



**Biennial Update Report
for the Idaho Spent Fuel (ISF) Facility
Independent Spent Fuel Storage Installation**

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1.0 Introduction

Special Nuclear Materials License No.2512 (SNM-2512) to operate the Idaho Spent Fuel (ISF) Facility Independent Spent Fuel Storage Installation (ISFSI) was transferred to the Department of Energy Idaho Operations Office (DOE-ID) from Foster Wheeler Corporation on September 9, 2009. This update report provides the following reports, which were last updated in September 2015.

- The biennial Safety Analysis Report (SAR) Update Report pursuant to 10 Code of Federal Regulations (CFR) 72.70 (b) and (c). The SAR Update Report is provided in the section titled “Description of Changes to the Safety Analysis Report.”
- The biennial 72.48 Evaluations Report pursuant to 10 CFR 72.48(d)(2). This report, comprised of summaries of evaluations of changes made pursuant to 10 CFR 72.48, is provided in the section titled “Changes, Tests, and Experiments.”
- The biennial Technical Specification (TS) Bases Evaluations Report pursuant to TS 5.5.1.d. This report is provided in the section titled “Changes to the Technical Specification Bases.”
- The biennial Essential Program Evaluations Report pursuant to TS 5.5.6.6. This report covers changes made during this reporting period to the DOE-ID essential programs as described in the sections titled “Radiological Environmental Monitoring Program Changes,” “Training Program Changes” and “Quality Assurance Program Changes.” (Note: Changes to the Physical Protection Program and the Emergency Response Program are provided separately because of the reporting time frames required by 10 CFR 72.44 (e) and (f), respectively.)

This report is provided in a combined format because many of the changes described in the SAR Update are also covered by evaluations of changes made without NRC approval pursuant to 10 CFR 72.48, TS 5.5.1, and TS 5.5.6. Technical Specification 5.5.1 requires 72.48 evaluations to be performed for any change to the Technical Specification Bases. TS 5.5.6 requires an evaluation of the change in program effectiveness (similar to the requirements of 10 CFR 72.44 (e) and (f)) for changes to the ISFSI Radiological Environmental Monitoring Program, Training Program, and Quality Assurance Program. These three programs are described in the ISF Facility ISFSI SAR.

2.0 Attachments

- ISF SAR-221-9 Chapter 9, Revision 5.
- ISF SAR-221-11 Chapter 11, Revision 5.

3.0 Section I - Description of Changes to the Safety Analysis Report

The previous update of the ISF Facility ISFSI SAR made pursuant to 10 CFR 72.70 was provided in September 2015. Changes were made to Chapters 9 and 11 in September of 2017 during this reporting period as follows:

- A. In September of 2017, changes were made to the ISF ISFSI SAR Chapter 9 (Revision 5) to revise Section 9.1, Organization Structure, to update various DOE-ID and contract personnel titles, responsibilities, and authorities throughout this Section. Figures 9.1-1 and 9.1-2, DOE-ID ISF Facility Organization and Contractor ISF Facility Project Organization respectively were updated to reflect the Section 9.1 changes.
- B. In September of 2017, a change was made to the ISF ISFSI SAR Chapter 11 (Revision 5) to Section 11.1, Organization, to update various DOE-ID and contract personnel titles, responsibilities, and authorities throughout this Section.

The changes to the SAR are the result of a change to the licensee delegation of authority from "Manager, DOE Idaho Operations Office" to "Deputy Manager, Idaho Cleanup Project" as documented in NRC's June 6, 2017 "Amendment No. 3 to Materials License No. SNM-2512 for the ISF Facility ISFSI." Facility design and operation parameters were not changed.

Attached to this report are the latest revisions of the SAR (Chapter 9 and Chapter 11) as required by 10 CFR 72.70.

4.0 Section II - Changes, Tests, and Experiments

The previous report of changes made pursuant to 10 CFR 72.48 was provided in September 2015. There were no changes made pursuant to 10 CFR 72.48 during the subsequent 24-month period.

5.0 Section III - Changes to the Technical Specification Bases

The previous update of the Technical Specification Bases made pursuant to TS 5.5.1 was provided in September 2015. There were no changes made to the Technical Specification Bases during the subsequent 24-month period.

