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PG&E Letter HIL-22-004

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Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Docket No. 72-27, License No. SNM-2514
Humboldt Bay Independent Spent Fuel Storage Installation (ISFSI)
Revision 1 to Humboldt Bay ISFSI Quality Assurance Plan

Dear Commissioners and Staff:

In accordance with 10 CFR 72.140(b) and (c) and 10 CFR 71.101(b) and (c), Pacific Gas and Electric Company (PG&E) is submitting Revision 1 to HBI-L6, Humboldt Bay ISFSI Quality Assurance Plan for NRC review and approval. In addition, this letter requests the NRC to issue a revision to PG&E's Quality Assurance Program Approval No. 0969, Docket 0710969, to reflect NRC approval of the proposed Revision 1 to the Humboldt Bay ISFSI Quality Assurance Plan included in Enclosure 3.

Enclosure 1 includes a detailed description and justification for the changes included in proposed Revision 1 of the Humboldt Bay ISFSI Quality Assurance Plan. Enclosure 2 provides a marked-up version of the proposed Revision 1 of the Humboldt Bay ISFSI Quality Assurance Plan. Enclosure 3 provides a clean version of the Humboldt Bay ISFSI Quality Assurance Plan with revision bars in the left-hand margin where changes were incorporated. Enclosure 4 provides the associated Updated Final Safety Analysis Report markups for information.

As described in Enclosure 1, the proposed changes will continue to satisfy the requirements of 10 CFR Part 72, Subpart G and 10 CFR Part 71, Subpart H for Quality Assurance Programs. PG&E requests Revision 1 of the Humboldt Bay ISFSI Quality Assurance Plan be made effective upon NRC issuance, to be implemented within 60 days from the date of issuance.

PG&E makes no new or revised regulatory commitments (as defined by 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*

July 19, 2022
*Date*

Enclosures
cc: Humboldt Bay ISFSI Distribution
cc/enc: William C. Allen, NRC Project Manager
Scott A. Morris, NRC Region IV Administrator

# Enclosure 1

## Description and Justification for Proposed Changes Included in Revision 1 of the Humboldt Bay Independent Spent Fuel Storage Installation Quality Assurance Plan

In accordance with 10 CFR 72.140(d), 10 CFR 71.106(a)(1) and NRC Information Notice 2002-35: Changes to 10 CFR Parts 71 and 72 Quality Assurance (QA) Programs, Pacific Gas and Electric Company (PG&E) seeks NRC approval for the following proposed changes to the Humboldt Bay (HB) Independent Spent Fuel Storage Installation (ISFSI) QA Plan:

1. Section 1.3, *Organization Responsibilities*, PG&E proposes to change the title from "Senior Vice President, Generation and Chief Nuclear Officer" to "Chief Nuclear Officer" to transition to functional organizational descriptions in the QA Plan. The proposed change aligns with 10 CFR 72.142 (a) which requires licensees to identify in the QA Program persons and organizations performing activities affecting important to safety functions. There are no changes to the Chief Nuclear Officer's authority or responsibilities described in the HB ISFSI QA Plan; therefore, the proposed title change is administrative.

   PG&E identified that the title of the Chief Nuclear Officer was previously revised without obtaining prior approval from the NRC. This issue was documented in the HB ISFSI corrective action program. The proposed change to Section 1.3 to transition to a functional organizational description for the Chief Nuclear Officer will prevent future minor title changes from impacting the information included in the QA Plan.

2. Section 2.6.2, *Staff Qualifications*, PG&E proposes to change the Radiation Protection Manager (RPM) training and qualification requirements from Regulatory Guide 1.8, Revision 2 to Regulatory Guide 1.8, Revision 4. Regulatory Guide 1.8, Revision 2 endorses ANSI/ANS 3.1-1981 and Regulatory Guide 1.8, Revision 4 endorses ANSI/ANS 3.1-2014, with additions and exceptions noted in the Regulatory Guide for both revisions. The guidance in Regulatory Guide 1.8, Revision 2 and Revision 4 applies to operating nuclear power plants but has been used at ISFSIs absent any specific RPM training and qualification guidance in 10 CFR Part 72 or related Regulatory Guides.

