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February 14, 2019

PG&E Letter HIL-19-001

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

10 CFR 72.140

Humboldt Bay Independent Spent Fuel Storage Installation
Docket No. 72-27, SNM-2514
Humboldt Bay Independent Spent Fuel Storage Installation Quality Assurance Plan, Revision 0

Dear Commissioners and Staff:

In accordance with License Condition 14 of Special Nuclear Material License Number 2514 (SNM-2514), Pacific Gas and Electric Company (PG&E) is submitting for NRC approval a stand-alone Humboldt Bay (HB) Independent Spent Fuel Storage Installation (ISFSI) Quality Assurance (QA) Plan. SNM-2514, Condition 14 states:

"The Commission's finding that the Quality Assurance Program complies with the requirements of 10 CFR Part 72, Subpart G is based on the existence of a Quality Assurance Program accepted by the Commission as satisfying the requirements of 10 CFR 50, Appendix B. The portion of the Commission-approved Quality Assurance Program that is applicable to the Humboldt Bay ISFSI is contained in the Humboldt Bay Quality Assurance Plan and is under the control of the Humboldt Bay Power Plant, Unit 3 Part 50 license. Prior to the termination of the Part 50 license for the Humboldt Bay Power Plant, Unit 3, the licensee must submit, for Commission approval, a Quality Assurance Program for the Humboldt Bay ISFSI that satisfies each of the elements of Subpart G."

The enclosed HB ISFSI QA Plan satisfies the requirements of 10 CFR 72, Subpart G. In addition, the HB ISFSI QA Plan satisfies the requirements of 10 CFR 71, Subpart H for the procurement, maintenance, repair and use of radioactive materials transport packages. As part of Revision 0 of the HB ISFSI QA Plan, PG&E will make future changes to the HB ISFSI QA Plan in accordance with the requirements in 10 CFR 71.106(b).

Enclosure 1 provides HBI-L6, Humboldt Bay ISFSI Quality Assurance Plan, Revision 0. Enclosure 2 is provided for information only and references the

applicable section in the QA Plan that addresses the 10 CFR 72, Subpart G and 10 CFR 71, Subpart H requirements.

Approval of the HB ISFSI QA Plan by August 30, 2019, is requested to support its implementation and preparations for terminating the Humboldt Bay Power Plant (HBPP) Part 50 License in early 2020. The HB ISFSI will continue to comply with SNM-2514, License Condition 14 and the current revision of the HBPP, 10 CFR 50, Appendix B, QA Plan, until this submittal is approved by the NRC.

Upon NRC approval of the HB ISFSI QA Plan, the changes will be implemented within 60 days. In addition, future changes to the HB ISFSI QA Plan and biennial updates will be submitted to the NRC in accordance with 10 CFR 71.106(b).

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 Hossein Hamzehee at 805-545-4720.

Sincerely,

James M. Welsch
Vice President, Nuclear Generation and Chief Nuclear Officer

bnsm/0892
Enclosures
cc: Humboldt Distribution
cc/enc: William C. Allen, NMSS Project Manager
John B. Hickman, NRR Project Manager
Scott A. Morris, NRC Region IV Administrator

HBI-L6

HUMBOLDT BAY ISFSI QUALITY ASSURANCE PLAN

Revision 0

HBI-L6

HUMBOLDT BAY ISFSI QUALITY ASSURANCE PLAN

Rev. 0

QUALITY RELATED

Humboldt Bay ISFSI

APPROVAL		
Approved By: SHARON KIRVEN / [signature] / 2/8/2019		
(Print Name)	(Signature)	(Date)
Effective Date:		

TABLE OF CONTENTS

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 also applies to the packaging and transportation of radioactive material as specified in NRC Approval No. 202, Revision 8 "Quality Assurance Program for Radioactive Material Packages."

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. Figure 1 illustrates the HB ISFSI 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 functional responsibilities shown in Figure 1 are further described below.

The VICE PRESIDENT, NUCLEAR 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 administrative procedures, 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 power generation assets, activities and operation as described herein that constitute a reduction in a commitment made to the NRC.

The SENIOR DIRECTOR, ENGINEERING, TECHNICAL AND EMERGENCY SERVICES, reports to the Vice President, Nuclear Generation and CNO, and has overall responsibility for safety, engineering, planning, staffing, and project execution for the HB ISFSI. In addition, the Senior Director, Engineering, Technical and Emergency Services is responsible for taking measures needed to ensure acceptable performance of ISFSI staff and provide technical support during the HB ISFSI operations.

