority over all contesting parties.

2.6 TRAINING AND QUALIFICATIONS

2.6.1 Indoctrination and Training

Indoctrination and training for personnel implementing ITS activities are conducted to assure suitable proficiency is achieved and maintained. The extent of indoctrination and training is commensurate with the scope, complexity, and importance to safety of the assigned task; in conjunction with the education and experience of the individual. Personnel involved in implementing the activities within the scope of the HB ISFSI QAP shall be responsible for the quality of their work. At a minimum, these personnel shall receive:

- Indoctrination in the requirements of the HB ISFSI QAP;
- Indoctrination in their organization's implementing procedures; and
- Training and qualification in tasks requiring special skills or knowledge, as required.

Indoctrination, training, qualification, and re-qualification (when applicable) shall be prescribed and performed in accordance with written procedures; and applicable codes, standards, and regulatory requirements; which specify the management responsibilities; training areas; frequency of training; method of qualification and requalification; and documentation requirements.

Training and qualification records are maintained in accordance with implementing procedures.

2.6.2 Staff Qualifications

Except as specified in other portions of the HB ISFSI QAP, each member of the HB ISFSI staff shall meet or exceed the minimum qualifications described in the HB ISFSI FSAR.

The RADIATION PROTECTION MANAGER ~~shall meet or exceed the requirements of Regulatory Guide 1.8, Revision 2, April 1987~~qualifications are described in the HB ISFSI FSAR.

The QUALITY DIRECTOR shall have knowledge of QA regulations, policies, practices, and standards; and experience working in QA, nuclear power plant, fuel storage facility, or in a similar highly technological industry. At the time of assignment to the active position, the Quality Director shall have six years of experience in implementing Quality Assurance.

At least one year of these six years of experience shall be nuclear power plant or fuel storage facility experience in the overall implementation of a Quality Assurance 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 one year of qualifying nuclear power plant or fuel storage facility experience in the overall implementation of the Quality Assurance program can be obtained outside the Quality Assurance organizations.

2.7 REGULATORY COMMITMENTS

Regulatory commitments, where applicable, are specified in the ISFSI FSAR, Technical Specifications, Licenses, or implementing procedures.

3.0 DESIGN CONTROL

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.

During long-term storage at the HB ISFSI, design activities for ITS SSCs are performed under the direction of the HB ISFSI Design Authority in accordance with an approved QA Program.

4.0 PROCUREMENT DOCUMENT CONTROL

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

During long-term storage at the HB ISFSI, procurement of ITS materials, parts, equipment, and services is performed under the direction of the HB ISFSI Design Authority in accordance with an approved QA Program.

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 GENERAL REQUIREMENTS

Activities shall be prescribed by and accomplished in accordance with documented instructions, procedures, and drawings. These documents shall include quantitative or qualitative acceptance criteria for verifying that an activity was satisfactorily accomplished, where applicable (i.e., verification activities for procurement, inspection tests).

5.2 PROCEDURE CHANGES

Changes to or deviations from established instructions, procedures, or drawings require the same review and approval as the original document. Instructions, procedures, or drawings, including changes and deviations, subject to the HB ISFSI QAP shall be maintained.

Administrative controls shall be established that provide the methods by which temporary changes can be made to approved procedures, including the designation of persons authorized to approve such changes.

6.0 DOCUMENT CONTROL

6.1 GENERAL REQUIREMENTS

Documents and changes to documents that prescribe or verify activities affecting quality shall be controlled in a manner that precludes the use of inadequate or outdated documents.

A document control system shall be established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents. Written procedures shall identify those responsible for preparing, reviewing, approving, and issuing documents.

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; and distributed for use prior to commencing work and are used at the location where the prescribed activity is performed.

6.2 QUALITY VERIFICATION REVIEWS

Quality Organization review and concurrence, when required, for procedures, instructions, and other documents, are specified in administrative procedures.

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

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

During long-term storage at the HB ISFSI, procurement of ITS materials, equipment and services is performed under the direction of the HB ISFSI Design Authority in accordance with an approved QA Program.

8.0 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.

During long-term storage at the HB ISFSI, procurement of ITS materials, parts and components is performed under the direction of the HB ISFSI Design Authority in accordance with an approved QA Program.

9.0 SPECIAL PROCESSES

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: welding, heat treating, nondestructive examination, and chemical cleaning.

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

During long-term storage at the HB ISFSI, there are no ITS operations or maintenance activities that require the use of special processes that are performed by HB ISFSI onsite personnel.

Special processes, if required during long-term storage at the HB ISFSI, will be performed under the direction of the HB ISFSI Design Authority or by contractor personnel in accordance with an approved QA Program.

10.0 INSPECTIONS

10.1 GENERAL REQUIREMENTS

A program for 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.

10.2 INSPECTION PLANNING AND PERFORMANCE

Inspections shall be planned in accordance with approved procedures, and based on drawings, specifications, and other controlled documents. Inspections shall be performed in accordance with written and approved inspection plans/procedures to verify that the quality of items and activities conform to applicable and documented instructions, procedures, and drawings.

Inspections shall be performed by qualified individuals other than those who performed or directly supervised the activity being inspected.

10.3 INSPECTION METHODS

If direct inspection is not practical, process monitoring methods, must be used. Both inspection and process monitoring must be used when quality control is inadequate without both.

Acceptance/rejection criteria and mandatory quality control inspection hold points shall be identified, where applicable. Work shall not proceed beyond such hold points without the appropriate documented concurrence by authorized personnel.