   Regulatory Guide 1.8, Revision 4 is comparable to Revision 2 and provides additional clarifications on the RPM education, experience, and training requirements. For example, Regulatory Guide 1.8, Revision 4, clarifies education alternatives for the RPM position that are not specifically addressed in Regulatory Guide 1.8, Revision 2 or ANSI 3.1-1981, Section 4.4.4. Attachment 1 provides a comparison between Regulatory Guide 1.8, Revision 2 and Revision 4. Additional justification is provided below for areas where the Regulatory Guide

1.8, Revision 2 RPM qualifications (experience and training) appear to exceed the Revision 4 RPM qualifications.

a. RPM Experience

There is a difference in the RPM qualifications related to the onsite experience. Revision 4 provides exceptions to the six-month onsite time requirement whereas Revision 2 does not. In lieu of the six-month onsite time requirement, Revision 4 allows licensees to evaluate required onsite time for experienced RPMs who are new to a site.

The NRC indicated in Regulatory Guide 1.8, Revision 4 that "The purpose of the onsite time is to provide a newly assigned RPM sufficient opportunity to learn the location and performance characteristics of key equipment and other plant-specific information that is necessary to make informed decisions concerning radiological safety." The intent of the six-month onsite requirement is not to meet a time requirement, but instead to help ensure the RPM is knowledgeable of characteristics and challenges unique to the plant. HB ISFSI is not an operating power plant, and onsite radiation protection (RP) is limited and mostly performed by off-site Diablo Canyon Power Plant (DCPP) radiation protection staff at periodicities of quarterly, annually, and once every 5 years for cask inspections. A minimum of six-months onsite, though useful to nuclear power plants, does not meet the NRC's intent for an ISFSI such as HB. Regulatory Guide 1.8, Revision 4 specifies that "a significant amount of the station RPM’s experience should be relevant to supervising in-field radiation protection program activities." During long-term storage after spent nuclear fuel has been loaded into the HB ISFSI, the focus of RP experience would be related to As Low As Reasonably Achievable; radioactive material storage, handling and shipping; environmental monitoring, and related NRC regulations/licenses. The periodic onsite RP support is considered sufficient to ensure the RPM is knowledgeable of characteristics and challenges to implement the limited RP activities described in the HB ISFSI QA Plan and RP Program during long-term storage. Therefore, the transition from Regulatory Guide 1.8, Revision 2 to Regulatory Guide 1.8, Revision 4 does not impact the RPM training and qualification requirements or capabilities to make informed decisions regarding radiological safety at the HB ISFSI.

b. RPM Training

Regulatory Guide 1.8, Revision 2 requires specific general training for RPMs (e.g., station emergency plan, security program, fire protection

training) and Revision 4 discusses general employee training but does not tie it specifically to the RPM qualification. General site awareness training (e.g., emergency plan, security, site operations) is provided to staff at the HB ISFSI performing activities affecting quality. Therefore, the transition from Regulatory Guide 1.8, Revision 2 to Regulatory Guide 1.8, Revision 4 does not impact the RPM general training requirements at the HB ISFSI.

PG&E also proposes to relocate the RPM training and qualification guidance from the HB ISFSI QA Plan to the Final Safety Analysis Report (FSAR). A supporting markup of the affected FSAR chapter is provided in Enclosure 4, for information. Relocation of the RPM training and qualification requirements to the FSAR is administrative and provides flexibility to adopt future revisions of NRC approved RPM related guidance and endorsed standards without having to obtain additional NRC approvals of the HB ISFSI QA Plan. NRC approval prior to implementing future changes to the HB ISFSI FSAR will be processed consistent with 10 CFR 72.48, as appropriate. Similar language referencing the FSAR for indoctrination and training requirements was previously approved by the NRC in the Trojan ISFSI QA Plan. The Trojan ISFSI QA Plan, Revision 30 (ADAMS Accession No. ML21309A111) specifies that indoctrination and training requirements for personnel performing quality activities are described in Trojan's Safety Analysis Report.

3. Section 12.1, *General Requirements,* PG&E proposes to revise the HB ISFSI QA Plan to align with the current status of Measuring and Test Equipment (M&TE) at HB ISFSI. 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.

The HB ISFSI QA Program continues to satisfy the requirements of 10 CFR 72, Subpart G and 10 CFR 71, Subpart H.

# Attachment 1

## Comparison between Regulatory Guide 1.8, Revision 2 and Revision 4, including endorsed ANSI/ANSI 3.1-1981 and ANSI/ANS 3.1-2014