6.0 Section IV - Radiological Environmental Monitoring Program Changes

The previous update of the Radiological Environmental Monitoring Program made pursuant to TS 5.5.6 was provided in September 2015. There were no changes made to the Radiological Environmental Monitoring Program described in the SAR during the subsequent 24-month period.

7.0 Section V - Training Program Changes

The previous update of the Training Program made pursuant to TS 5.5.6 was provided in September 2015. There were no changes made to the Training Program described in the SAR during the subsequent 24-month period.

8.0 Section VI - Quality Assurance Program Changes

The previous update of the Quality Assurance Program made pursuant to TS 5.5.6 was provided in September 2015. Changes were made to the Quality Assurance Program as documented in Chapter 11 of the ISF Facility SAR and as previously discussed in Section 3.0 to update various DOE-ID and contract personnel titles, responsibilities, and authorities. This change was approved by the NRC as documented in NRC's June 6, 2017 "Amendment No. 3 to Materials License No. SNM-2512 for the ISF Facility ISFSI." There were no other changes made to the Quality Assurance Program described in the SAR during the subsequent 24-month period.

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9. CONDUCT OF OPERATIONS

This chapter describes the organization and general plans for the ISF Facility Independent Spent Fuel Storage Installation (ISFSI). The organization section includes a brief description of the DOE-ID organization, contractor transitional organizations, and responsibilities of key personnel. The preoperational testing program is described. The training program for the facility staff is described. Procedures that govern routine operations and maintenance and the records developed as a result of those operations are also discussed.

9.1 ORGANIZATIONAL STRUCTURE

This section discusses the organizational structures established for ISF Facility design, construction, pre-operation testing, startup, operation, and decommissioning. Figure 9.1-1, Figure 9.1-2 and Figure 9.1.3 illustrate these organizational structures. Section 9.1.1 discusses DOE's organization, relationships with contractors and suppliers, and technical staffing. Section 9.1.2.2 and Section 9.1.2.3 discuss the ISF Facility construction and operating organization.

9.1.1 Corporate Organization

The Deputy Manager for Idaho Cleanup Project (ICP), Office of Environmental Management (EM) is authorized to be the license holder for the ISF Facility (materials license SNM-2512). This authority was delegated and responsibility was assigned to the DOE-ID Deputy Manager Idaho Cleanup Project by the Secretary of Energy pursuant to 10 CFR 72.16(b) (Ref. 9-8) in a delegation order. As the facility owner and licensee, DOE retains ultimate responsibility for the safe operation of the facility and for compliance with all license conditions.

9.1.1.1 DOE-ID Functions, Responsibilities, and Authorities

The Deputy Manager for Idaho Cleanup Project, (ICP) is the authorized DOE representative having direct authority and responsibility for compliance with the ISF Facility license. The Deputy Manager for ICP is responsible for overall executive management of the Idaho Operations Office, has signature authority for the ISF Facility license, and is the person ultimately responsible for compliance with the facility's license conditions and overall nuclear safety. The Deputy Manager for ICP shall take any measures needed to ensure acceptable performance of the staff in operating, maintaining, and providing technical support to the facility to ensure nuclear safety and compliant operations. The responsibilities of the personnel reporting directly to the DOE-ID Manager, as depicted in Figure 9.1-1, are describe below.

The actual day-to-day execution of programs and operations associated with the NRC-licensed ISFSs is performed by a contractor. NRC is notified of DOE's intent to rebid its contractor support contract, the selection of the subsequent contractor, and an

evaluation of contractor performance within 180 days of the contract effective date. The DM for ICP and staff provide management direction and oversight of contractor performance in accordance with DOE-ID's Quality Assurance Program and commitments herein.

ISFSI Support services are provided by the DOE-ID, Office of Nuclear Engineering (NE). The DOE-ID Office of Operations Support (NE) is independent of facility line management and is responsible for providing environmental protection, safety, health, quality assurance, and security support services. This Office provides DOE-ID oversight of the contractor for licensed activities, independent of the ICP organization.

The DOE-ID Office of Administration Support (EM) has responsibility for developing appropriate revisions to the contract.