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 DIRECTOR – NUCLEAR SECURITY and EMERGENCY SERVICES (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.

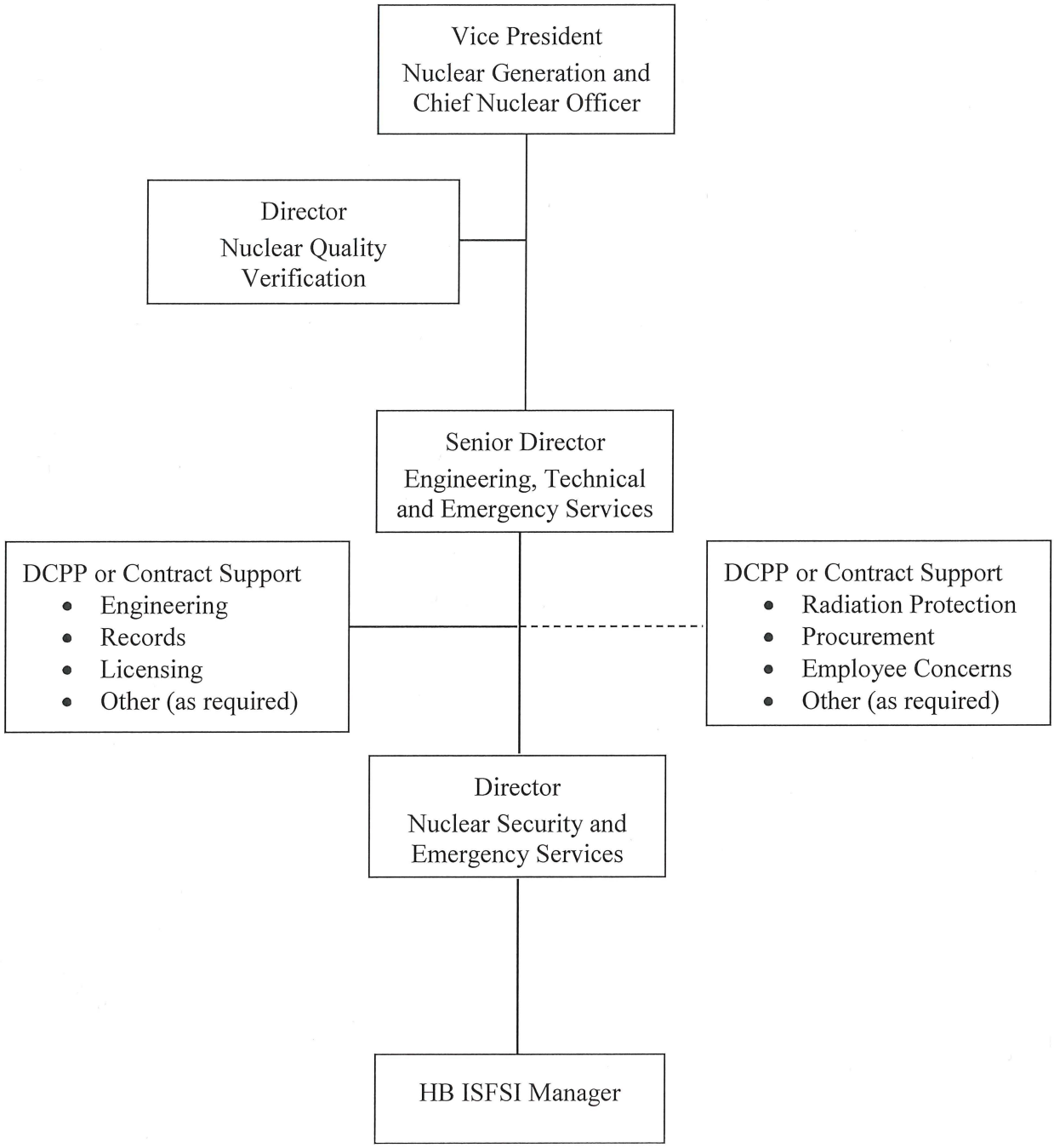
The DCPP DIRECTOR ENGINEERING SERVICES is the design authority for HB ISFSI and is responsible for technical aspects of the engineering and design of HB ISFSI SSC including, performance of modifications; configuration control and design bases defense and management; quality classification of SSC; and the specification of technical and quality requirements for the purchase of services, materials and equipment.

