12 QUALITY ASSURANCE

12.1 Conduct of Review

This chapter of the SER evaluates the applicant's Quality Assurance (QA) Program. The QA Program submitted by the applicant is described in the "Private Fuel Storage Quality Assurance Program Description" dated August 30, 1996, as supplemented by Chapter 11, Quality Assurance, of the Safety Analysis Report (SAR).

The requirements of 10 CFR Part 72, Subpart G, and the guidance in the draft final report of NUREG 1567, "Standard Review Plan for Spent Fuel Storage Facilities," were used to perform a review of the QA Program. The purpose of the review was to determine whether the QA Program complied with the requirements of 10 CFR Part 72, Subpart G. The staff's evaluation of the QA Program for the PFS Facility is given below.

12.1.1 Organization

The description of the PFS organization was reviewed for conformance with the following requirements:

- 10 CFR 72.142, "Quality assurance organization," requires that: "The licensee shall be responsible for the establishment and execution of the quality assurance program....The licensee shall clearly establish and delineate in writing the authority and duties of persons and organizations....The quality assurance functions are: (a) Assuring that an appropriate quality assurance program is established and effectively executed and (b) Verifying...that activities affecting the functions that are important to safety have been correctly performed. The persons and organizations performing quality assurance functions must have sufficient authority and organizational freedom....The persons and organizations performing quality assurance functions shall report to a management level that assures that the required authority and organizational freedom...are provided."

In its application, PFS stated that: (1) the QA Program applies to all activities affecting quality; (2) the QA Program assures safe operation of facilities for independent spent nuclear fuel storage, high level radioactive waste storage, and use of radioactive shipping packagings; (3) QA personnel are responsible for establishing and executing the QA Program which meets the requirements of 10 CFR Part 72, Subpart G; (4) QA personnel have the authority and organizational freedom to assure that applicable requirements are met; and (5) QA personnel have direct access to the PFS Board of Directors. In its QA Program, the applicant describes the interrelationships, responsibilities, and authority of persons and organizations for the day-to-day execution of the QA Program.

The staff reviewed the QA Program and determined that PFS established and delineated the authority and duties of persons and organizations to assure that its QA Program is effectively executed. The staff determined that PFS organizations performing QA functions have sufficient authority and organizational freedom to perform their duties, and that activities affecting the functions that are important to safety are correctly performed. The staff, therefore, concludes

that the PFS organizational structure, responsibilities, and authority, as described in the QA Program, satisfy the requirements specified in 10 CFR 72.142.

12.1.2 Quality Assurance Program

The description of the PFS QA Program was reviewed for conformance with the following requirements:

- 10 CFR 72.144, "Quality assurance program," requires that: "The licensee shall establish...a quality assurance program....The licensee...shall provide control over activities affecting the quality of the identified systems, structures, and components to an extent commensurate with the importance to safety....The licensee shall provide for indoctrination and training of personnel performing activities affecting quality....The licensee shall review the status and adequacy of the quality assurance program at established intervals."

In its application, PFS stated that: (1) the QA Program is in full compliance with the requirements of 10 CFR Part 72, Subpart G; (2) the QA Program is comprised of the QA Program description and QA procedures which contain detailed implementing instructions; (3) the QA Program sets forth the requirements for the control of quality in the design, fabrication, operation, and maintenance of ISFSIs and the use of shipping containers; (4) the QA Program provides control over activities affecting quality in systems, structures, and components that are important to safety; (5) training and evaluation of personnel qualifications are required for all QA functions; and (6) the QA Program will be reviewed at established intervals to assure its adequacy and status and that the program is being effectively implemented.

The staff reviewed the QA Program and determined that PFS has established a QA Program that provides control over activities affecting the quality of the identified structures, systems, and components to an extent commensurate with the importance to safety. The staff determined that the QA Program provides for indoctrination and training of PFS personnel performing activities affecting quality and requires that qualified PFS personnel review the QA Program for adequacy at established intervals. The staff, therefore, concludes that the QA Program, as described in the SAR, satisfies the requirements of 10 CFR 72.144.

12.1.3 Design Control

The description of the PFS design control process was reviewed for conformance with the following requirements:

- 10 CFR 72.146(a), "Design control," requires that: "The licensee shall establish measures to assure that applicable regulatory requirements and the design basis...are correctly translated into specifications, drawings, procedures, and instructions...."