The responsibility for DOE-ID's role of providing direction to the contractor for spent fuel management lies with the Deputy Manager for Idaho Cleanup Project (DOE-ID (EM)). Oversight of the ISF Facility and other NRC-licensed ISFSs, is delegated by the Deputy Manager for ICP to the Principal Project Manager, NRC Licensed Facilities Team.

The DOE-ID (EM) ISF Facility Director reports directly to the NRC Licensed Facilities Supervisor, NRC Licensed Facilities Team. The ISF Facility Director is responsible for the direction to and oversight of the contractor in accordance with the ISF Technical Specifications and to ensure that approved requirements and performance objectives are met for the ISF Facility. The ISF Facility Director has direct access to the Deputy Manager for ICP on issues affecting the safety and surety of ISFSI operations. An alternate for the ISF Facility Director authorized to act in the Facility Director's absence is designated in writing and meets training and qualification requirements specified below for the Facility Director.

The NRC Licensing Manager reports to the Principal Project Manager, NRC Licensed Facilities, through the Supervisor, NRC Licensed Facilities. The Licensing Manager is responsible for the preparation and submittal of license applications (including any necessary amendments thereto), timely response to NRC communications and inquiry, and providing other licensing and interface support to the ISF Facility Director.

The responsibility for oversight of both the contractor's QA Program for the NRC-licensed ISFSs as well as the DOE-ID (NE) oversight program of the ISFSI operations is delegated through the Quality and Safety Director. The Quality and Safety Director has delegated the responsibility for QA oversight of the ISFSs to the ISFSI QA Program Manager (NE) for the ISFSI. The roles and responsibilities of the ISFSI QA Program Manager (NE) are further described in Chapter 11 of this SAR. As with the ISF Facility Director, the ISFSI QA Program Manager has direct access to the Deputy Manager for ICP (EM) on issues affecting the safety and surety of ISFSI operations.

9.1.1.2 Interrelationships with Contractors and Suppliers

The DOE utilizes a contractor for the ISF Facility construction and operations activities. Prior to a decision to proceed with construction and operation of the ISF Facility, the responsibility for compliance with license requirements and applicable regulations is contractually tasked to the contractor. The authority for the construction, management, and operation of the facility will be contractually awarded/assigned at some future time. To exercise DOE's ultimate responsibility, DOE will: (1) retain responsibility for and perform independent audits of the contractor's ISFSI QAP (both the achievement of quality by contractor management and the verification of quality by contractor QA personnel), (2) ensure the license requirements for the facility are included in the contract, (3) assess the performance of the contractor against the terms of the contract, (4) retain the responsibility to budget funds necessary and sufficient to safely operate the facility, and (5) retain the authority to revise the contract in the event contract deficiencies are found relative to proper implementation of license requirements.

The key relationships between the DOE-ID (EM) ISF Facility Director Licensing Manager, and ISFSI QA Program Manager and its contractor's current organization are depicted, in Figure 9.1-2.

9.1.1.3 ISFSI Oversight Program

The Facility Director is the day-to-day management employee responsible for the compliance of ISF Facility construction and operations. The ISF Facility Director shall verify or audit the ISF Facility for compliance with regulatory requirements and license basis commitments and apprise DOE-ID management of ISF Facility status based on observations.

The ISF Facility Director or alternate shall perform surveillances of the contractor's as low as reasonably achievable (ALARA) Committee and the ISFSI Safety Review Committee, and shall be an ex officio member (as a quorum requirement) of these committees when they meet to review ISFSI matters to ensure these committees' functions are satisfactory and report to DOE-ID management as necessary.

The ISF Facility Director or alternate shall review the results of management assessments performed for the following contractors' programs: training, security, emergency, quality assurance, and radiation protection.

The ISF Facility Director or alternate shall review and concur with all of the following with respect to the ISF Facility:

- All 72.48 evaluations and TS Basis evaluations (TS 5.5.1)

- 10 CFR 72.44(e)-Physical Protection Plan evaluations, 10 CFR 72.44(f)-Emergency Plan evaluations, and evaluations of changes to DOE-ID's other essential programs (TS 5.5.2)
- Changes to TS Bases
- All changes to the SAR
- 10 CFR 72.70 SAR update
- Nuclear Material Status Reports (submitted electronically)
- Annual environmental report
- Other reports which may be submitted to NRC in response to conditions or events that are not submitted by the Manager of DOE-ID.