CORPORATE SUPPORT for ITS and quality activities includes, but is not limited to, procurement, records, employee concerns, and licensing. Each organization documents and maintains a written description of its internal organization.

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 71, Subpart H; or 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.

Figure 1
HB ISFSI Organization Chart



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 that is compliant with the applicable requirements in 10CFR 50 Appendix B, 10CFR Part 71 Subpart H, or 10CFR 72, Subpart G.

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. 10 CFR 72 Subpart G and 10 CFR 71 Subpart H requirements that do not apply to the operation and maintenance activities of HB ISFSI ITS SSCs are described in the HB ISFSI QAP, as applicable.

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 review regularly 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. Changes to the HB ISFSI QAP requirements shall be made in accordance with 10 CFR 72 Subpart G and 10 CFR 71.106. Changes to the HB ISFSI QAP that do not reduce commitments shall be included in the periodic updates required by 10 CFR 71.106. Prior to issuance for use, proposed changes to the HB ISFSI QAP that reduce commitments are reviewed and concurred with in writing by the Quality Director; approved by the Vice President, Nuclear Generation and CNO, or designee, prior to being submitted to the NRC; and approved by the NRC in accordance with 10 CFR 71.106.

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.

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 that is compliant with the applicable requirements in 10CFR 50 Appendix B, 10CFR Part 71 Subpart H, or 10CFR 72, Subpart G.

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 that is compliant with the applicable requirements in 10CFR 50 Appendix B, 10CFR Part 71 Subpart H, or 10CFR 72, Subpart G.

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 that is compliant with the applicable requirements in 10CFR 50 Appendix B, 10CFR Part 71 Subpart H, or 10CFR 72, Subpart G.

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 that is compliant with the applicable requirements in 10CFR 50 Appendix B, 10CFR Part 71 Subpart H, or 10CFR 72, Subpart G.

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 that is compliant with the applicable requirements in 10CFR 50 Appendix B, 10CFR Part 71 Subpart H, or 10CFR 72, Subpart G.

10.0 INSPECTIONS

10.1 GENERAL REQUIREMENTS

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

10.2 INSPECTION PLANNING AND PERFORMANCE

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

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

10.3 INSPECTION METHODS

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

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

10.4 INSPECTION RESULTS

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

11.0 TEST CONTROL

11.1 GENERAL REQUIREMENTS

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

11.2 TEST CONTROL PROGRAM

The Test Control program shall ensure that the necessary testing is identified and performed at the appropriate time in accordance with written test procedures that incorporate or reference the requirements and acceptance limits contained in the applicable design documents.

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

11.3 TEST RESULTS

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

Test records shall be maintained

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 GENERAL REQUIREMENTS

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

During long-term storage at the HB ISFSI, 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 in accordance with 10CFR 50 Appendix B, 10CFR Part 71 Subpart H, or 10CFR 72, Subpart G.

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 that is compliant with the applicable requirements in 10CFR 50 Appendix B, 10CFR Part 71 Subpart H, or 10CFR 72, Subpart G.

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).

Compliance Matrix
(For Information Only)

HB ISFSI QA Plan, Revision

Compliance Matrix Between 10CFR71/10CFR72 Quality Requirements and the Applicable HB ISFSI QA Plan Sections

10 CFR 72 Subpart G—Quality Assurance	10 CFR 71 Subpart H—Quality Assurance	Corresponding HB ISFSI QAP Requirement
72.140, QUALITY ASSURANCE REQUIREMENTS	**71.101, QUALITY ASSURANCE REQUIREMENTS**	
(a) Purpose. This subpart describes quality assurance requirements that apply to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, modification of structures, systems, and components, and decommissioning that are important to safety. As used in this subpart, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements.	(a) *Purpose.* This subpart describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this subpart, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements.	Introduction
The certificate holder is responsible for the quality assurance requirements as they apply to the design, fabrication, and testing of a spent fuel storage cask until possession of the spent fuel storage cask is transferred to the licensee. The licensee and the certificate holder are also simultaneously responsible for these quality assurance requirements through the oversight of contractors and subcontractors.	Each certificate holder and applicant for a package approval is responsible for satisfying the quality assurance requirements that apply to design, fabrication, testing, and modification of packaging subject to this subpart. Each licensee is responsible for satisfying the quality assurance requirements that apply to its use of a packaging for the shipment of licensed material subject to this subpart.	Appendix A
(b) Establishment of program. Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of this subpart, and satisfying any specific provisions which are applicable to the licensee's activities. The licensee shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirements' importance to safety. The quality assurance program must cover the activities identified in this subpart throughout the life of the activity. For licensees, this includes activities from the site selection through decommissioning prior to termination of the license.	(b) Establishment of program. Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of §§ 71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.	Introduction