10.4 INSPECTION RESULTS

The inspection results, including acceptance/rejection criteria, shall be documented and evaluated. Unacceptable inspection results shall be evaluated and resolved in accordance with procedures. Where applicable, modifications, repairs and replacements; are re-inspected to the same standard or method to verify acceptability. Inspection records shall be maintained.

11.0 TEST CONTROL

11.1 GENERAL REQUIREMENTS

A program of testing shall be conducted, as necessary, to demonstrate that SSCs will perform satisfactorily in service.

11.2 TEST CONTROL PROGRAM

The Test Control 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 procedures that implement testing shall specify the appropriate prerequisites for the test (e.g., environmental conditions, specification of instrumentation, and completeness of tested item), sufficient instruction for the performance of the test, witness or hold points, acceptance/rejection criteria and limits, and the required test documentation.

11.3 TEST RESULTS

The procedures shall provide for evaluation and documentation of the test results; data; and their acceptability as determined by a qualified person or group. Test results that do not meet the acceptance criteria shall be documented and evaluated to determine the appropriate corrective action. Where applicable, modifications, repairs, and replacements; are re-tested to verify acceptability.

Test records shall be maintained

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 GENERAL REQUIREMENTS

Organizational responsibilities shall be delineated for establishing, implementing, and assuring the effectiveness of the calibration program for measuring and test equipment (M&TE).

During long-term storage at the HB ISFSI, proper control, calibration, and adjustments of M&TE is performed by DCPP organizations or by contractor personnel in accordance with an approved QA Program. ~~During long-term storage at the HB ISFSI, the DCPP Radiation Protection organization is responsible for the calibration program for HB ISFSI measuring and test equipment (M&TE).~~

~~The calibration program shall be compliant with an approved QA Program.~~

13.0 HANDLING, STORAGE, AND SHIPPING CONTROL

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.

During long-term storage at the HB ISFSI, design and procurement of ITS material and equipment are performed under the direction of the HB ISFSI Design Authority in accordance with an approved QA Program.

14.0 INSPECTION, TEST, AND OPERATING STATUS

14.1 GENERAL REQUIREMENT

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

The procedures implementing control of inspection, test, and operating status shall clearly delineate authority for the application, change, or removal of a status identifier.

14.2 INSPECTION AND TEST CONTROLS

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.

Procedures shall specify the necessary controls for indicating inspection and test status, assuring that required inspections and tests are performed in the prescribed sequence; to prevent inadvertent use or operation.

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.

15.0 NONCONFORMANCES

15.1 GENERAL REQUIREMENTS

Items and activities that do not conform to requirements shall be controlled in a manner that will prevent their inadvertent use or installation.

15.2 CONTROL OF NONCONFORMING ITEMS

Measures shall be established to identify, label and segregate nonconforming items to indicate their unacceptable status and to prevent inadvertent use or installation until the nonconformance is properly dispositioned. Labels associated with a nonconforming item shall only be removed by authorized personnel.

Nonconforming conditions are documented, reviewed and accepted, rejected, repaired or reworked in accordance with procedures. The acceptability of nonconforming items shall be verified and documented prior to use. Organizations affected by nonconforming conditions shall be notified of such conditions.

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. The materials or equipment shall not be used until acceptability of nonconforming items shall be verified.

Nonconforming conditions shall be processed as conditions adverse to quality in accordance with Section 16.0.

16.0 CORRECTIVE ACTION

16.1 GENERAL REQUIREMENTS

Conditions adverse to quality may include, but not be limited to: engineering, design, and drafting errors; equipment failures and malfunctions; deficiencies; deviations; and defective material, equipment, and nonconformances.

Conditions adverse to quality shall be identified, controlled, reviewed, and evaluated to determine remedial action and corrective action and implement those actions as soon as practicable.

The evaluation should be based on safety significance. Corrective actions shall be accomplished in a timely manner commensurate with the safety significance.

16.2 SIGNIFICANT CONDITIONS ADVERSE TO QUALITY

Significant conditions adverse to quality, the cause of the condition, and the corrective action taken to preclude recurrence shall be documented and reported to appropriate levels of management.

Follow-up reviews shall be conducted to verify that the corrective action was properly implemented and effective in correcting the identified condition.

17.0 QA RECORDS

17.1 GENERAL REQUIREMENTS

Records shall be maintained to furnish evidence of both the quality of items and activities affecting quality and to meet applicable code, standard, regulatory, and license requirements. The records include all documents referred to or described in the HB ISFSI QAP as records or required by quality procedures.

At a minimum quality records include design records, records of use, and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. Records also include related data, such as qualifications of personnel, procedures, and equipment. Inspection and test records shall identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any noted efficiencies.

Records required by the HB ISFSI QAP, and furnished by vendors, suppliers, subcontractors, and contractors that perform or supply quality activities or ITS SSCs are also QA records and shall be maintained.

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.

Design, fabrication, erection, testing, maintenance records for ITS SSC in Appendix A shall be maintained and controlled until the NRC terminates the license.

17.2 RECORDS MANAGEMENT

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

17.3 ELECTRONIC RECORDS

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 (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, “Plant Record Storage on Optical Disk,” dated October 20, 1988. Information Systems 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.

Electronic QA records, including backup copies, are stored in two redundant electronic media storage systems at physically-independent electronic locations. QA records in electronic format (e.g., pdf format) may be filed and stored on the electronic media storage systems.