9.1.1.4 DOE-ID Technical Staff

The DOE Idaho Operations Office has a technical staff representing several areas of expertise with the wide variety of projects and activities at the INL. This staff is available to assist the management and oversight of the DOE activities at the ISF Facility. Staff assigned to assist the management and oversight in the areas of security, radiation protection, emergency preparedness, and quality assurance are trained and qualified in accordance with Licensing Management Procedures, or perform work directly under the supervision of the ISF Facility Director.

9.1.2 Contractor Organization, Management, and Administrative Control System

The construction and operating organizations, line management, and administrative control systems are provided by DOE's contractor personnel. The DOE and its contractor commit to provide the NRC with ready access to the ISF Facility, personnel, and records that NRC considers necessary to carry out its regulatory responsibilities.

DOE-ID (EM) has assigned responsibility and delegated authority for the management and operation of the facility to the contractor. DOE-ID policy requirements for constructing and operating the ISF Facility are assigned to the contractor through the contract. Specifically, the contract requires the contractor to manage and operate the ISF Facility in compliance with all applicable:

- Human health and safety regulations,
- Environmental regulations,
- NRC regulations and license conditions, and
- Quality assurance requirements.

DOE-ID (EM) commits to providing a contractor with management and staff for construction, routine operation and maintenance of the ISF Facility and support organizations to implement DOE's program commitments in quality assurance,

security, training, radiological protection, environmental monitoring, and spent fuel accountability.

9.1.2.1 Transition Organization

Until such time a decision is made to proceed with construction of the ISF Facility and a contract award/selection is made, the incumbent contractor's (organization structure provides the necessary resources for maintaining the ISF Facility license. and license basis documents in accordance with '10 CFR 72. The contractor organization supports the Environmental Management missions at the INL, which include but are not limited to the management and operation of the ISF Facility for transition purposes. The following organizational descriptions document the organization resources necessary to manage the ISF Facility.

The contractor's Chief Executive Officer is responsible for overall management of contractor activities and is ultimately accountable for complying with the contract conditions. Authorities are delegated and resources are provided to manage the ISF Facility in the areas of emergency preparedness, engineering, environmental management, operations, maintenance, quality assurance, radiological control, safety and health, security, training, and transportation. In addition to the interfaces shown on Figure 9.1-2, personnel assigned to the above functions maintain interfaces with their functional counterparts at DOE- ID.

Reporting to the ISFSI Program Manager the ISF ISFSI Manager, and the Licensing and Regulatory Compliance Lead. Support staff for essential positions within the ISFSI Management department report to the ISF Facility Manager for services provided for the ISF Facility. The ISFSI Program Manager is accountable to the ISF Facility Director. This interface is the primary operations interface between DOE- ID (EM) and its contractor for the ISF Facility during the transition period.

The Quality Assurance Director assigned to the ISF Facility reports to a level equal to or above the reporting level of the ISFSI Program Manager. The Quality Assurance Director assigned to the ISF Facility also interfaces with the DOE-ID ISFSI QA Program Manager who is responsible for the ISF Facility QA Program (see Chapter 11).

9.1.2.2 Construction Organization

This section describes the management and organizational relationships established for the design and construction review, including QA functions. Figure 9.1-3 shows the key management positions and their relationships within the ISF Facility Project Organization.

The ISF Facility Project Director reports to the Chief Executive Officer and has responsibility and authority for the design review and construction of the ISF Facility. The ISF Facility Project Director is also responsible for ensuring that procedures, programs, and policies are developed, implemented, and maintained to ensure that design and construction activities are performed consistent with the QAP.

The Chief Engineer is responsible for ensuring that:

- design activities are properly defined, planned, controlled, verified, and documented;
- plans and procedures are developed, maintained, and implemented describing the design process, design interfaces, design verification, and design changes;
- applicable design specification requirements are correctly translated into drawings, procedures, and instructions;
- design documents (e.g., design specifications, design reports, code data reports, construction specifications, drawings, specifications, reports, and calculations) have been properly prepared, reviewed, approved, and certified (when required);
- analysis and design adequacy are independently verified, and for computational accuracy and appropriate use of computer programs that perform analytical operations; and
- As Low As Reasonably Achievable (ALARA) considerations have been appropriately incorporated into the ISF Facility design.