- 10 CFR 72.146(b) requires that: "The licensee shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations...The licensee shall apply design control measures to items such as: 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....For the verifying or checking process, the licensee shall designate individuals or groups other than those who were responsible for the original design...."

- 10 CFR 72.146(c) requires that: "The licensee shall subject design changes...to design control measures commensurate with those applied to the original design."

In its application, PFS stated that it will establish the requirements to assure that structures, systems, and components are designed, added, deleted, or modified in accordance with applicable regulatory requirements, codes, and standards. Specifically, the applicant states that: (1) The design control process shall be implemented in accordance with written procedures; (2) Design input and criteria are translated into specifications, drawings, procedures, calculations, instructions, and procurement documents prepared and reviewed by qualified personnel; (3) The procedures shall provide identification and control of design interfaces and for coordination among participating design organizations; (4) 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; (5) The procedure shall provide for a design review by qualified personnel other than those performing the design; and (6) Any design change or field change shall be subjected to the same design control measures as specified for the original design.

The staff reviewed the QA Program and determined that PFS has established measures to assure that applicable regulatory requirements and the design basis are correctly translated into specifications, drawings, procedures, and instructions. The staff determined that the QA Program has established measures to assure that design interfaces are identified and controlled; there is coordination among participating design organizations; design control measures apply to items important in the development of the design; design changes are subjected to design control measures commensurate with those applied to the original design; and individuals or groups, other than those who were responsible for the original design, will review the design. The staff, therefore, concludes that PFS's program for design control, as described in the QA Program, satisfies the requirements of 10 CFR 72.146.

12.1.4 Procurement Document Control

The description of the PFS procurement document control process was reviewed for conformance with the following requirements:

- 10 CFR 72.148, "Procurement document control," requires that: “The licensee shall establish measures to assure that applicable regulatory requirements, design bases, and other requirements...are included or referenced in the documents for procurement....the licensee shall require contractors or subcontractors to provide a quality assurance program.”

In its application, PFS stated that it will establish measures to assure that procurement documents covering materials, equipment, and services specify appropriate quality requirements. Specifically, the applicant states that: (1) The procurement documents shall specify or reference the applicable requirements, design bases, codes, and standards to assure quality, and that purchase orders shall include specifications which contain all the information necessary to assure that material, equipment, and services are of adequate quality; (2) All procurement activity shall be performed in accordance with written procedures delineate the requirements for preparation, review, approval, and control of procurement documentation; and (3) To the extent necessary, procurement documents shall require suppliers of material, equipment, and services to have QA Programs complying with the pertinent provisions of 10 CFR Part 72, Subpart G.

The staff reviewed the QA Program and determined that PFS has establish measures to assure that applicable regulatory requirements, design bases, and other requirements are included or referenced in the documents for procurement, and that the contractors or subcontractors are required, as appropriate, to provide quality assurance programs. The staff, therefore, concludes that PFS's procurement document control program, as described in the QA Program, satisfies the requirements of 10 CFR 72.148.

12.1.5 Instructions, Procedures, and Drawings

The description of the PFS instruction, procedures, and drawings development and control process was reviewed for conformance with the following requirements:

- 10 CFR 72.150, "Instructions, procedures, and drawings," requires that: "The licensee shall prescribe activities affecting quality by documented instructions, procedures, or drawings....The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished."

In its application, PFS stated that it will establish the measures to assure that activities affecting quality are performed in accordance with approved instructions, procedures, and drawings. Specifically, the applicant states that: (1) Procedures shall be developed and implemented for those operations affecting quality; (2) All instruction, procedures, and drawings are to be developed, reviewed, approved, utilized, and controlled in accordance with the requirements of approved procedures; and (3) Procedures and instructions shall be established and maintained to assure that sufficient records are specified, reflect the quality of work performed, and comply with appropriate codes, standards, and regulatory requirements.

The staff reviewed the QA Program and determined that PFS has prescribed activities affecting quality by documented instructions, procedures, or drawings, and that the instructions, procedures, and drawings will include appropriate quantitative or qualitative acceptance criteria for determining that activities important to quality have been satisfactorily accomplished. The staff, therefore, concludes that PFS's control of instructions, procedures, and drawings, as described in the QA Program, satisfies the requirements of 10 CFR 72.150.

12.1.6 Document Control

The description of the PFS document control process was reviewed for conformance with the following requirements:

- 10 CFR 72.152, "Document control," requires that: “The licensee shall establish measures to control the issuance of documents such as instructions, procedures, and drawings....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 assure that changes to documents are reviewed and approved.”

