

Private Fuel Storage, LLC

P.O. Box C4010, La Crosse, WI 54602-4010

John D. Parkyn, Chairman of the Board

August 29, 2001

Chief, Transportation and Storage Safety and Inspection Section
Spent Fuel Project Office
Office of Nuclear Material Safety and Safeguards
U. S. Nuclear Regulatory Commission
11555 Rockville Pike
One White Flint North
Rockville, MD 20852-2738

72-22

Gentlemen:

SUBJECT: Request for Renewal of Private Fuel Storage L. L. C.
Quality Assurance Program

REFERENCES: 1. 10 CFR 71, Subpart H, 71.101(c)
2. 10 CFR 72, Subpart G, 72.140(c)

In accordance with references 1 and 2, we are submitting Issue 3 of our Quality Assurance Program (QAP) for renewal. Please remove the previous Issue and replace it in its entirety with Issue 3.

Changes are indicated by a change bar in the left-hand margin and include the following:

- ◆ Section 0.0 Introduction – in the fourth paragraph the word “Corporation” has been changed to “Company”.
- ◆ Section 1.0 Organization – removed the “Licensing Manager, Public Relations Director, Technology Group and Human Resources Development Group” from the first paragraph. Added “Project Director” to the first paragraph. These changes were inadvertently omitted in the last revision.
- ◆ Figure 1 – correctly worded the title in the lower right-hand box to state “Administrative Group” rather than “Architect Engineer”.

The above changes are administrative in nature and do not constitute a reduction in commitment to quality.

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Chief, Transportation and Storage Safety and Inspection Section

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We understand that there is no fee required for renewal.

Please contact Don Egge who is a member of our Quality Assurance Committee at (608) 787-1484 with any questions or comments you may have regarding this submittal.

Sincerely,

PRIVATE FUEL STORAGE L. L. C.



John D. Parkyn, Chairman
Board of Managers

JDP:DGE:pjs

Enclosure

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PRIVATE FUEL STORAGE L.L.C.
QUALITY ASSURANCE PROGRAM

August 2001

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PRIVATE FUEL STORAGE LLC

STATEMENT OF QUALITY ASSURANCE POLICY

The Quality Assurance Program described herein has been developed by Private Fuel Storage LLC (PFSLLC) to assure safe and reliable operation of facilities for independent spent nuclear fuel storage, high level radioactive waste storage, and the use of radioactive shipping packaging. The Program is designed to meet the requirements of Title 10 of the Code of Federal Regulations (CFR), Part 71, Subpart H and Part 72, Subpart G.

The Quality Assurance Program applies to all activities affecting quality and includes design, operation, documentation, procurement, repair, material, fabrication, inspection, testing, equipment operation and use, maintenance, modification, inventory, shipment and records retention.

Design and fabrication of shipping casks shall not be conducted under this Quality Assurance Program.

Quality Assurance is responsible for the establishment of the Quality Assurance Program which meets the requirements of 10 CFR 71, Subpart H and 10 CFR 72, Subpart G, and assuring implementation of the Program.

Chairman, Board of Managers

Date

0.0 Introduction

This Quality Assurance Program (QAP) has been developed to ensure that necessary controls are in place to assure the quality of all materials and processes used for the independent storage of spent nuclear fuel and high level radioactive waste as well as the use of radioactive shielding, casks, containers and other equipment pertaining to shipping packaging for radioactive materials.

The QAP delineates requirements and procedures necessary to exercise control over design, operation, documentation, procurement, material, fabrication, inspection, operational testing, equipment operation and use, maintenance, repair, modification, inventory, shipment and quality records retention.

The QAP and implementing procedures shall be designed and administered to meet the 18 criteria of 10 CFR 71, Subpart H and 10 CFR 72, Subpart G.

The QAP contains a statement of policy and authority, signed by the Chairman of the Board which defines the QAP as the Company's policy related to quality. The QAP states the policies, assigns the responsibilities and describes and summarizes the procedures governing the design, procurement, construction, testing and operations of safety important components, systems and structures as defined by contract in compliance with applicable licensing/certification regulations.