18.0 AUDITS

18.1 GENERAL REQUIREMENTS

Measures shall establish a comprehensive system of planned and periodic audits to assess, monitor and verify compliance with all aspects of the quality assurance program and determine the effectiveness of the HB ISFSI QAP and implementing activities.

Internal, external and supplier audits are performed in accordance with written procedures and/or check lists. Audits are performed by qualified personnel not having direct responsibility in the areas audited. Auditors shall have experience, training, or qualifications commensurate with the scope and complexity of their audit responsibility.

18.2 AUDIT PERFORMANCE

18.2.1 Audit Scope and Frequency

Audit scopes and schedules are established to meet applicable regulatory requirements and are based on the status and safety significance of the activities to be audited. Scheduling, preparation, personnel selection, performance, reporting, response, follow-up action, and records management are performed in accordance with written procedures.

At a minimum, internal audits of HB ISFSI operations, applicable regulatory requirements are at least once every 24 months or more frequently as performance dictates.

External audits of suppliers providing ITS materials, parts, equipment, or services to access the effectiveness of the control of quality are scheduled and performed based on the importance of an SSC or activity to confirm implementation of their Quality Program requirements, but at least once every 3 years.

18.2.2 Grace Periods

Audits that are not mandated by regulation have a grace period of up to 90 days, when the urgency of other priorities makes meeting the specified schedule dates impractical. For audit activities deferred using a grace period, the next scheduled due date shall be based on the originally scheduled due date but may not exceed the original due date plus 90 days.

18.3 AUDIT REPORTS

Audit reports shall be prepared, issued to, and reviewed by responsible management of the audited and auditing organizations. Audit records shall be generated and retained. Follow-up action, including re-audit of deficient areas, shall be taken, where applicable.

19.0 RESPONSIBLE ORGANIZATION

Quality Verification

APPENDIX A

IMPORTANT TO SAFETY STRUCTURES, SYSTEMS AND COMPONENTS

The pertinent quality assurance requirements of 10 CFR 71 Subpart H and 10 CFR 72 Subpart G will be applied, as a minimum, to quality activities affecting the ITS SSC associated with spent fuel storage and transportation package that are listed below. The quality category is based on the guidance in NUREG/CR-6407. The HB ISFSI FSAR, Holtec International HI-STORM Safety Analysis Report (SAR), Holtec International HI-STAR SAR and associated specifications include additional classification information.

NOTE

The quality classification of NRC Licensed HB ISFSI Dry Fuel Storage Components and Transportation Packages is made by the NRC Certificate Holder. The Certificate Holder is responsible for design and licensing controls for these components under their NRC approved Quality Assurance Program. PG&E utilizes these types of components and packages under the provisions of a NRC General License for Radioactive Material Transportation Packages (10 CFR 71) and Spent Fuel and GTCC Storage (10 CFR 72).

IMPORTANT TO SAFETY AS DEFINED BY 10 CFR 71 AND 10 CFR 72

A. Dry Spent Fuel and GTCC Storage (10 CFR 72)

SSC	Quality Category	Design/License Responsible
Multi-Purpose Canister	A	PG&E
Fuel Basket and Basket Spacers	A	PG&E
Damaged Fuel Container	A	PG&E
HI-STAR 100 HB Overpack	A	PG&E
Transporter Lift Links	A	PG&E
GTCC Waste Container	A	PG&E
HI-STAR HB GTCC Overpack	A	PG&E
HB ISFSI Storage Vault	B	PG&E
HB ISFSI Storage Vault Lid and Plugs	B	PG&E
Fuel Spacers	B	PG&E
Transporter Connector Pins	B	PG&E
Helium Fill Gas	B	PG&E
Lid Retention Device	B	PG&E
Cask Transporter	B	PG&E
Process Waste Container	B	PG&E

B. Transport of Spent Fuel and GTCC Waste (10 CFR 71)

SSC	Quality Category	Design/License Responsible
Multi-Purpose Canister	A	Holtec International
Fuel Basket and Basket Spacers	A	Holtec International
Damaged Fuel Container	A	Holtec International
HI-STAR 100 HB Overpack	A	Holtec International
GTCC Waste Container	A	Holtec International
HI-STAR HB GTCC Overpack	A	Holtec International
Fuel Spacers	B	Holtec International
Helium Fill Gas	B	Holtec International

APPENDIX B

ADMINISTRATIVE PROGRAMS AND CONTROLS

1.0 PROGRAMS AND PROCEDURES

The program and procedures listed below shall be established and controlled to support the HB ISFSI. Applicable regulatory and quality requirements for the administrative programs in Appendix B are designated in administrative programs and procedures.

a) Radiation Protection Program

b) Emergency Plan

c) Radiological Environmental Monitoring Program

d) Security Program (as defined in security license bases documents)

2.0 TECHNICAL SPECIFICATION ACTIVITIES

In addition to the applicable quality assurance requirements specified in the HB ISFSI QAP, Technical Specification activities shall be controlled in accordance with the Limiting Conditions for Operations and Surveillance Requirements.

3.0 RADIOLOGICAL ENVIRONMENTAL MONITORING

As documented in Revision 6 of the HB ISFSI FSAR Section 7.7, no radioactive gas, liquid, or solid waste effluents are released from the HB ISFSI during operation. Therefore, a radioactive effluent monitoring system is not required, routine monitoring for effluents is not performed, and the reporting requirements of 10 CFR 72.44(d)(3) do not apply.

The HB ISFSI Radiological Environmental Monitoring Program (REMP) monitors direct radiation pathway to the environment. The HB ISFSI REMP is implemented by posting thermoluminescent dosimeters (TLDs) in the vicinity of the Owner-Controlled Area fence and on the Security Area Fence. TLDs are read quarterly to monitor direct radiation from the ISFSI.