Compliance Matrix Between 10CFR71/10CFR72 Quality Requirements and the Applicable HB ISFSI QA Plan Sections

10 CFR 72 Subpart G—Quality Assurance	10 CFR 71 Subpart H—Quality Assurance	Corresponding HB ISFSI QAP Requirement
72.142 QUALITY ASSURANCE ORGANIZATION	**71.103, QUALITY ASSURANCE ORGANIZATION**	
(a) The licensee shall be responsible for the establishment and execution of the quality assurance program. The licensee may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, but the licensee shall retain responsibility for the program. The licensee shall clearly establish and delineate in writing the authority and duties of persons and organizations performing activities affecting the functions of structures, systems, and components which are important to safety. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.	(a) The licensee shall be responsible for the establishment and execution of the quality assurance program. The licensee may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.	Introduction, Section 1.1 Section 1.2 Section 1.3 Section 2.5
(b) The quality assurance functions are-- (1) Assuring that an appropriate quality assurance program is established and effectively executed; and (2) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed. The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions.	(b) The quality assurance functions are— (1) Assuring that an appropriate quality assurance program is established and effectively executed; and (2) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed. (c) The persons and organizations performing quality assurance functions must have sufficient authority and organizational freedom to— (1) Identify quality problems; (2) Initiate, recommend, or provide solutions; and (3) Verify implementation of solutions.	Section 1.3

Compliance Matrix Between 10CFR71/10CFR72 Quality Requirements and the Applicable HB ISFSI QA Plan Sections

10 CFR 72 Subpart G—Quality Assurance	10 CFR 71 Subpart H—Quality Assurance	Corresponding HB ISFSI QAP Requirement
72.142 QUALITY ASSURANCE ORGANIZATION	**71.103, QUALITY ASSURANCE ORGANIZATION**	
(c) The persons and organizations performing quality assurance functions shall report to a management level that ensures that the required authority and organizational freedom, including sufficient independence from cost and schedule considerations when these considerations are opposed to safety considerations, are provided. Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this section are being performed, must have direct access to the levels of management necessary to perform this function.	(d) The persons and organizations performing quality assurance functions shall report to a management level that assures that the required authority and organizational freedom, including sufficient independence from cost and schedule, when opposed to safety considerations, are provided. (e) Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom. (f) Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this section are being performed, must have direct access to the levels of management necessary to perform this function.	Section 1.3

Compliance Matrix Between 10CFR71/10CFR72 Quality Requirements and the Applicable HB ISFSI QA Plan Sections

10 CFR 72 Subpart G—Quality Assurance	10 CFR 71 Subpart H—Quality Assurance	Corresponding HB ISFSI QAP Requirement
72.144 QUALITY ASSURANCE PROGRAM	**71.105 QUALITY ASSURANCE PROGRAM**	
(a) The licensee shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program which complies with the requirements of this subpart. The licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with these procedures throughout the period during which the ISFSI is licensed. The licensee shall identify the structures, systems, and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.	(a) The licensee shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of §§ 71.101 through 71.137. The licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee shall identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.	Section 2.1 Section 2.2
(b) The licensee through their quality assurance program(s), shall provide control over activities affecting the quality of the identified structures, systems, and components to an extent commensurate with the importance to safety and, as necessary, to ensure conformance with the approved design of each ISFSI or spent fuel storage cask. The licensee shall ensure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee shall take into account the need for special controls, processes, test equipment, tools and skills to attain the required quality and the need for verification of quality by inspection and test.	(b) The licensee, through its quality assurance program, shall provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material. The licensee shall assure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.	Section 2.3 Sections 10 (Inspections) and 11 (Test Control)

Compliance Matrix Between 10CFR71/10CFR72 Quality Requirements and the Applicable HB ISFSI QA Plan Sections