In its application, PFS stated that it will control the issue, use, review, approval, distribution, and revision of quality related documents. Specifically, the applicant states that: (1) Procedures shall be developed to identify individuals/organizations responsible for control, review, approval, and issuance of documents; (2) Documents, including revisions, that are to be controlled, shall be prepared, reviewed, and approved by qualified personnel using documented control procedures; and (3) Documents shall be distributed to, and used at, the location where the activity prescribed by the document is performed.

The staff reviewed the QA Program and determined that PFS has established measures to control the issuance of documents such as instructions, procedures, and drawings; 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; and assure that changes to documents are reviewed and approved by authorized personnel. The staff, therefore, concludes that PFS’s document control program, as described in the QA Program, satisfies the requirements of 10 CFR 72.152.

12.1.7 Control of Purchased Material, Equipment, and Services

The description of the PFS purchased material, equipment, and services control process was reviewed for conformance with the following requirements:

- 10 CFR 72.154(a), "Control of purchased material, equipment, and services," requires that: “The licensee shall establish measures to assure that purchased material, equipment and services...conform to the procurement documents."

- 10 CFR 72.154(b) requires that: “The licensee shall have available documentary evidence that material and equipment conform to the procurement specifications prior to installation or use."

- 10 CFR 72.154(c) requires that: “The licensee or designee shall assess the effectiveness of the control of quality by contractors and subcontractors.”

In its application, PFS stated that it will assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. Specifically, the applicant states that: (1) Procedures shall be

implemented and used for determining supplier selection and evaluation and that this would include the supplier's capability to comply with codes and standards, supplier performance, and review of the supplier's QA Program and Facility operation; (2) Supplier performance evaluations shall be performed based on the importance, complexity, and quantity of the product or services; and (3) Receipt inspection consistent with the importance and complexity shall be performed using approved procedures to assure: (a) The material, components, or equipment is properly identified and corresponds with the receiving documentation; (b) The material, component, or equipment, and acceptance records are inspected and are acceptable; (c) Inspection records and certificates of conformance attesting to the acceptance of material and components are available; and (d) Accepted items are identified as to the inspection status prior to release.

The staff reviewed the QA Program and determined that PFS has established measures to assure that purchased material, equipment and services conform to the procurement documents; documentation will be available showing that material and equipment conform to the procurement specifications; and the effectiveness of the control of quality by contractors and subcontractors will be assessed. The staff, therefore, concludes that PFS's control of purchased materials, equipment, and services, as described in the QA Program, satisfies the requirements of 10 CFR 72.154.

12.1.8 Identification and Control of Materials, Parts, and Components

The description of the PFS material, parts, and components identification and control process was reviewed for conformance with the following regulation:

- 10 CFR 72.156, "Identification and control of materials, parts, and components," requires that: "The licensee shall establish measures for the identification and control of materials, parts, and components. These measures must assure that identification of the items is maintained...either on the item or on records traceable to the item as required, throughout fabrication, installation, and use of the item."

In its application, PFS stated that it will identify and control material, parts, and components from the time of receipt through installation and use. Specifically, the applicant states that: (1) Approved instructions and procedures shall be implemented for the identification and control of materials, parts, and components; (2) An identification system shall be established using purchase order numbers, heat numbers, serial numbers, or other means to identify and control materials, parts, and components; and (3) 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.

The staff reviewed the QA Program and determined that PFS has established measures for the identification and control of materials, parts, and components. The staff determined that PFS's measures assure that identification of the items are maintained either on the items or on records traceable to the items, throughout fabrication, installation, and use of the items. The staff, therefore, concludes that PFS's identification and control of materials, parts, and components, as described in the QA Program, satisfy the requirements of 10 CFR 72.156.

12.1.9 Control of Special Processes

The description of the PFS special processes controls were reviewed for conformance with the following requirements:

- 10 CFR 72.158, Control of special processes," requires that: “The licensee shall establish 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.”

In its application, PFS stated that it will 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. Specifically, the applicant states that: (1) 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; (2) Each special process shall be performed in accordance with instructions, procedures, drawings, checklists, or other appropriate means; (3) Equipment used for accomplishing special processes shall be calibrated, maintained, stored, handled, and issued in accordance with applicable procedures; and (4) Personnel shall be qualified to assure proficiency in the special skills required for the process.