Compliance with the dose limits in 10 CFR 72.104 is verified by the environmental program using direct radiation measurements. Thus, there is no longer any requirement to participate in an Inter-Laboratory Comparison Program (ICP). Vendor(s) supplying the direct radiation monitoring devices are certified under a National Voluntary Laboratory Accreditation Program (NVLAP).

HBI-L6
HUMBOLDT BAY ISFSI QUALITY ASSURANCE PLAN
Revision 1
(clean version)

HBI-L6

HUMBOLDT BAY ISFSI QUALITY ASSURANCE PLAN

Rev. 1

QUALITY

Humboldt Bay ISFSI

APPROVAL			
Approved By:	Shawn P Kirven (Print Name)	/ Shawn P Kirven (Signature)	/ 02/07/2023 (Date)
Effective Date:			

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INTRODUCTION

Pacific Gas and Electric (PG&E) has established and is implementing a Quality Assurance Program for Humboldt Bay Independent Spent Fuel Storage Installation (HB ISFSI) that satisfies the requirements of 10 CFR 72 Subpart G and 10 CFR 71 Subpart H for the procurement, maintenance, repair and use of radioactive materials transport packages.

The HB ISFSI QA Program prescribes the quality requirements and controls that govern the Important to Safety (ITS) operations and maintenance activities for the long-term storage of the Humboldt Bay spent nuclear fuel and Greater Than Class C (GTCC) waste. Required HB ISFSI QA Program changes to support the HB ISFSI unloading campaign for transfer of spent fuel and GTCC to the Department of Energy (DOE) will accompany changes to the HB ISFSI License and Technical Specification for the specific activities.

The HB ISFSI QA Program consists of the HB ISFSI QA Plan (QAP) and implementing procedures and instructions. The HB ISFSI QA Program applies to the ITS Structures Systems and Components (SSCs) in Appendix A and administrative programs in Appendix B of the HB ISFSI QAP.

The HB ISFSI QAP describes the organizational structure; levels of authority; lines of communication; and the functional responsibilities for implementing quality requirements, establishing and maintaining the QA Program, and assessing the performance of activities subject to the HB ISFSI QAP.

Implementation of the HB ISFSI QAP requirements is performed in a graded approach commensurate with any items or activities importance to safety. The HB ISFSI QAP is implemented through the use of approved procedures (i.e. policies, procedures, manuals, instructions, or other documents) that provide written guidance for the control of ITS items and activities.

The requirements and commitments contained in the HB ISFSI QAP are mandatory and must be implemented, enforced, and adhered to by all individuals and organizations performing activities affecting quality. Workers are encouraged to actively participate in the continued improvement and implementation of the HB ISFSI QAP. Any necessary changes should be promptly communicated and implemented.

1.0 ORGANIZATION

1.1 GENERAL REQUIREMENTS

PG&E personnel are responsible for the operation and maintenance of the HB ISFSI and packaging and transportation of radioactive material. Assignment of the responsibility for an item or activity includes responsibility for its quality.

1.2 DELEGATION OF AUTHORITY

Specific responsibilities pertaining to quality assurance matters are assigned by the HB ISFSI QAP and its implementing procedures and instructions to various individuals throughout PG&E. The work of executing selected portions of the HB ISFSI QAP may be delegated to organizations external to PG&E; however, in all such instances, PG&E retains overall responsibility. 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.

Delegations of functions, tasks, activities, and authority shall be documented. Individuals may fulfill more than one function unless prevented by the need to maintain independence as specified in the HB ISFSI QAP.

1.3 ORGANIZATIONAL RESPONSIBILITIES

PG&E has assumed full responsibility for the establishment and execution of the HB ISFSI QAP, administrative programs and implementing procedures, prescribed herein. The HB ISFSI QAP describes the organizational structure for key personnel, functional responsibilities, levels of authority, line of communication, and interfaces of persons and organizations performing activities governed by the HB ISFSI QAP. Generic titles are used for the functions and responsibilities. Differences (if any) between actual titles used in the organization are traceable to the HB ISFSI QAP titles by the use of administrative procedures.

The CHIEF NUCLEAR OFFICER (CNO) establishes the corporate policies, goals and objectives related to PG&E's nuclear power generation assets, activities and operation. The CNO, or designee, as specified in writing, approves and signs official company correspondence to the U.S. Nuclear Regulatory Commission (NRC) or its representatives pertaining to the HB ISFSI.

The CNO approves revisions to the QA Program for nuclear generation assets, activities and operation as described herein that require prior NRC approval.

The SENIOR LEADER responsible for HB ISFSI reports to the CNO and has overall responsibility for the safe storage of nuclear fuel and for taking measures to ensure acceptable performance of HB ISFSI operations and project execution.

The DIRECTOR - NUCLEAR QUALITY VERIFICATION (Quality Director) reports to the CNO for HB ISFSI quality activities, and has access to the President, the HB ISFSI Director, and appropriate managers for any significant quality problem or deficiency related to the HB ISFSI. The Quality Director has the organizational freedom and requisite authority to assess, review, inspect, audit, and monitor the conduct of quality activities to assure compliance with the HB ISFSI QAP and other regulatory requirements.

The Quality Director is responsible for assuring that the HB ISFSI QAP and its implementing procedures are effectively implemented and complied with by all involved organizations, both internal and external to PG&E. The Quality Director is also responsible for maintaining and submitting for approval changes to the HB ISFSI QAP, and the review of all regulatory submittals as they pertain to the HB ISFSI QAP and his/her concurrence is required prior to submittal.