| | Current Requirements (Revision 2) | Proposed Requirements (Revision 4) |
|---|---|---|
| **Education** | (ANSI/ANS 3.1-1981, Section 4.4.4a.)<br>Bachelor's Degree in a science or engineering subject, including formal training in radiation protection. | (ANSI/ANS 3.1-2014, Section 4.3.3)<br>Baccalaureate in related physical science or engineering and specific formal training in radiation protection. |
| **Alternatives to Education** | (ANSI/ANS 3.1-1981, Section 4.1)<br>Individuals who do not possess the formal educational requirements specified in this section<br>shall not be automatically eliminated where other factors provide sufficient demonstration of their abilities. These other factors shall be evaluated on a case-by-case basis and approved and documented by the plant manager. The positive factors listed as follows may be considered in making the evaluation of an acceptable alternative to the educational requirements.<br>•High school diploma or GED.<br>•Academic and related technical training.<br>•Qualified as an NRC senior operator at the assigned plant.<br>•Four years of additional experience in his area of responsibility.<br>•Four years of supervisory or management experience.<br>•Demonstrated ability to communicate clearly (orally and in writing).<br>•Certification of academic ability and knowledge by corporate management.<br>•Successful completion of the Engineer-In-Training examination.<br>•Professional Engineer License.<br>•Associate Degree in Engineering or | (ANSI/ANS 3.1-2014, Section 4.1.1.1 and 4.1.1.2)<br>If individuals do not possess the formal educational requirements specified in this section, other factors may provide sufficient demonstration of their abilities to fulfill the duties of a specific position. These factors shall be evaluated on a case-by-case basis and approved and documented by the owner organization.<br><br>The following are examples of acceptable alternatives to educational requirements:<br><br>Baccalaureate:<br>-Professional Engineer License, or<br>-Successful completion of the Engineer-In-Training examination, or<br>-Successful completion of 80 semester credit hours of the technical portions of an engineering, engineering technology, or related science program may be substituted for the baccalaureate. The course shall be in appropriate technical subjects relevant to the position to be filled.<br><br>Related experience may be substituted for education at the rate of 6 semester credit hours for each year of experience up to a maximum of 60 credit hours. |

| | Current Requirements (Revision 2) | Proposed Requirements (Revision 4) |
|---|---|---|
| | related science | |
| **Experience** | (ANSI/ANS 3.1-1981, Section 4.4.4b.)<br>At the time of initial core loading or appointment to the active position, whichever is later, the responsible individual shall have four years of experience in applied radiation protection. At least three years of this experience shall be in applied radiation protection<br>work in a nuclear facility dealing with radiological problems similar to those encountered in nuclear power plants, preferably in a nuclear power plant. During the three years, the individual shall participate in the radiation protection section of an operating nuclear power plant during the following periods.<br>(1) Routine refueling outages (one to two months).<br>(2) Two months operation above 20 percent power.<br>Six months experience shall be onsite.<br><br>(Regulatory Guide 1.8, Section C1(k))<br>The radiation protection manager should have the qualifications described in Section 4.4.4 of ANSI/ANS 3.1-1981 with the clarification that 3 of the 4 years of experience in applied radiation protection should be professional-level experience. | (ANSI/ANS 3.1-2014, Section 4.3.3)<br>5 years related experience which shall include:<br>-3 years Nuclear power plant experience (NPP)<br>-1 year Supervisor or Management experience, including 1 month during outage and 2 months of operation above 20% power.<br><br>The three years of NPP experience should at least be at the level requiring policy, planning, and decision making related to the programmatic aspects of the radiation protection program as a whole.<br><br>The individual filling the radiation protection manager responsibilities for the station shall have three year of experience in two or more function areas of radiological protections (e.g., field As Low As Reasonably Achievable (ALARA), dosimetry, Radiological Environmental Monitoring Program (REMP), radioactive waste shipping), and radiation protection operations).<br><br>(Regulatory Guide 1.8, Section C.1.3.)<br><br>As a modification to item (3) in the Special Requirements section<br>of 4.3.3 [above], a significant amount of the station RPM's experience should be relevant to supervising in-field radiation protection program activities (e.g., As Low As Reasonably Achievable (ALARA), radiation protection operations, and radioactive waste shipping).<br>… individuals with no prior RPM experience should have six months of time onsite before being assigned RPM duties. Licensees should evaluate required onsite time for experienced |