The staff reviewed the QA Program and determined that PFS has established measures to assure that special processes are controlled and accomplished by qualified personnel using qualified procedures. The staff determined that these measures include planning and performing special processes using instructions, procedures, drawings, checklists, or other appropriate means; qualifying the personnel performing special processes to assure their proficiency in the skills required for the process; and specifying the proper use and control of equipment, materials, and supplies to be used in the performance of special processes. The staff, therefore, concludes that PFS’s control of special processes, as described in the QA Program, satisfies the requirements of 10 CFR 72.158.

12.1.10 Inspection

The description of the PFS inspection process was reviewed for conformance with the following requirements:

- 10 CFR 72.160, "Licensee inspection," requires that: The licensee shall establish and execute a program for inspection of activities affecting quality...to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. 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....If mandatory inspection

hold points...are required, the specific hold points must be indicated in appropriate documents."

In its application, PFS stated that it will establish a program for inspection of all activities affecting quality, whether performed by company or contractor personnel, to verify conformance with approved procedures, drawings, and specifications. Specifically, the applicant states that: (1) Approved procedures shall be implemented delineating inspection methods, characteristics, and documentation; (2) Inspections shall be performed by qualified personnel other than those who performed or supervised the work being inspected; and (3) Mandatory inspection hold points, which require witnessing or inspecting of an activity before processing, shall be indicated in the appropriate procedures or specifications.

The staff reviewed the QA Program and determined that PFS has established a program for inspection of activities affecting quality to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. The staff determined that the program will assure that inspections are performed by individuals other than those who performed the activities being inspected; examinations, measurements, or tests of material or products processed will be performed for each work operation where necessary to assure quality; and if mandatory inspection hold points are required, the hold points will be indicated in appropriate documents. The staff, therefore, concludes that PFS's inspection control program, as described in the QA Program, satisfies the requirements of 10 CFR 72.160.

12.1.11 Test Control

The description of the PFS test control process was reviewed for conformance with the following requirements:

- 10 CFR 72.162, "Test control," requires that: "The licensee shall establish a test program to assure that all testing required...is identified and performed in accordance with written test procedures....The licensee shall document and evaluate the test results to assure that test requirements have been satisfied."

In its application, PFS stated that it will establish a test program to demonstrate that structures, systems, and components will perform satisfactorily in service. Specifically, the applicant states that: (1) 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; (2) Test results shall be documented and evaluated to assure that test requirements have been satisfied; and (3) Test results which fail to meet the requirements and acceptance criteria shall be properly noted and appropriate corrective action taken.

The staff reviewed the QA Program and determined that PFS established a test program to assure that all testing required is identified and performed in accordance with written test procedures. The staff determined that the test program assures that all required testing will be identified and documented; testing will be performed in accordance with approved test procedures that incorporate or reference the requirements and acceptance criteria; test results will be documented and evaluated to assure that test requirements have been satisfied; and appropriate corrective action will be taken when test results fail to meet the test requirements

and acceptance criteria. The staff, therefore, concludes that PFS's test control program, as described in the QA Program, satisfies the requirements of 10 CFR 72.162.

12.1.12 Control of Measuring and Test Equipment

The description of the PFS measuring and test equipment control process was reviewed for conformance with the following requirements:

- 10 CFR 72.164, "Control of measuring and test equipment," requires that: "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...."

In its application, PFS stated that it has established the requirements for the control, calibration, and periodic adjustment of tools, gauges, instruments, and other measuring and test equipment (IM&TE) used to verify conformance to requirements. Specifically, the applicant states that: (1) Inspection, test, and work procedures shall include provisions to assure that IM&TE used in activities affecting quality are of the proper range, type, and accuracy to verify conformance to established requirements and test parameters; and (2) To assure equipment accuracy, IM&TE shall be controlled, calibrated, adjusted, and maintained periodically, or prior to use.

The staff reviewed the QA Program and determined that PFS has establisheded measures to assure that IM&TE used in activities affecting quality are properly controlled, calibrated, adjusted, and maintained to assure equipment accuracy. The staff determined that PFS has established measures to implement procedures that will assure that IM&TE used in activities affecting quality are of the proper range, type, and accuracy to verify conformance to requirements. The staff, therefore, concludes that PFS's control of measuring and test equipment, as described in the QA Program, satisfies the requirements of 10 CFR 72.164.

12.1.13 Handling, Storage, and Shipping

The description of the PFS handling, storage, and shipping control process was reviewed for conformance with the following requirements:

- 10 CFR 72.166, "Handling, storage, and shipping control," requires that: "The licensee shall establish measures to control...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."