The NUCLEAR QUALITY VERIFICATION ORGANIZATION (Quality Organization) reports to the Quality Director and include the quality assurance, supplier quality and independent quality control inspection functions. These individuals or groups do not have direct responsibility for performing the work being verified; are trained and qualified in QA concepts and practices; are independent of the organization responsible for performing the task and have direct access to the management levels necessary to perform this function.

The Quality Organization is sufficiently free from direct pressures for cost and schedule that assures the ability to: (a) identify quality problems; (b) initiate, recommend, or provide solutions through designated channels; and (c) verify implementation of solutions.

Individuals within the Quality Organization have the authority to stop unsatisfactory work and control further processing, delivery, or installation of nonconforming material. Organizational positions with stop work authority are identified in the implementing procedures.

The HB ISFSI DIRECTOR is responsible for the conduct of activities related to the HB ISFSI. This includes responsibility for operation, maintenance, training, security, and emergency preparedness. The day-to-day responsibilities are delegated to and executed by the HB ISFSI management team. Specific responsibilities are described in administrative procedures.

The HB ISFSI Director is also responsible for the development of programs, procedures, and instructions required for HB ISFSI within the requirements and/or limits established in the HB ISFSI QAP; HB ISFSI Technical Specifications; and administrative guidelines established in the HB ISFSI Final Safety Analysis Report (FSAR).

The HB ISFSI Director shall delegate these responsibilities to other members of the HB ISFSI management team during his/her absence.

The ISFSI MANAGER is responsible for the operation and maintenance of the HB ISFSI, maintenance of the Physical Security Plan and interfacing with outside agencies.

The Diablo Canyon Power Plant (DCPP) RADIATION PROTECTION MANAGER is responsible for implementing the HB ISFSI radiation protection program for the protection of the workers and members of the public.

The SENIOR LEADER of DCPP Engineering is the Design Authority for HB ISFSI and is responsible for technical aspects of the engineering and design of HB ISFSI SSC including, performance of modifications; configuration control and design bases defense and management; quality classification of

SSC; and the specification of technical and quality requirements for the purchase of services, materials, and equipment.

SUPPLIERS that provide ITS SSCs or services are required to comply with the HB ISFSI QAP or to a QA Program approved by PG&E. Supplier QA Programs are required to meet or exceed the applicable portions of 10 CFR 72, Subpart G. The Quality Program requirements are defined in the contract or similar procurement document.

Suppliers to PG&E are required to document their internal organization, 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.

2.0 QUALITY ASSURANCE PROGRAM

2.1 GENERAL REQUIREMENTS

The Quality Assurance Program for the HB ISFSI is established to satisfy the requirements of 10 CFR 72 Subpart G and 10 CFR 71 Subpart H for the procurement, maintenance, repair and use of radioactive materials transport packages.

The HB ISFSI Quality Assurance Program is documented in approved procedures (i.e., policies, procedures, manuals, instructions, or other documents).

2.2 PROGRAM APPLICABILITY

The HB ISFSI QA Program prescribes the quality requirements and controls that govern the ITS operations and maintenance activities for the long-term storage of the Humboldt Bay spent nuclear fuel and Greater than Class C waste. The quality requirements are identified in the HB ISFSI QAP and the quality controls are identified in implementing procedures.

The ITS SSCs in Appendix A are subject to the HB ISFSI QAP requirements described herein. The ITS SSCs in Appendix A are assigned quality classification/category commensurate with the SSCs' importance to safety.

Select HB ISFSI QAP requirements are applicable to the administrative programs in Appendix B as identified in implementing procedure.

HB ISFSI ITS support activities performed by PG&E or contractor personnel are in accordance with an approved QA Program.

The effectiveness of the implementation of the HB ISFSI QAP shall be assured through Quality programs and documentation as specified in implementing procedures.

2.3 GRADED APPROACH

A graded approach is used to establish the controls applied to ITS SSCs in Appendix A. The level of quality applied to administrative programs in Appendix B is commensurate with the activity's importance to safety. In some cases, additional quality requirements for the administrative programs may apply based on other regulatory requirements (e.g., 10CFR20 for Radiation Protection; NRC Security Orders).

The graded approach also applies to the level of quality oversight for quality activities.

2.4 PROGRAM CONTROL

The status and adequacy of the HB ISFSI QAP and implementing procedures shall be regularly monitored and revised, as necessary, to improve its effectiveness or reflect changing conditions.

Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of quality assurance program they are executing.

The HB ISFSI QAP, including any changes, supplements, or appendices are issued and maintained as controlled documents.

Implementation of the HB ISFSI QAP is accomplished through separately issued procedures, instructions, and drawings. Each organization is responsible for the establishment and implementation of detailed procedures and instructions prescribing the quality activities for which they are responsible. Such documents are derived from the requirements and reflect the responsibilities specified in the HB ISFSI QAP. Each organization is responsible for identifying, assessing, and correcting conditions adverse to quality as described in Section 16.0.

2.5 RESOLUTION OF DIFFERENCES

Questions or disputes involving interpretations of HB ISFSI QAP requirements and commitments are referred to the Quality Director for resolution. Questions or disputes involving the responsibilities defined in the HB ISFSI QAP 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 the management level which has direct authority over all contesting parties.