The Chief Engineer has authority for the following:

- approves design documents,
- assures certification of design documents, and
- approves design staff assignments.

Four principal subcontractors support the ISF Facility design. Section 9.1.2.2.1 discusses their responsibilities and oversight. During design and construction of the ISF Facility, the technical staff reports to the Chief Engineer.

The Chief Engineer is also responsible for establishing and maintaining procedures and programs associated with configuration management including:

- the control, maintenance, and implementation of a configuration management program;
- proper preparation, review, and approval of configuration management procedures, and
- establishment, implementation, and maintenance of the document control and records management systems.

The Chief Engineer has authority for the following:

- approves configuration management procedures and submittals, and
- approves configuration staff assignments.

The Construction Manager reports to the ISF Facility Project Director and is responsible for performing constructability reviews during initial design and subsequent modifications. During construction, the Construction Manager oversees procurement and construction activities to ensure that the ISF Facility is constructed in accordance with design requirements. The Construction Manager is responsible for oversight of the acceptance testing of SSCs before turnover to operations for pre-operational testing. The Construction Manager is responsible for ensuring that construction and construction-related procurement activities are performed in accordance with the QAP.

The Construction Manager has authority for the following:

- cease work (construction phase),
- secure properly trained and experienced craft personnel, and
- source and recommend vendors and suppliers.

The ESH&Q Manager, during design, assists the Chief Engineer, to ensure that industrial safety standards are incorporated into design. During construction, the ESH&Q Manager assists the Construction Manager in establishing safety programs and has the authority and responsibility for conducting assessments and audits to ensure that safety programs are effectively implemented. During construction the ESH&Q Manager's functions include the review and qualification of subcontractors before performance of onsite work. The ESH&Q Manager is responsible for providing results of these assessments and audits to the ISF Facility Project Director, and requesting support for resolution of related issues. The ESH&Q Manager has authority for the following:

- cease work,
- audit/surveillance of project ESH&Q performance,
- establish compliance with ESH&Q requirements, and
- approves ESH&Q assignments.

The ESH&Q Manager also has the authority and responsibility to verify the adequacy and implementation effectiveness of the quality programs of the ISF Facility organization, including contractors and subcontractors. The ESH&Q Manager is responsible for overseeing the ISF Facility activities to ensure that quality activities are implemented in accordance with the QAP and integrated with other facility management, administrative, and oversight programs as appropriate. During design and construction, the ESH&Q Manager has the authority and responsibility to verify that

structures, systems, and components (SSC) important to safety (ITS) are designed, procured, fabricated, inspected, and tested in accordance with the QAP. The ESH&Q Manager has cease work authority for quality related issues.

The Licensing Manager assists the ISF Facility organization to ensure that NRC regulatory requirements are incorporated into the design and administrative programs. The Licensing Manager is responsible for establishing procedures to ensure that the license basis documents remain consistent with facility operation and design. The Licensing Manager has authority for the following:

- cease work, and
- approve licensing staff assignments.

The Facility Manager is responsible for providing operations input and operability reviews on the facility design during design and construction.

9.1.2.2.1 Interrelationships with Subcontractors and Suppliers

The ISF Facility design is under the direct control and supervision of DOE-ID. DOE-ID, as licensee, maintains full responsibility, authority, and accountability for all project activities. Management of design, construction, and operation activities is provided by DOE's contractor personnel. The following table summarizes key subcontractors to FWENC that supported the current ISF Facility design, and whom may be called upon (through subcontracts) as necessary by DOE's contractor to provide future technical support.

Company	Responsibility
RWE NUKEM LTD	Transfer Area design
ALSTEC, Ltd. (ALSTEC)	Storage Area design
Utility Engineering (UE)	Building steel, steel structures design, and balance-of-plant design
Tetra Tech FW, Inc.	Storage Tube and Canister design

In accordance with contractual requirements, a QA Program is established and maintained to ensure quality oversight of subcontractors. Activities are overseen in accordance with the QAP. The Tetra Tech FW, Inc., Storage Tube and Canister design is conducted in accordance with an ASME nuclear certified QA program. An Authorized Nuclear Inspector oversees the activities.