In its application, PFS stated that it will control the handling, storage, shipping, cleaning, packaging, and preservation of material and equipment to prevent damage, deterioration, or loss through shipment, installation, or use. Specifically, the applicant states that: (1) Approved procedures and instructions shall be implemented delineating the requirements for handling, storage, shipping, cleaning, and preservation of materials and equipment; and (2) When required, procedures shall describe special equipment to be used, protective environments and coatings, or other protective measures.

The staff reviewed the QA Program and determined that PFS has established measures to control the handling, storage, shipping, cleaning, and preservation of materials and equipment to prevent damage or deterioration. The staff determined that PFS has established measures to specify in approved procedures and instructions the requirements for handling, storage, shipping, cleaning, and preservation of materials and equipment, and to specify special equipment to be used, protective environments, coatings, or other protective measures, and required documentation. The staff, therefore, concludes that PFS's control of handling, storage, and shipping, as described in the QA Program, satisfies the requirements of 10 CFR 72.166.

12.1.14 Inspection, Test, and Operating Status

The description of the PFS inspection, test, and operating status control process was reviewed for conformance with the following requirements:

- 10 CFR 72.168(a), "Inspection, test, and operating status," requires that: "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."

- 10 CFR 72.168(b) requires that: "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."

In its application, PFS stated that it will indicate the inspection, test, and operating status of components and systems. Specifically, the applicant states that: (1) The status of inspections and tests shall be indicated on the item to the extent possible, or in documents traceable to the item; (2) The status is identified by the use of tags, markings, stamps, or other means to assure required inspections or tests are not bypassed; (3) The operating status of systems and components shall be controlled through the use of tags secured to appropriate valves, switches, or control mechanisms.

The staff reviewed the QA Program and determined that PFS has established measures to indicate the status of inspections and tests performed upon individual structures, systems, and components to preclude inadvertent bypassing of the inspections and tests and to identify the operating status of structures, systems, and components. The staff determined that PFS has established measures to indicate the status of inspections and tests on items or in documents traceable to the items; use tags, markings, stamps, or other means to assure that required inspections and tests are not bypassed; and prevent the operation of equipment or systems using status indicators. The staff, therefore, concludes that PFS's inspection, test, and operating status control program, as described in the QA Program, satisfies the requirements of 10 CFR 72.168.

12.1.15 Nonconforming Material, Parts, or Components

The description of the PFS nonconforming material, parts, and components control process was reviewed for conformance with the following requirements:

- 10 CFR 72.170, "Nonconforming material, parts, or components," requires that: “The licensee shall establish measures to control materials, parts, or components that do not conform to the licensee's 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.”

In its application, PFS stated that it will control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. Specifically, the applicant states that: (1) Approved procedures shall be implemented to provide requirements for identifying, segregating, and reporting discrepancies and dispositioning of non-conforming items as well as notification to affected organizations; (2) Materials, parts, or components which do not conform to requirements shall be identified and placed in a hold status; (3) Nonconforming items shall remain in a segregated area as appropriate until approved disposition has been received; (4) The disposition of nonconformances shall be evaluated and approved by appropriate personnel in accordance with approved procedures; and (5) Nonconformances shall be closed by qualified personnel in accordance with written procedures to include verification that the corrective action was adequate, complete, and documented appropriately.

The staff reviewed the QA Program and determined that PFS has establish measures to control materials, parts, or components that do not conform to the licensee's requirements in order to prevent their inadvertent use or installation. The staff determined that PFS has established measures to identify, segregate, and disposition non-conforming items and report discrepancies to affected organizations; segregate non-conforming items until properly dispositioned by appropriate personnel; and close nonconformances using qualified personnel to verify that corrective actions were adequate, complete, and documented. The staff, therefore, concludes that PFS’s nonconformance control program, as described in the QA Program, satisfies the requirements of 10 CFR 72.170.

12.1.16 Corrective Action

The description of the PFS corrective action control process was reviewed for conformance with the following requirements:

- 10 CFR 72.172, "Corrective action," requires that: “The licensee shall establish measures to assure that conditions adverse to quality...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 is taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the

corrective action token must be documented ane reported to appropriate levels of management."

In its application, PFS stated that it will promptly identify and correct conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances. Specifically, the applicant states that: (1) 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; (2) 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; and (3) Appropriate levels of management will be notified of significant conditions adverse to quality and the disposition of these conditions.