10 CFR 72 Subpart G—Quality Assurance	10 CFR 71 Subpart H—Quality Assurance	Corresponding HB ISFSI QAP Requirement
72.144 QUALITY ASSURANCE PROGRAM	**71.105 QUALITY ASSURANCE PROGRAM**	
(c) The licensee shall base the requirements and procedures of their quality assurance program(s) on the following considerations concerning the complexity and proposed use of the structures, systems, or components: (1) The impact of malfunction or failure of the item on safety; (2) The design and fabrication complexity or uniqueness of the item; (3) The need for special controls and surveillance over processes and equipment; (4) The degree to which functional compliance can be demonstrated by inspection or test; and (5) The quality history and degree of standardization of the item.	(c) The licensee shall base the requirements and procedures of its quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components: (1) The impact of malfunction or failure of the item to safety; (2) The design and fabrication complexity or uniqueness of the item; (3) The need for special controls and surveillance over processes and equipment; (4) The degree to which functional compliance can be demonstrated by inspection or test; and (5) The quality history and degree of standardization of the item.	Section 2.3 Section 2.4
(d) The licensee shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to ensure that suitable proficiency is achieved and maintained. (e) The licensee shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program must regularly review the status and adequacy of that part of the quality assurance program which they are executing.	(d) The licensee shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The licensee shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are executing.	Section 2.6.1 Section 2.4

Compliance Matrix Between 10CFR71/10CFR72 Quality Requirements and the Applicable HB ISFSI QA Plan Sections

10 CFR 72 Subpart G—Quality Assurance	10 CFR 71 Subpart H—Quality Assurance	Corresponding HB ISFSI QAP Requirement
NO COMPARISON	**71.106 CHANGES TO QUALITY ASSURANCE PROGRAM**	
	(a) Each quality assurance program approval holder shall submit, in accordance with § 71.1(a), a description of a proposed change to its NRC-approved quality assurance program that will reduce commitments in the program description as approved by the NRC. The quality assurance program approval holder shall not implement the change before receiving NRC approval. (1) The description of a proposed change to the NRC-approved quality assurance program must identify the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the applicable requirements of subpart H of this part. (b) Each quality assurance program approval holder may change a previously approved quality assurance program without prior NRC approval, if the change does not reduce the commitments in the quality assurance program previously approved by the NRC. Changes to the quality assurance program that do not reduce the commitments shall be submitted to the NRC every 24 months, in accordance with § 71.1(a). In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, and non-substantive changes to punctuation or editorial items, the following changes are not considered reductions in commitment: (1) The use of a quality assurance standard approved by the NRC that is more recent than the quality assurance standard in the current quality assurance program at the time of the change;	Section 2.4

Compliance Matrix Between 10CFR71/10CFR72 Quality Requirements and the Applicable HB ISFSI QA Plan Sections

10 CFR 72 Subpart G—Quality Assurance	10 CFR 71 Subpart H—Quality Assurance	Corresponding HB ISFSI QAP Requirement
NO COMPARISON	**71.106 CHANGES TO QUALITY ASSURANCE PROGRAM**	
	(2) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles, provided that there is no substantive change to either the functions of the position or reporting responsibilities; (3) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text, provided that there is no substantive change to the functional relationships, authorities, or responsibilities; (4) The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the quality assurance program approval holder has committed to on record; and (5) Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations. (c) Each quality assurance program approval holder shall maintain records of quality assurance program changes.	Section 17 (QA Records)

Compliance Matrix Between 10CFR71/10CFR72 Quality Requirements and the Applicable HB ISFSI QA Plan Sections

10 CFR 72 Subpart G—Quality Assurance	10 CFR 71 Subpart H—Quality Assurance	Corresponding HB ISFSI QAP Requirement
72.146 DESIGN CONTROL	**71.107 PACKAGE DESIGN CONTROL**	
(a) The licensee shall establish measures to ensure that applicable regulatory requirements and the design basis, as specified in the license for those structures, systems, and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to ensure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the structures, systems, and components which are important to safety.	(a) The licensee shall establish measures to assure that applicable regulatory requirements and the package design, as specified in the license for those materials and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the materials, parts, and components of the packaging that are important to safety.	Section 3.0
(b) The licensee shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures must provide for verifying or checking the adequacy of design by methods such as design reviews, alternate or simplified calculational methods, or by a suitable testing program. For the verifying or checking process, the licensee shall designate individuals or groups other than those who were	(b) The licensee shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures, among participating design organizations, for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures must provide for verifying or checking the adequacy of design, by methods such as design reviews, alternate or simplified calculational methods, or by a suitable testing program. For the verifying or checking process, the licensee shall designate individuals or groups other than those who were	