The policies described in the QAP implement the requirements of Title 10, CFR Part 71, Subpart H; and Part 72, Subpart G as well as additional requirements of ANSI, ASME, regulatory guides, and military standards as applied to organizations performing design, procurement, construction, testing and operation activities for nuclear applications to the extent specified by contract and licensing/certification regulations.

The statement of policy and authority includes provision to specify that attainment of quality objectives is the responsibility of all personnel of the PFSLLC. It also states that compliance with the Quality Assurance Program as is mandatory for all PFSLLC personnel whose activities affect quality.

Quality Assurance, reporting to the Board of Managers, is given full responsibility for maintaining the QA Manual and for assuring uniform implementation of the Quality Assurance Program requirements. Quality Assurance has the authority and resources to maintain oversight and initiate management action to limit further processing on items of indeterminate quality, to initiate management action to resolve any deficiencies, and to assure that satisfactory resolutions have been achieved prior to authorizing further processing.

1.0 Organization

The PFSLLC Organization (see Figure 1) consists of a Board of Managers, Quality Assurance, Business Services Unit, Project Director, Project Manager, Architect Engineer and Administrative Group who have responsibilities as follows:

Board of Managers are responsible for budget approval, financial oversight, planning, utility liaison, and business development as well as assuring the effective and efficient implementation of this program.

Quality Assurance is responsible for establishing this program as well as determining the effective implementation by performing audits. Quality Assurance has the authority to stop fabrication, construction, installation or testing of components, systems or structures which do not conform to applicable regulatory requirements, codes and standards and specifications or procedures.

Quality Assurance shall be independent from other organizations and shall have direct access to the Board of Managers.

Business Services Unit is responsible for accounts payable, accounts receivable, payroll, and other business related services associated with the operation of the PFSLLC.

Project Director is responsible for the day-to-day direction of all aspects associated with the creation of the PFSLLC, including licensing activities and enforcement actions.

Project Manager is responsible for all public information and government relations.

Architect Engineer is responsible for project design, preparation of license applications and any other activities as directed by the Project Manager.

Administrative Group supplies all clerical needs and on-site record controls to support the project.

2.0 Quality Assurance Program

The QA Program described herein sets forth the requirements for the control of quality in the design, fabrication, operation and maintenance of independent spent fuel storage installations/monitored retrievable storage facilities (ISFSIs and MRSs) and the use of shipping containers for nuclear products.

The QA Program shall be implemented through Quality Assurance Procedures which contain detailed implementing instructions.

The QA Program is designed to provide control of activities affecting quality in systems, structures and components that involve approved package design or facility licensing requirements that are important to safety.

Training and/or evaluation of personnel qualifications are required for all Quality Assurance functions in accordance with written procedures. The training program requires that all employees who participate in the QA Program will receive a level of classroom and on-the-job training commensurate with their involvement in the licensed activities. When required by applicable codes and standards, qualified personnel shall be appropriately certified in accordance with approved procedures.

The QA program shall be reviewed at established intervals to assure its adequacy and status and the program is being effectively implemented. Management of other organizations participating in the Quality Assurance program shall regularly review the status and adequacy of that part of the program which they are executing.

3.0 Design Control

This section establishes the requirements to assure that structures, systems and components are designed, added, deleted or modified in accordance with applicable regulatory requirements, codes and standards.

The design control process shall be implemented in accordance with written procedures. Design input and criteria are translated into specifications, drawings, procedures, calculations, instructions and procurement documents prepared and reviewed by qualified personnel. Design inputs include the design basis, regulatory requirements, applicable codes and standards and quality assurance requirements.

Design control procedures shall be prepared to describe and control the design and any changes from inception through final approval, release, distribution and implementation. The procedure shall provide identification and control of design interfaces and for coordination among participating design organizations. The procedures shall provide for the review of items such as: stress, hydraulic, thermal, criticality physics, radiation, shielding, and accident analyses; compatibility of materials; accessibility for inspection, maintenance and repair; features to facilitate decontamination; and delineation of acceptance criteria for inspections and tests. The procedure shall provide for a design review by qualified personnel other than those performing the design.

Any design change or field change shall be subjected to the same design control measures as specified for the original design.