| | Current Requirements (Revision 2) | Proposed Requirements (Revision 4) |
|---|---|---|
| | | RPMs who are new to a site or a reactor technology (e.g., Pressurized Water Reactor (PWR) or Boiling Water Reactor (BWR)). |
| **Alternatives to Experience** | Not provided. Leniency to experience is provided in experience descriptions (e.g., "preferably in an NPP") | (ANSI/ANS 3.1-2014, Section 4.1.2.1 – 4.1.2.4)<br>Alternatives to (or exemptions from) experience requirements may be allowed based on a case-by-case evaluation of the position requirements and the experience that the alternative(s) provide. Alternatives to experience should be allowed if the alternate experience was acquired by performing duties similar to those for which the individual seeks qualification.<br><br>On-site experience. Applicable work performed at the plant for which the individual seeks qualification. Work shall involve that plant's systems and procedures. Time spent performing job-based training and qualification activities in the workplace, such as under-instruction watch standing or power plant staff duties, on-the-job training (OJT), task performance evaluation (TPE), watch station qualification, or power plant staff qualification activities, may be counted toward the on-site requirements. OJT/TPE should be specifically documented if such time is used to meet on-site experience requirements. Time spent in plant access, radworker, utility new employee orientation training, and time in classroom training for the intended position cannot be counted toward the on-site requirement. Non-structured observation of others performing work is not experience. On-site experience does not imply any particular reporting arrangement or organizational structure.<br><br>Nuclear power plant experience is |

| | Current Requirements (Revision 2) | Proposed Requirements (Revision 4) |
|---|---|---|
| | | applicable work performed in a nuclear power plant (commercial or military) during preoperational, startup testing, construction, or operational activities. Time spent performing job-based training and qualification activities in the workplace, such as under- instruction watch standing or power plant staff duties, OJT, TPE, watch station qualification, or power plant staff qualification activities, may be counted toward the nuclear power plant experience requirements. OJT/TPE should be specifically documented if such time is used to meet nuclear power plant experience requirements. Non-structured observation of others performing work is not experience.<br><br>Related experience is experience in performing job duties similar to that for which the individual seeks qualification, and which may or may not be at a nuclear power plant.<br><br>An acceptable alternative to the experience requirements specified in Section 4 may be successful completion of a training program based on a systems approach to training (SAT) (see Section 6.2.1) and a minimum of 1 year of nuclear power plant experience as described in Section 4.1.2.3.<br><br>Where course work is related to job duties, postsecondary education may be substituted for related experience at a ratio of 2 years of education for 1 year of experience. The total credit for postsecondary education shall not exceed 2 years of experience credit. For example, completion of trade school or community college technical programs designed for a specific position may be substituted at the rate of 0.5 years of |

| | Current Requirements (Revision 2) | Proposed Requirements (Revision 4) |
|---|---|---|
| | | experience credit for each year of education. |
| **Training** | (ANSI/ANS 3.1-1981, Section 5.3.2 and 5.4)<br>Training shall be provided to compensate for deficiencies identified by comparing the individual's experience and knowledge to the task analysis. The required training of these professional-technical personnel can be implemented by involvement in related training programs. These training programs may include assignment at operating reactors or simulators, or both, and at vendor facilities. The training shall be for periods of time sufficient to develop the proficiency required, for safe and competent supervision and performance.<br><br>All persons regularly employed in the nuclear power plant shall be trained in the following areas commensurate with their job duties:<br>General Description of Plant and Facilities, Job Related Procedures and Instructions, Radiological Health and Safety Program, Station Emergency Plans, Industrial Safety Program, Fire Protection Program, Security Program, and Quality Assurance Program.<br><br>Temporary maintenance and service personnel shall be trained also in the areas listed in the preceding paragraph, to the extent necessary to assure safe execution of their duties.<br><br>The individual's understanding of the information provided by this program shall be evaluated by administering an examination of sufficient difficulty | Provided, but no longer specifically tied to the RPM qualification. |

| | Current Requirements (Revision 2) | Proposed Requirements (Revision 4) |
|---|---|---|
| | covering the previously listed areas to ensure the individual has sufficient knowledge to work independently at the facility. Individuals who do not pass this examination shall not be permitted inside the protected area without a full-time escort. | |
| **Temporary Replacement** | (ANSI/ANS 3.1-1981, Section 4.4.4d.)<br>The individual who temporarily replaces the radiation protection group leader shall have a Bachelor's degree in a science or engineering subject and two years' experience, one of which shall be nuclear power plant experience. Six months experience shall be onsite. | (ANSI/ANS 3.1-2014, Section 4.1)<br>Individuals shall meet the requirements for a given position. Individuals needing exceptions to this may be temporarily assigned to fill that positions. Such assignments shall be justified and a time period for the temporary assignment shall be specified and documented. Individuals temporarily filling a position due to the absence of its principal individual shall possess, as a minimum, the qualifications required for the corresponding position in the next lower functional level.<br><br>(Regulatory Guide 1.8, Section C.1.3.)<br>Personnel who are temporarily assigned to fill the RPM position and who do not meet the requirements to serve as an RPM should have first line supervisor experience of in-field radiation protection program activities. Personnel who do not meet the requirements for this position should not be assigned to temporarily fill the position for periods exceeding one year. |