2.6 TRAINING AND QUALIFICATIONS

2.6.1 Indoctrination and Training

Indoctrination and training for personnel implementing ITS activities are conducted to assure suitable proficiency is achieved and maintained. The extent of indoctrination and training is commensurate with the scope, complexity, and importance to safety of the assigned task; in conjunction with the education and experience of the individual. Personnel involved in implementing the activities within the scope of the HB ISFSI QAP shall be responsible for the quality of their work. At a minimum, these personnel shall receive:

- Indoctrination in the requirements of the HB ISFSI QAP;
- Indoctrination in their organization's implementing procedures; and
- Training and qualification in tasks requiring special skills or knowledge, as required.

Indoctrination, training, qualification, and re-qualification (when applicable) shall be prescribed and performed in accordance with written procedures; and applicable codes, standards, and regulatory requirements; which specify the management responsibilities; training areas; frequency of training; method of qualification and requalification; and documentation requirements.

Training and qualification records are maintained in accordance with implementing procedures.

2.6.2 Staff Qualifications

Except as specified in other portions of the HB ISFSI QAP, each member of the HB ISFSI staff shall meet or exceed the minimum qualifications described in the HB ISFSI FSAR.

The RADIATION PROTECTION MANAGER qualifications are described in the HB ISFSI FSAR.

The QUALITY DIRECTOR shall have knowledge of QA regulations, policies, practices, and standards; and experience working in QA, nuclear power plant, fuel storage facility, or in a similar highly technological industry. At the time of assignment to the active position, the Quality Director shall have six years of experience in implementing Quality Assurance.

At least one year of these six years of experience shall be nuclear power plant or fuel storage facility experience in the overall implementation of a Quality Assurance 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 one year of qualifying nuclear power plant or fuel storage facility experience in the overall implementation of the Quality Assurance program can be obtained outside the Quality Assurance organizations.

2.7 REGULATORY COMMITMENTS

Regulatory commitments, where applicable, are specified in the ISFSI FSAR, Technical Specifications, Licenses, or implementing procedures.

3.0 DESIGN CONTROL

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.

During long-term storage at the HB ISFSI, design activities for ITS SSCs are performed under the direction of the HB ISFSI Design Authority in accordance with an approved QA Program.

4.0 PROCUREMENT DOCUMENT CONTROL

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

During long-term storage at the HB ISFSI, procurement of ITS materials, parts, equipment, and services is performed under the direction of the HB ISFSI Design Authority in accordance with an approved QA Program.

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 GENERAL REQUIREMENTS

Activities shall be prescribed by and accomplished in accordance with documented instructions, procedures, and drawings. These documents shall include quantitative or qualitative acceptance criteria for verifying that an activity was satisfactorily accomplished, where applicable (i.e., verification activities for procurement, inspection tests).

5.2 PROCEDURE CHANGES

Changes to or deviations from established instructions, procedures, or drawings require the same review and approval as the original document. Instructions, procedures, or drawings, including changes and deviations, subject to the HB ISFSI QAP shall be maintained.

Administrative controls shall be established that provide the methods by which temporary changes can be made to approved procedures, including the designation of persons authorized to approve such changes.

6.0 DOCUMENT CONTROL

6.1 GENERAL REQUIREMENTS

Documents and changes to documents that prescribe or verify activities affecting quality shall be controlled in a manner that precludes the use of inadequate or outdated documents.

A document control system shall be established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents. Written procedures shall identify those responsible for preparing, reviewing, approving, and issuing documents.

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; and distributed for use prior to commencing work and are used at the location where the prescribed activity is performed.

6.2 QUALITY VERIFICATION REVIEWS

Quality Organization review and concurrence, when required, for procedures, instructions, and other documents, are specified in administrative procedures.

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

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

During long-term storage at the HB ISFSI, procurement of ITS materials, equipment and services is performed under the direction of the HB ISFSI Design Authority in accordance with an approved QA Program.

8.0 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.

During long-term storage at the HB ISFSI, procurement of ITS materials, parts and components is performed under the direction of the HB ISFSI Design Authority in accordance with an approved QA Program.

9.0 SPECIAL PROCESSES

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: welding, heat treating, nondestructive examination, and chemical cleaning.

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

During long-term storage at the HB ISFSI, there are no ITS operations or maintenance activities that require the use of special processes that are performed by HB ISFSI onsite personnel.

Special processes, if required during long-term storage at the HB ISFSI, will be performed under the direction of the HB ISFSI Design Authority or by contractor personnel in accordance with an approved QA Program.

10.0 INSPECTIONS

10.1 GENERAL REQUIREMENTS

A program for 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.

10.2 INSPECTION PLANNING AND PERFORMANCE

Inspections shall be planned in accordance with approved procedures, and based on drawings, specifications, and other controlled documents. Inspections shall be performed in accordance with written and approved inspection plans/procedures to verify that the quality of items and activities conform to applicable and documented instructions, procedures, and drawings.

Inspections shall be performed by qualified individuals other than those who performed or directly supervised the activity being inspected.

10.3 INSPECTION METHODS

If direct inspection is not practical, process monitoring methods, must be used. Both inspection and process monitoring must be used when quality control is inadequate without both.

Acceptance/rejection criteria and mandatory quality control inspection hold points shall be identified, where applicable. Work shall not proceed beyond such hold points without the appropriate documented concurrence by authorized personnel.

10.4 INSPECTION RESULTS

The inspection results, including acceptance/rejection criteria, shall be documented and evaluated. Unacceptable inspection results shall be evaluated and resolved in accordance with procedures. Where applicable, modifications, repairs and replacements; are re-inspected to the same standard or method to verify acceptability. Inspection records shall be maintained.