4.0 Procurement Document Control

This section establishes the measures to assure that procurement documents covering material, equipment, and services specify appropriate quality requirements. The procurement documents shall specify or reference the applicable requirements, design bases, codes, and standards to assure quality.

All procurement activity shall be performed in accordance with written procedures delineating requirements for preparation, review, approval and control of procurement documentation. Revisions to procurement documentation shall be reviewed and approved by the same cognizant groups as the original.

Supplier evaluation and selection, objective evidence of supplier quality, assignment of quality requirements to procurement documents, including related design documents, and source, in-process and receiving inspection shall be administered and controlled in accordance with approved procedures.

Purchase orders shall include specifications which contain all the information necessary to assure that material, equipment, and services are of adequate quality. Documentation required to provide evidence that materials, equipment, and services are of adequate quality shall be clearly delineated in purchase orders.

To the extent necessary, procurement documents shall require suppliers of material, equipment, and services to have a quality assurance program complying with the pertinent provisions of 10 CFR 71, Subpart H or 10 CFR 72, Subpart G. The requirements of 10 CFR Part 21 shall be specified on procurement documents as applicable. Suppliers will be required to provide access to their facilities and records for inspection and audit, as required, to determine compliance with provisions of purchase orders. These requirements shall extend to lower tier procurements, as determined by management.

5.0 Instructions, Procedures and Drawings

This section establishes the measures to assure that activities affecting quality are performed in accordance with approved instructions, procedures and drawings.

All instructions, procedures and drawings are to be developed, reviewed, approved, utilized and controlled in accordance with the requirements of approved procedures. Changes to instructions, procedures and drawings shall be developed, reviewed, approved, utilized and controlled using the same requirements as applied to the original documents.

Procedures shall be developed and implemented for those operations that affect quality. Procedures define the manner in which quality objectives will be attained, such as criteria for workmanship to comply with standards, inspections, tests and verification activities. Documented work instructions define suitable equipment, working environments, work processes and approvals. Work instructions include methods to measure performance against established technical and quality requirements. Procedures and instructions shall be established and maintained to ensure that sufficient records are specified, reflect the quality of the work performed and comply with appropriate codes, standards and regulatory requirements.

6.0 Document Control

This section describes the system to control the issue, use, review, approval, distribution and revision of quality related documents.

Procedures shall be developed to identify individuals/organizations responsible for control, review, approval and issuance of documents.

Documents, including revisions, that are to be controlled shall be prepared, reviewed and approved by qualified personnel using document control procedures. Procedures shall be implemented specifying required reviews and approvals and distribution of documents.

Documents shall be distributed to and used at the location where the activity prescribed by the document is performed.

7.0 Control of Purchased Material, Equipment and Services

This section establishes the requirements to assure that purchased material, equipment and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents.

Procedures shall be implemented and used for determining supplier selection and evaluation. Procedures shall include criteria for the performance of supplier audits. This would include items such as: the supplier's capability to comply with codes and standards, supplier performance and review of the supplier's QA program and facility operation.

Suppliers of radioactive shipping packaging shall be evaluated to ensure that the design and fabrication of packaging are performed under the control of an NRC-approved QA Program.

Supplier performance evaluations shall be performed on a periodic basis. The time intervals shall be established based on the importance, complexity and quantity of the product or services.

Receipt inspection consistent with importance and complexity shall be performed using approved procedures to assure:

- a. The material, component or equipment is properly identified and corresponds with the identification of the applicable receiving documentation.
- b. Material, components, equipment and acceptance records are inspected and are acceptable in accordance with inspection instructions, prior to installation or use.
- c. Inspection records and/or certificates of conformance attesting to the acceptance of material and components are available prior to installation or use.
- d. Items accepted and released are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for further work.

8.0 Identification and Control of Materials, Parts and Components

This section establishes the requirements for the identification and control of material, parts and components from receipt through installation or use.

Approved instructions and procedures shall be implemented for the identification and control of materials, parts and components. An identification system shall be established using purchase order numbers, heat numbers, part numbers, serial numbers, or other means to identify and control materials, parts and components.

Specifications shall require that materials, parts and components are identified by some means and shall require that documentation have identification providing traceability to the item.