Compliance Matrix Between 10CFR71/10CFR72 Quality Requirements and the Applicable HB ISFSI QA Plan Sections

10 CFR 72 Subpart G—Quality Assurance	10 CFR 71 Subpart H—Quality Assurance	Corresponding HB ISFSI QAP Requirement
72.146 DESIGN CONTROL	**71.107 PACKAGE DESIGN CONTROL**	
responsible for the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, the licensee shall include suitable qualification testing of a prototype or sample unit under the most adverse design conditions. The licensee shall apply design control measures to items such as the following: criticality physics, radiation, shielding, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for in-service inspection, maintenance, and repair; features to facilitate decontamination; and delineation of acceptance criteria for inspections and tests.	responsible for the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, the licensee shall include suitable qualification testing of a prototype or sample unit under the most adverse design conditions. The licensee shall apply design control measures to the following: (1) Criticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyses; (2) Compatibility of materials; (3) Accessibility for in-service inspection, maintenance, and repair; (4) Features to facilitate decontamination; and (5) Delineation of acceptance criteria for inspections and tests.	
(c) The licensee shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the license require prior NRC approval.	(c) The licensee shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the CoC require prior NRC approval.	

Compliance Matrix Between 10CFR71/10CFR72 Quality Requirements and the Applicable HB ISFSI QA Plan Sections

10 CFR 72 Subpart G—Quality Assurance	10 CFR 71 Subpart H—Quality Assurance	Corresponding HB ISFSI QAP Requirement
72.148 PROCUREMENT DOCUMENT CONTROL	**71.109 PROCUREMENT DOCUMENT CONTROL**	
The licensee shall establish measures to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the licensee or by their contractors and subcontractors. To the extent necessary, the licensee shall require contractors or subcontractors to provide a quality assurance program consistent with the applicable provisions of this subpart.	The licensee shall establish measures to assure that adequate quality is required in the documents for procurement of material, equipment, and services, whether purchased by the licensee or by its contractors or subcontractors. To the extent necessary, the licensee shall require contractors or subcontractors to provide a quality assurance program consistent with the applicable provisions of this part.	Section 4.0
72.150 INSTRUCTIONS, PROCEDURES, AND DRAWINGS	**71.111 INSTRUCTIONS, PROCEDURES, AND DRAWINGS**	
The licensee shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.	The licensee shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.	Section 5.1

Compliance Matrix Between 10CFR71/10CFR72 Quality Requirements and the Applicable HB ISFSI QA Plan Sections

10 CFR 72 Subpart G—Quality Assurance	10 CFR 71 Subpart H—Quality Assurance	Corresponding HB ISFSI QAP Requirement
72.152 DOCUMENT CONTROL	**71.113 DOCUMENT CONTROL**	
The licensee shall establish measures to control the issuance of documents such as instructions, procedures, and drawings, including changes, which prescribe all activities affecting quality. These measures must assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed. These measures must ensure that changes to documents are reviewed and approved.	The licensee shall establish measures to control the issuance of documents such as instructions, procedures, and drawings, including changes that prescribe all activities affecting quality. These measures must assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed.	Section 6.1
72.154 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES	**71.115 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES**	
(a) The licensee shall establish measures to ensure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.	(a) The licensee shall establish measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products on delivery.	Section 7.0

Compliance Matrix Between 10CFR71/10CFR72 Quality Requirements and the Applicable HB ISFSI QA Plan Sections