11.0 TEST CONTROL

11.1 GENERAL REQUIREMENTS

A program of testing shall be conducted, as necessary, to demonstrate that SSCs will perform satisfactorily in service.

11.2 TEST CONTROL PROGRAM

The Test Control 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 procedures that implement testing shall specify the appropriate prerequisites for the test (e.g., environmental conditions, specification of instrumentation, and completeness of tested item), sufficient instruction for the performance of the test, witness or hold points, acceptance/rejection criteria and limits, and the required test documentation.

11.3 TEST RESULTS

The procedures shall provide for evaluation and documentation of the test results; data; and their acceptability as determined by a qualified person or group. Test results that do not meet the acceptance criteria shall be documented and evaluated to determine the appropriate corrective action. Where applicable, modifications, repairs, and replacements; are re-tested to verify acceptability.

Test records shall be maintained

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 GENERAL REQUIREMENTS

Organizational responsibilities shall be delineated for establishing, implementing, and assuring the effectiveness of the calibration program for measuring and test equipment (M&TE).

During long-term storage at the HB ISFSI, proper control, calibration, and adjustments of M&TE is performed by DCPP organizations or by contractor personnel in accordance with an approved QA Program.

13.0 HANDLING, STORAGE, AND SHIPPING CONTROL

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.

During long-term storage at the HB ISFSI, design and procurement of ITS material and equipment are performed under the direction of the HB ISFSI Design Authority in accordance with an approved QA Program.

14.0 INSPECTION, TEST, AND OPERATING STATUS

14.1 GENERAL REQUIREMENT

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

The procedures implementing control of inspection, test, and operating status shall clearly delineate authority for the application, change, or removal of a status identifier.

14.2 INSPECTION AND TEST CONTROLS

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.

Procedures shall specify the necessary controls for indicating inspection and test status, assuring that required inspections and tests are performed in the prescribed sequence; to prevent inadvertent use or operation.

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.

15.0 NONCONFORMANCES

15.1 GENERAL REQUIREMENTS

Items and activities that do not conform to requirements shall be controlled in a manner that will prevent their inadvertent use or installation.

15.2 CONTROL OF NONCONFORMING ITEMS

Measures shall be established to identify, label and segregate nonconforming items to indicate their unacceptable status and to prevent inadvertent use or installation until the nonconformance is properly dispositioned. Labels associated with a nonconforming item shall only be removed by authorized personnel.

Nonconforming conditions are documented, reviewed and accepted, rejected, repaired or reworked in accordance with procedures. The acceptability of nonconforming items shall be verified and documented prior to use. Organizations affected by nonconforming conditions shall be notified of such conditions.

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. The materials or equipment shall not be used until acceptability of nonconforming items shall be verified.

Nonconforming conditions shall be processed as conditions adverse to quality in accordance with Section 16.0.

16.0 CORRECTIVE ACTION

16.1 GENERAL REQUIREMENTS

Conditions adverse to quality may include, but not be limited to: engineering, design, and drafting errors; equipment failures and malfunctions; deficiencies; deviations; and defective material, equipment, and nonconformances.

Conditions adverse to quality shall be identified, controlled, reviewed, and evaluated to determine remedial action and corrective action and implement those actions as soon as practicable.

The evaluation should be based on safety significance. Corrective actions shall be accomplished in a timely manner commensurate with the safety significance.

16.2 SIGNIFICANT CONDITIONS ADVERSE TO QUALITY

Significant conditions adverse to quality, the cause of the condition, and the corrective action taken to preclude recurrence shall be documented and reported to appropriate levels of management.

Follow-up reviews shall be conducted to verify that the corrective action was properly implemented and effective in correcting the identified condition.

17.0 QA RECORDS

17.1 GENERAL REQUIREMENTS

Records shall be maintained to furnish evidence of both the quality of items and activities affecting quality and to meet applicable code, standard, regulatory, and license requirements. The records include all documents referred to or described in the HB ISFSI QAP as records or required by quality procedures.

At a minimum quality records include design records, records of use, and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. Records also include related data, such as qualifications of personnel, procedures, and equipment. Inspection and test records shall identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any noted efficiencies.

Records required by the HB ISFSI QAP, and furnished by vendors, suppliers, subcontractors, and contractors that perform or supply quality activities or ITS SSCs are also QA records and shall be maintained.

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.

Design, fabrication, erection, testing, maintenance records for ITS SSC in Appendix A shall be maintained and controlled until the NRC terminates the license.

17.2 RECORDS MANAGEMENT

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

17.3 ELECTRONIC RECORDS

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 (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, “Plant Record Storage on Optical Disk,” dated October 20, 1988. Information Systems 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.

Electronic QA records, including backup copies, are stored in two redundant electronic media storage systems at physically-independent electronic locations. QA records in electronic format (e.g., pdf format) may be filed and stored on the electronic media storage systems.

18.0 AUDITS

18.1 GENERAL REQUIREMENTS

Measures shall establish a comprehensive system of planned and periodic audits to assess, monitor and verify compliance with all aspects of the quality assurance program and determine the effectiveness of the HB ISFSI QAP and implementing activities.

Internal, external and supplier audits are performed in accordance with written procedures and/or check lists. Audits are performed by qualified personnel not having direct responsibility in the areas audited. Auditors shall have experience, training, or qualifications commensurate with the scope and complexity of their audit responsibility.