A means of physical identification should be used to the maximum extent possible for relating an item at any time to applicable documentation. Identification shall be either on the item or records traceable to the item. Where physical identification is impractical, physical separation, procedural control, or other appropriate means shall be employed.

9.0 Control of Special Processes

This section establishes the measures to assure that special processes, including welding, heat treating, radioactive waste processing, and non-destructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

Special processes shall be planned through items such as: documented work instructions defining the sequence of operations, special environments, suitable equipment, and criteria for workmanship standards. Process controls shall be established to ensure characteristics are maintained within specified requirements.

Each special process shall be performed in accordance with instructions, procedures, drawings, checklists, or other appropriate means. Measures will be taken to ensure process parameters are controlled and that environmental conditions such as temperature, humidity, and cleanliness are maintained. The written procedures for special processes shall specify the qualifications of personnel, the proper equipment to be used, and control of materials and supplies.

Equipment used for accomplishing special processes shall be calibrated, maintained, stored, handled and issued in accordance with applicable procedures.

Personnel shall be qualified to ensure proficiency in the special skills required for the process. The knowledge and capabilities required of personnel performing special processes shall be delineated in written instructions, including requirements for periodic evaluations of continuing proficiency.

10.0 Inspection

This section establishes a program for inspection of activities affecting quality to verify conformance with approved procedures, drawings and specifications.

Approved procedures shall be implemented delineating inspection methods, characteristics and documentation. Inspections shall be performed by qualified personnel other than those who performed or supervised the work being inspected.

Mandatory inspection hold points, which require witnessing or inspecting of an activity before processing, shall be indicated in the appropriate procedures or specifications. The inspection shall be documented to indicate approval and release prior to continuation of the activity.

Inspection requirements shall apply to all activities whether performed by company personnel or contractor personnel, and shall require that inspection procedures and instructions are provided with necessary drawings prior to commencing inspection activities.

Inspection requirements governing modifications, repairs and replacement shall be in accordance with the original design and inspection requirements or as amended by approved changes to the original design.

Where direct inspections of processed material or products cannot be called out, indirect controls will be utilized to control quality.

11.0 Test Control

This section establishes the requirements for a test program to demonstrate that structures, systems and components will perform satisfactorily in service.

A program shall be established to assure that all testing required to demonstrate that structures, systems and components will perform satisfactorily in service is identified and documented.

Testing shall be performed in accordance with approved test procedures which incorporate or reference the requirements and acceptance criteria contained in applicable design documents and specifications.

Test procedures shall incorporate, but not be limited to, requirements for such items as: hold points, witness points, caution notes, and emergency requirements.

Test results shall be documented and evaluated to ensure that test requirements have been satisfied.

Test results which fail to meet the requirements and acceptance criteria shall be properly noted and appropriate corrective action taken.

12.0 Control of Measuring and Test Equipment

This section establishes the requirements for the control, calibration, and periodic adjustment of tools, gauges, instruments, and other measuring and test equipment used to verify conformance to established requirements.

Inspection, test, and work procedures shall include provisions to assure that tools, gauges, instruments, and other inspection, measuring, and test equipment and devices used in activities affecting quality are of the proper range, type, and accuracy to verify conformance to established requirements and test parameters.

To assure equipment accuracy, inspection, measuring, and test equipment shall be controlled, calibrated, adjusted, and maintained periodically, or prior to use. Calibrations are performed against certified measurement standards that are traceable to nationally recognized standards. Where national standards do not exist, provisions will be established to document the basis for calibration.

13.0 Handling, Storage and Shipping

This section establishes the measures to control the handling, storage, shipping, cleaning, packaging, and preservation of material and equipment to prevent damage, deterioration, or loss through shipment, installation or use.

Approved procedures and instructions shall be implemented delineating the requirements for handling, storage, shipping, cleaning and preservation of materials and equipment.

When required, procedures shall describe special equipment to be used, protective environments and coatings, or other protective measures. Documentation such as records of inspections or maintenance or required shipping documentation shall also be specified in procedures and instructions.

14.0 Inspection, Test and Operating Status

This section describes the system for indicating the inspection, test and operating status of components and systems.

Approved procedures shall be implemented that include measures to preclude bypassing of inspections and tests, or prevent the operation of equipment or systems until authorized by designated personnel.