10 CFR 72 Subpart G—Quality Assurance	10 CFR 71 Subpart H—Quality Assurance	Corresponding HB ISFSI QAP Requirement
72.154 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES	**71.115 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES**	
(b) The licensee shall have available documentary evidence that material and equipment conform to the procurement specifications prior to installation or use of the material and equipment. The licensee shall retain or have available this documentary evidence for the life of the ISFSI or spent fuel storage cask. The licensee shall ensure that the evidence is sufficient to identify the specific requirements met by the purchased material and equipment.	(b) The licensee shall have available documentary evidence that material and equipment conform to the procurement specifications before installation or use of the material and equipment. The licensee shall retain, or have available, this documentary evidence for the life of the package to which it applies. The licensee shall assure that the evidence is sufficient to identify the specific requirements met by the purchased material and equipment.	
(c) The licensee, or a designee, shall assess the effectiveness of the control of quality by contractors and subcontractors at intervals consistent with the importance, complexity, and quantity of the product or services.	(c) The licensee shall assess the effectiveness of the control of quality by contractors and subcontractors at intervals consistent with the importance, complexity, and quantity of the product or services.	Section 18.2
72.156 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS	**71.117 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS**	
The licensee shall establish measures for the identification and control of materials, parts, and components. These measures must ensure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item as required, throughout fabrication, installation, and use of the item. These identification and control measures must be designed to prevent the use of incorrect or defective materials, parts, and components.	The licensee shall establish measures for the identification and control of materials, parts, and components. These measures must assure that identification of the item is maintained by heat number, part number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, installation, and use of the item. These identification and control measures must be designed to prevent the use of incorrect or defective materials, parts, and components.	Sections 8.0

Compliance Matrix Between 10CFR71/10CFR72 Quality Requirements and the Applicable HB ISFSI QA Plan Sections

10 CFR 72 Subpart G—Quality Assurance	10 CFR 71 Subpart H—Quality Assurance	Corresponding HB ISFSI QAP Requirement
72.158 CONTROL OF SPECIAL PROCESSES	**71.119 CONTROL OF SPECIAL PROCESSES**	
The licensee shall establish measures to ensure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.	The licensee shall establish measures to assure that special processes, including welding, heat treating, and nondestructive testing are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.	Section 9.0
72.160 LICENSEE INSPECTION	**71.121 INTERNAL INSPECTION**	
The licensee shall establish and execute a program for inspection of activities affecting quality by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity.	The licensee shall establish and execute a program for inspection of activities affecting quality by or for the organization performing the activity, to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity.	Section 10.2
The inspection must be performed by individuals other than those who performed the activity being inspected.	The inspection must be performed by individuals other than those who performed the activity being inspected.	
Examinations, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality.	Examination, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality.	
If direct inspection of processed material or products cannot be carried out, indirect control by monitoring processing methods, equipment, and personnel must be provided.	If direct inspection of processed material or products is not carried out, indirect control by monitoring processing methods, equipment, and personnel must be provided.	Section 10.3
Both inspection and process monitoring must be provided when quality control is inadequate without both.	Both inspection and process monitoring must be provided when quality control is inadequate without both.	
If mandatory inspection hold points that require witnessing or inspecting by the licensee's designated representative, and beyond which work should not proceed without the consent of its designated representative, are required, the specific hold points must be indicated in appropriate documents.	If mandatory inspection hold points, which require witnessing or inspecting by the licensee's designated representative and beyond which work should not proceed without the consent of its designated representative, are required, the specific hold points must be indicated in appropriate documents.	

Compliance Matrix Between 10CFR71/10CFR72 Quality Requirements and the Applicable HB ISFSI QA Plan Sections

10 CFR 72 Subpart G—Quality Assurance	10 CFR 71 Subpart H—Quality Assurance	Corresponding HB ISFSI QAP Requirement
72.162 TEST CONTROL	**71.123 TEST CONTROL**	
The licensee shall establish a test program to ensure that all testing, required to demonstrate that the structures, systems, and components will perform satisfactorily in service, is identified and performed in accordance with written test procedures that incorporate the requirements of this part and the requirements and acceptance limits contained in the ISFSI license.	The licensee shall establish a test program to assure that all testing required to demonstrate that the packaging components will perform satisfactorily in service is identified and performed in accordance with written test procedures that incorporate the requirements of this part and the requirements and acceptance limits contained in the package approval.	Section 11.1 Section 11.2
The test procedures must include provisions to ensure that all prerequisites for the given test are met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions.	The test procedures must include provisions for assuring that all prerequisites for the given test are met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions.	
The licensee shall document and evaluate the test results to ensure that test requirements have been satisfied.	The licensee shall document and evaluate the test results to assure that test requirements have been satisfied.	Section 11.3

Compliance Matrix Between 10CFR71/10CFR72 Quality Requirements and the Applicable HB ISFSI QA Plan Sections