As part of ISF Facility design, FWENC contracted equipment suppliers to provide SSCs ITS. FWENC issued specifications to these suppliers to develop system and component design, fabrication requirements, construction and installation details, and testing criteria. DOE ID's contractor will continue to oversee these activities (if and when reinitiated) in accordance with the QAP. The table below identifies major equipment suppliers.

Company	Equipment, System, Component
ALSTEC	Canister handling machine (CHM) turret
American Crane and Equipment Co.	Cask receipt crane
Ederer, Inc.	Cask trolley, canister trolley, cask handling machine bridge and trolley
Mid Columbia Engineering	Decanning machine
PAR, Inc.	Fuel handling machine (FHM)
Hot Cell Services	Shield windows

Electrical, plumbing, and other specialty subcontractors will be used to complete ISF Facility construction activities as appropriate. Subcontractors must be qualified to perform activities in accordance with the QAP. Quality of work is ensured by routine oversight of activities by ISF Facility construction supervision and management and oversight in accordance with the QAP.

9.1.2.2.2 Technical Staff

This section describes the contractor technical staff under the direction of the Chief Engineer. Contractor technical staff and consultant support for ISF Facility engineering, construction, and operation report functionally to the ISF Facility Project Director. Section 9.1.2.3 discusses staffing for the construction, pre-operational testing, and operation. Contractor and consultant technical staff support must meet the qualification requirements for onsite technical staff as provided in Section 9.1.3.

The Chief Engineer retains design oversight of the entire facility and is supported project engineers and discipline-area engineers. Tetra Tech FW, Inc., Utility Engineering, RWE NUKEM LTD., and ALSTEC support the project engineers.

Civil Engineers responsible for review and approval of the civil design associated with ISF Facility structures prepare, review, and approve the site seismic analysis, structural drawings, calculations, and analyses to ensure compliance with applicable design codes.

Mechanical Engineers responsible for review and approval of the mechanical design aspects of the ISF Facility SSCs prepare, review, and approve mechanical drawings, calculations, and analyses including the thermal and stress analyses of the storage components (e.g., ISF canisters and storage tubes).

Nuclear Engineers are responsible for the preparation, review, and approval of analyses related to criticality, nuclear decay heat generation, and radiation dose calculations.

Process Engineers are responsible for the preparation, review, and approval of the fuel and waste handling processes, and ensure that the processes are integrated with the design.

Electrical Instrument and Control Engineers are responsible for the preparation, review, and approval of design activities associated with electrical distribution, instrumentation, and control systems.

Utility Engineering, or its successor, provides civil/structural design support for the steel structures in the Cask Receipt Area, Transfer Area, and Storage Area. In addition, Utility Engineering, or its successor, provides design support for the heating, ventilation, and air conditioning (I-IVAC) systems. DOE-ID (EM) retains responsibility and approval authority for the design. Such work is overseen by review by DOE-ID and contractor engineering staff in addition to the oversight required by the QAP.

RWE NUKEM LTD., formerly AEA, is responsible for the Fuel Packaging Area layout and for supporting development of design requirements and specifications of SSCs used for receipt and handling of the received fuel, including:

- cask trolley,
- Transfer Area port plugs,
- shield windows,
- master/slave manipulators,
- special lifting fixtures (e.g., FHM lifting fixtures),
- FHM,
- worktable and ancillary equipment, and
- canister trolley.

DOE-ID (EM) retains responsibility and approval authority for the design specifications. The work performed by RWE NUKEM LTD. is overseen by review by DOE-ID and contractor engineering staff, in addition to the oversight required by the QAP.

ALSTEC, formerly ALSTOM, is responsible for the design of the Canister Closure Area (CCA), storage vault, ISF canister internals (baskets), and the design and fabrication of the CHM. DOE-ID retains responsibility and approval authority for the

design. ALSTEC's work is overseen by review by DOE-ID and contractor engineering staff, in addition to the oversight required by the QAP.

The ISF canisters and storage tubes are to be designed and fabricated to ASME Boiler and Pressure Vessel Code Section III, Division I requirements (see Section 4.2.1). The work is to be performed by Tetra Tech FW, Inc., in its Richland, Washington, Operations Office, which is an ASME-certified design organization. An Authorized Nuclear Inspector will oversee ASME work performed by Tetra Tech FW, Inc.