**Proposed Revision 1 to HBI-L6, Humboldt Bay ISFSI Quality Assurance Plan**
**Marked-up Version**

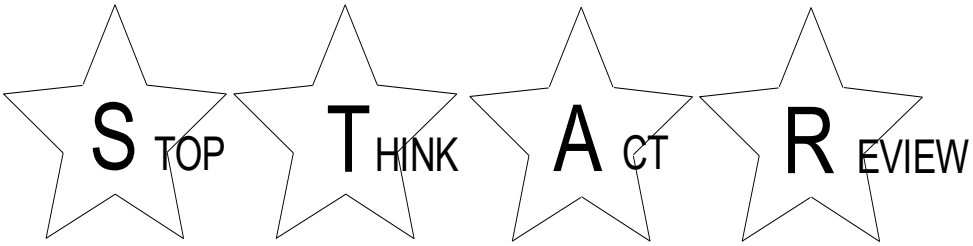
# HBI-L6

# HUMBOLDT BAY ISFSI QUALITY ASSURANCE PLAN

Rev. ~~0~~1

**QUALITY ~~RELATED~~**

# Humboldt Bay ISFSI




| APPROVAL |
| --- |
| Approved By: _____ / _____ / _____<br>(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).

Proper control, calibration, and adjustments at specified periods to maintain accuracy of M&TE is described in HB ISFSI facility procedures as appropriate.~~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).

**Proposed Revision 1 to HBI-L6, Humboldt Bay ISFSI Quality Assurance Plan (Clean Version)**

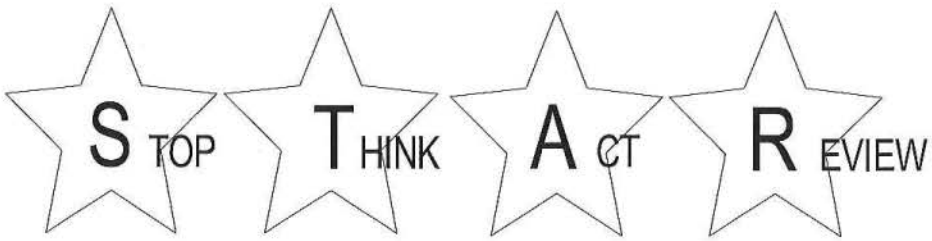
# HBI-L6

# HUMBOLDT BAY ISFSI QUALITY ASSURANCE PLAN

Rev. 1

## QUALITY

# Humboldt Bay ISFSI




| APPROVAL | | |
|---|---|---|
| Approved By: SHAWN P. KIRVEN (Print Name) | / (Signature) | / 4/12/22 (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).

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.

## 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).

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### 9.1.7 PERSONNEL QUALIFICATION REQUIREMENTS

The DCPP Radiation Protection Manager meets or exceeds the qualifications of Regulatory Guide 1.8 Revision 4 (Reference 1). In addition, the HB ISFSI Director, ISFSI personnel and security staff are qualified as described below:

- The HB ISFSI Director, shall have a minimum of 8 years of power plant experience, of which a minimum of 3 years shall be nuclear power plant experience. A maximum of 2 years of the remaining 5 years of power plant experience may be fulfilled by satisfactory completion of academic or related technical training on a one-for-one basis.

- The ISFSI personnel and security staff, at the time of appointment to their positions, shall have a high school diploma or successfully completed the General Education Development test. Consistent with the assigned duties, ISFSI personnel are trained and qualified in accordance with the Humboldt Bay ISFSI Training Program described in Section 9.3. Security staff that supports the ISFSI are trained and qualified in accordance with the Security Training and Qualifications Plan requirements.

- During ISFSI operations, operation of equipment and controls that are identified as important to safety for the ISFSI are limited to personnel who are trained and qualified in accordance with the Humboldt Bay ISFSI Training and Certification Program described in Section 9.3.3, or personnel who are under the direct visual supervision of an individual who is trained and qualified in accordance with the Humboldt Bay ISFSI Training and Certification Program.

### 9.1.8 LIAISON WITH OUTSIDE ORGANIZATIONS

All activities associated with ISFSI operations are managed and approved by PG&E. These activities are performed in accordance with approved procedures. Qualified vendors may be selected to provide specialty services and/or equipment. Interface with DOE, cask vendor, and other outside organizations is performed in accordance with contractual agreements.

### 9.1.9 REFERENCES

1. Regulatory Guide 1.8, Qualification and Training of Personnel for Nuclear Power Plants, USNRC, Revision 4, June 2019

2. Humboldt Bay ISFSI Training and Certification Program