The operating status of systems and components shall be controlled through the use of tags secured to appropriate valves, switches, or control mechanisms. The use of tags and authorization for application and removal shall be specified in approved procedures. The use of status indicators shall be utilized on systems or components when operation, or removal from operation, would adversely affect performance of the system, constitute an operational safety or environmental hazard, or violate statutory/regulatory compliance requirements.

The status of inspections and tests shall be indicated on the item to the extent possible, or in documents traceable to the item. The status is identified by the use of tags, markings, stamps, or other means to ensure required inspections or tests are not bypassed. Status indicators shall be specified in approved procedures.

15.0 Non-Conforming Materials, Parts or Components

This section establishes the measures to control materials, parts or components which do not conform to specified requirements in order to prevent their inadvertent use or installation.

Approved procedures shall be implemented to provide requirements for identifying, segregating, reporting discrepancies and dispositioning of non-conforming items as well as notification to affected organizations.

Materials, parts, or components which do not conform to requirements shall be identified and placed in a hold status. Nonconforming items shall remain in a segregated area as appropriate until approved disposition has been received.

The disposition of nonconformances shall be evaluated and approved by appropriate personnel in accordance with approved procedures. Nonconforming items shall be controlled until final disposition is approved by authorized personnel.

Disposition of a nonconformance involving repair or rework shall include provisions to retest or reinspect to the original acceptance criteria. Any changes to design require the same design control as those applied to the original design.

Nonconformances shall be closed by qualified personnel in accordance with written procedures. Closure activities include verification that the corrective action was adequate, complete and documented appropriately.

Approved procedures shall identify methods for reporting adverse quality conditions in accordance with 10 CFR Part 21 requirements. Nonconformances are evaluated by appropriate personnel to determine reporting requirements.

16.0 Corrective Action

This section establishes measures to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment and nonconformances are promptly identified and corrected.

Conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations and defective material and equipment, shall be identified and reported to appropriate personnel using approved procedures. For significant conditions adverse to quality, the cause of the condition and corrective action necessary to prevent recurrence shall be identified, implemented and then followed-up to verify corrective action effectiveness using approved procedures.

Appropriate levels of management will be notified of significant conditions adverse to quality and the disposition of these conditions.

17.0 Quality Assurance Records

This section establishes measures for maintaining records of activities affecting quality.

Approved procedures shall be developed and implemented to establish controls for the identification, receipt, storage, preservation, safekeeping, traceability, retrieval and disposition of records.

Records to be maintained would include, but not be limited to, design, engineering, procurement, manufacturing, construction, inspection and test, installation, operations, maintenance, modification, calibration, audit, personnel qualifications, and procedures.

Inspection and test records shall identify as applicable: inspection type; evidence of completion and verification of manufacturing, inspection on test operation; date and results of inspection or test; information relating to noted discrepancies; inspection or data recorder; evidence of acceptance.

Records shall be maintained in facilities designed to prevent their loss or deterioration and shall comply with one of the following: 1) two sets of identical records are maintained at separate storage locations, or 2) the official copy of QA records is maintained in approved fireproof files or vaults at a single location.

A system shall be established to identify all documents and record retention for the project. At a minimum, records pertaining to the design, fabrication, erection, testing, maintenance and use of structures, systems and components important to safety shall be maintained until termination of the license.

18.0 Audits

This section establishes the requirements for a system of planned and documented audits to verify compliance with all aspects of the Quality Assurance Program and to assess the effectiveness of the program. The system provides for the reporting and review of audit results by appropriate levels of supervision and management.

Audits shall be performed in accordance with written procedures or checklists by appropriately trained personnel having no direct responsibilities in the area audited.

Audit and surveillance results shall be documented and reviewed with supervision responsible for the area audited who shall take necessary action to correct reported deficiencies.

Audit results shall be documented and reported to the management having responsibility in the area audited.

Deficiencies or nonconformances uncovered during an audit shall be documented and brought to the attention of the appropriate management personnel. Follow-up actions, including a reaudit, shall be performed to verify that corrective actions have been taken to correct the deficiencies or nonconformances.

Figure 1