18.2 AUDIT PERFORMANCE

18.2.1 Audit Scope and Frequency

Audit scopes and schedules are established to meet applicable regulatory requirements and are based on the status and safety significance of the activities to be audited. Scheduling, preparation, personnel selection, performance, reporting, response, follow-up action, and records management are performed in accordance with written procedures.

At a minimum, internal audits of HB ISFSI operations, applicable regulatory requirements are at least once every 24 months or more frequently as performance dictates.

External audits of suppliers providing ITS materials, parts, equipment, or services to access the effectiveness of the control of quality are scheduled and performed based on the importance of an SSC or activity to confirm implementation of their Quality Program requirements, but at least once every 3 years.

18.2.2 Grace Periods

Audits that are not mandated by regulation have a grace period of up to 90 days, when the urgency of other priorities makes meeting the specified schedule dates impractical. For audit activities deferred using a grace period, the next scheduled due date shall be based on the originally scheduled due date but may not exceed the original due date plus 90 days.

18.3 AUDIT REPORTS

Audit reports shall be prepared, issued to, and reviewed by responsible management of the audited and auditing organizations. Audit records shall be generated and retained. Follow-up action, including re-audit of deficient areas, shall be taken, where applicable.

19.0 RESPONSIBLE ORGANIZATION

Quality Verification

APPENDIX A

IMPORTANT TO SAFETY STRUCTURES, SYSTEMS AND COMPONENTS

The pertinent quality assurance requirements of 10 CFR 71 Subpart H and 10 CFR 72 Subpart G will be applied, as a minimum, to quality activities affecting the ITS SSC associated with spent fuel storage and transportation package that are listed below. The quality category is based on the guidance in NUREG/CR-6407. The HB ISFSI FSAR, Holtec International HI-STORM Safety Analysis Report (SAR), Holtec International HI-STAR SAR and associated specifications include additional classification information.

NOTE

The quality classification of NRC Licensed HB ISFSI Dry Fuel Storage Components and Transportation Packages is made by the NRC Certificate Holder. The Certificate Holder is responsible for design and licensing controls for these components under their NRC approved Quality Assurance Program. PG&E utilizes these types of components and packages under the provisions of a NRC General License for Radioactive Material Transportation Packages (10 CFR 71) and Spent Fuel and GTCC Storage (10 CFR 72).

IMPORTANT TO SAFETY AS DEFINED BY 10 CFR 71 AND 10 CFR 72

A. Dry Spent Fuel and GTCC Storage (10 CFR 72)

SSC	Quality Category	Design/License Responsible
Multi-Purpose Canister	A	PG&E
Fuel Basket and Basket Spacers	A	PG&E
Damaged Fuel Container	A	PG&E
HI-STAR 100 HB Overpack	A	PG&E
Transporter Lift Links	A	PG&E
GTCC Waste Container	A	PG&E
HI-STAR HB GTCC Overpack	A	PG&E
HB ISFSI Storage Vault	B	PG&E
HB ISFSI Storage Vault Lid and Plugs	B	PG&E
Fuel Spacers	B	PG&E
Transporter Connector Pins	B	PG&E
Helium Fill Gas	B	PG&E
Lid Retention Device	B	PG&E
Cask Transporter	B	PG&E
Process Waste Container	B	PG&E

B. Transport of Spent Fuel and GTCC Waste (10 CFR 71)

SSC	Quality Category	Design/License Responsible
Multi-Purpose Canister	A	Holtec International
Fuel Basket and Basket Spacers	A	Holtec International
Damaged Fuel Container	A	Holtec International
HI-STAR 100 HB Overpack	A	Holtec International
GTCC Waste Container	A	Holtec International
HI-STAR HB GTCC Overpack	A	Holtec International
Fuel Spacers	B	Holtec International
Helium Fill Gas	B	Holtec International

APPENDIX B

ADMINISTRATIVE PROGRAMS AND CONTROLS

1.0 PROGRAMS AND PROCEDURES

The program and procedures listed below shall be established and controlled to support the HB ISFSI. Applicable regulatory and quality requirements for the administrative programs in Appendix B are designated in administrative programs and procedures.

a) Radiation Protection Program

b) Emergency Plan

c) Radiological Environmental Monitoring Program

d) Security Program (as defined in security license bases documents)

2.0 TECHNICAL SPECIFICATION ACTIVITIES

In addition to the applicable quality assurance requirements specified in the HB ISFSI QAP, Technical Specification activities shall be controlled in accordance with the Limiting Conditions for Operations and Surveillance Requirements.

3.0 RADIOLOGICAL ENVIRONMENTAL MONITORING

As documented in Revision 6 of the HB ISFSI FSAR Section 7.7, no radioactive gas, liquid, or solid waste effluents are released from the HB ISFSI during operation. Therefore, a radioactive effluent monitoring system is not required, routine monitoring for effluents is not performed, and the reporting requirements of 10 CFR 72.44(d)(3) do not apply.

The HB ISFSI Radiological Environmental Monitoring Program (REMP) monitors direct radiation pathway to the environment. The HB ISFSI REMP is implemented by posting thermoluminescent dosimeters (TLDs) in the vicinity of the Owner-Controlled Area fence and on the Security Area Fence. TLDs are read quarterly to monitor direct radiation from the ISFSI.

Compliance with the dose limits in 10 CFR 72.104 is verified by the environmental program using direct radiation measurements. Thus, there is no longer any requirement to participate in an Inter-Laboratory Comparison Program (ICP). Vendor(s) supplying the direct radiation monitoring devices are certified under a National Voluntary Laboratory Accreditation Program (NVLAP).