The staff reviewed the QA Program and determined that PFS has established measures to assure that conditions adverse to quality are promptly identified and corrected. The staff determined that PFS has established measures to identify and report to appropriate personnel conditions adverse to quality; for significant conditions adverse to quality, identify the causes of the conditions, determine the corrective actions necessary to prevent recurrence of the conditions, and notify appropriate levels of management of the conditions and the dispositions of the conditions; and verify corrective action effectiveness. The staff, therefore, concludes that PFS's corrective action program, as described in the QA Program, satisfies the requirements of 10 CFR 72.172.

12.1.17 Quality Assurance Records

The description of the PFS QA records control process was reviewed for conformance with the following requirements:

- 10 CFR 72.174, "Quality assurance records," requires that: "The licensee shall maintain sufficient records to furnish evidence of activities affecting quality....Records must be identifiable and retrievable. Records pertaining to the design, fabrication, erection, testing, maintenance, and use of structures, systems, and components important to safety shall be maintained by or under the control of the licensee until the Commission terminates the license."

In its application, PFS stated that it will maintain records of activities affecting quality. Specifically, the applicant states that: (1) Approved procedures shall be developed and implemented to establish controls for the identification, receipt, storage, preservation, safekeeping, traceability, retrieval, and disposition of records; and (2) 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.

The staff reviewed the QA Program and determined that PFS has established measures to maintain sufficient records to furnish evidence of activities affecting quality. The staff determined that PFS has established measures to control the identification, receipt, storage, preservation, safekeeping, traceability, retrieval and disposition of records, and to maintain

records pertaining to the design, fabrication, erection, testing, maintenance, and use of structures, systems, and components important to safety until termination of the license. The staff, therefore, concludes that PFS's QA records control program, as described in the QA Program, satisfies the requirements of 10 CFR 72.174.

12.1.18 Audits

The description of the PFS audit control process was reviewed for conformance with the following requirements:

- 10 CFR 72.176, "Audits," requires that: "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 audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Follow-up action, including re-audit of deficient areas must be taken where indicated."

In its application, PFS stated that it will establish a system of planned and documented audits to verify compliance with all aspects of the QA Program and to assess the effectiveness of the program. Specifically, the applicant states that: (1) Audits shall be performed in accordance with written procedures or checklists by appropriately trained personnel having no direct responsibilities in the area audited; (2) Audit results shall be documented and reported to the management having responsibility in the area audited; and (3) Follow-up actions, including a re-audit, shall be performed to verify that corrective actions have been taken to correct the deficiencies or nonconformances.

The staff reviewed the QA Program and determined that PFS has established measures to carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the QA Program and to determine the effectiveness of the program. The staff determined that PFS has established measures to perform audits in accordance with written procedures or checklists using trained personnel having no direct responsibilities in the area audited; document and review audit results with management responsible for the area audited; and perform audits to verify that corrective actions have been taken to correct deficiencies and nonconformances. The staff, therefore, concludes that PFS's audit program, as described in the QA Program, satisfies the requirements of 10 CFR 72.176.

12.2 Evaluation Findings

Based upon its review and evaluation of the PFS QA Program described in the SAR, the staff concludes that the PFS QA Program:

- establishes and delineates the authority and duties of persons and organizations performing activities affecting quality;

- provides for indoctrination and training of personnel performing activities affecting quality;

- assures conformance to the approved design of structures, systems, and components;
- provides for approved procedures or instructions to document the QA Program and requires that these procedures and instructions be followed;
- provides control over activities affecting quality to an extent commensurate with the importance to safety;
- defines and establishes requirements, processes, and controls that will comply with the requirements of 10 CFR 72, Subpart G;
- assures management review of the QA Program to determine program status and adequacy; and
- satisfies the requirements of 10 CFR 72.40(a)(7).

Therefore, the staff has determined that, when properly implemented, the PFS QA Program is acceptable.

12.3 References

Private Fuel Storage Limited Liability Company. 2000. *Safety Analysis Report for Private Fuel Storage Facility*. Revision 18. Docket No. 72-22. La Crosse, WI: Private Fuel Storage Limited Liability Company.

Private Fuel Storage Limited Liability Company. 1996. *Private Fuel Storage Quality Assurance Program Description*. Docket No. 72-22. La Crosse, WI: Private Fuel Storage Limited Liability Company. August 30, 1996.