10 CFR 72 Subpart G—Quality Assurance	10 CFR 71 Subpart H—Quality Assurance	Corresponding HB ISFSI QAP Requirement
72.164 CONTROL OF MEASURING AND TEST EQUIPMENT	**71.125 CONTROL OF MEASURING AND TEST EQUIPMENT**	
The licensee shall establish measures to ensure that tools, gauges, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.	The licensee shall establish measures to assure that tools, gauges, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified times to maintain accuracy within necessary limits.	Section 12.0
72.166 HANDLING, STORAGE, AND SHIPPING CONTROL	**71.127 HANDLING, STORAGE, AND SHIPPING CONTROL**	
The licensee shall establish measures to control, in accordance with work and inspection instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels must be specified and provided.	The licensee shall establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels must be specified and provided.	Section 13.1
72.168 INSPECTION, TEST, AND OPERATING STATUS	**71.129 INSPECTION, TEST, AND OPERATING STATUS**	
(a) The licensee shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the ISFSI. These measures must provide for the identification of items which have satisfactorily passed required inspections and tests where necessary to preclude inadvertent bypassing of the inspections and tests.	(a) The licensee shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of the inspections and tests.	Section 14.2
(b) The licensee shall establish measures to identify the operating status of structures, systems, and components of the ISFSI, such as tagging valves and switches, to prevent inadvertent operation.	(b) The licensee shall establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.	Section 14.2
72.170 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS	**71.131 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS**	

Compliance Matrix Between 10CFR71/10CFR72 Quality Requirements and the Applicable HB ISFSI QA Plan Sections

10 CFR 72 Subpart G—Quality Assurance	10 CFR 71 Subpart H—Quality Assurance	Corresponding HB ISFSI QAP Requirement
The licensee shall establish measures to control materials, parts, or components that do not conform to their requirements in order to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.	The licensee shall establish measures to control materials, parts, or components that do not conform to the licensee's requirements to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.	Section 15.2
72.172 CORRECTIVE ACTION	**71.133 CORRECTIVE ACTION**	
The licensee shall establish measures to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition identified as adverse to quality, the measures must ensure that the cause of the condition is determined and corrective action is taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.	The licensee shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.	Section 16.1 Section 16.2
72.174 QUALITY ASSURANCE RECORDS	**71.135 QUALITY ASSURANCE RECORDS**	
The licensee shall maintain sufficient records to furnish evidence of activities affecting quality.	The licensee shall maintain sufficient written records to describe the activities affecting quality. These records must include changes to the quality assurance program as required by § 71.106, the instructions, procedures, and drawings required by § 71.111 to prescribe quality assurance activities, and closely related specifications such as	Section 17.1 Section 2.4

Compliance Matrix Between 10CFR71/10CFR72 Quality Requirements and the Applicable HB ISFSI QA Plan Sections

10 CFR 72 Subpart G—Quality Assurance	10 CFR 71 Subpart H—Quality Assurance	Corresponding HB ISFSI QAP Requirement
	required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures that establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility.	Section 17.2
The records must include the following: design records, records of use, and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses.		
The records must include closely related data such as qualifications of personnel, procedures, and equipment.		
Inspection and test records must, at a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any noted deficiencies.		Section 17.2
Records must be identifiable and retrievable.		Section 17.1
Records pertaining to the design, fabrication, erection, testing, maintenance, and use of structures, systems, and components important to safety must be maintained by or under the control of the licensee until the NRC terminates the license.		
	The licensee shall retain these records for 3 years beyond the date when the licensee last engage in the activity for which the quality assurance program was developed. If any portion of the quality assurance program, written procedures or instructions is superseded, the licensee shall retain the superseded material for 3 years after it is superseded.	

Compliance Matrix Between 10CFR71/10CFR72 Quality Requirements and the Applicable HB ISFSI QA Plan Sections

10 CFR 72 Subpart G—Quality Assurance	10 CFR 71 Subpart H—Quality Assurance	Corresponding HB ISFSI QAP Requirement
72.176 AUDITS	**71.137 AUDITS**	
The licensee shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.	The licensee shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.	Section 18.1
The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited.	The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited.	Section 18.1
Audited results must be documented and reviewed by management having responsibility in the area audited.	Audited results must be documented and reviewed by management having responsibility in the area audited.	Section 18.3
Follow-up action, including reaudit of deficient areas, must be taken where indicated.	Follow-up action, including reaudit of deficient areas, must be taken where indicated.	Section 18.3