9.1.2.3 Operations Organization

The ISF Facility project organization will transition to an operations organization under the facility Manager when facility construction is complete. The ISF Facility operations organization, similar to the contractor's organization shown in Figure 9.1-1, but more expanded, will be set up along functional lines that integrate assigned responsibilities and interrelationships of functional areas such as design, engineering, procurement, licensing, business, ES&H, quality, maintenance, and operations.

Responsibilities and authorities of key personnel are summarized in Section 9.1.2.3.1. ITS functions and responsibilities such as nuclear criticality safety, QA, operations, health physics, maintenance, engineering, training and qualification, and emergency planning and response are noted in the applicable position descriptions. Each functional area manager is responsible for ensuring that personnel are properly qualified and authorized to perform assigned duties.

The ISF Facility modes of operation are based on the spent nuclear fuel (SNF) handling activities, which fall into the following four operational modes:

- receipt operations,
- loading operations,
- canister handling, and
- storage operations.

Operations at the ISF Facility can encompass any combination of these activities. Each operational mode can be related to the confinement boundary provided for the SNF handling activities. For each operational mode, minimum staffing levels are established. Each of these operational modes is discussed below.

Receipt Operations

Receipt operations include activities associated with handling the SNF while it is contained in a transfer cask. Receipt operations begin when the transfer cask is received at the ISF Facility, and end when the first transfer cask lid bolt is detensioned. During receipt operations, the confinement boundary for the fuel is the transfer cask. Minimum

operational staffing during receipt operations will consist of one shift supervisor and one equipment operator.

Loading Operations

Loading operations include activities associated with repackaging the fuel into ISF canisters. Loading operations exist whenever: (1) SNF is contained in a transfer cask without a fully tensioned closure lid; (2) fuel is in the fuel packaging area; or (3) fuel is in an ISF canister that has not completed its leak rate acceptance test. During loading operations, the confinement boundary for the SNF consists of the ISF Facility structures and systems as described in Section 3.3.2. During loading operations the minimum staffing include one shift supervisor, one certified operator, one equipment operator, and one radiation protection technician.

Canister Handling

Canister handling operations exist when SNF is contained in an ISF canister that has passed its leak rate acceptance test and the ISF canister is not contained in a sealed storage tube. During canister handling operations, the confinement boundary for the SNF is provided by the ISF canister structural integrity. Minimum operational staffing during canister handling operations will be one shift supervisor.

Storage Operations

Storage operations exist when an ISF canister containing SNF is contained in a sealed storage tube. During this mode of operation, the fuel is contained within a double confinement boundary, and decay heat is passively removed by natural convection. With the ISF Facility in this configuration there will be no active operations, and the minimum operational staffing will consist of one shift supervisor.

Adequate staffing levels will be maintained to ensure radiation doses for individuals remain below occupational radiation exposure limits. Section 7.4.1 provides a summary of the operational dose assessments. Section 7.I discusses the ISF Facility's commitment to an ALARA program and the monitoring of personnel exposure to ensure compliance with administrative and regulatory limits.

9.1.2.3.1 Personnel Functions, Responsibilities, and Authorities

The daily management of the ISFSI operation is provided by the ISF Facility Manager. The ISF Facility Manager reports to the ISFSI Program Manager. Assuring requirements are satisfied in the operation of the ISFSI is the responsibility of the ISF Facility Manager.

Personnel assigned to ISF Facility operations report to the ISF Facility Manager. Other personnel from the INL that may be assigned to work at the ISFSI will report to the ISF Facility Manager while at the ISFSI site. The ISF Facility Manager is responsible for maintaining the Operations Log that will be used to note the performance of all significant on-site activities and conditions.

ISF Facility staff-level committees include an ALARA Committee and staff level safety review committee(s) or board(s) responsible to review changes to license basis documents and any associated evaluations.

ISF Facility Manager

During construction the ISF Facility Manager reports to the ISF Facility Project Director. During operations ISF Facility Manager reports to the ISFSI Program Manager and provides leadership and overall direction and coordination for the facility. The ISF Facility Manager is responsible for the safe overall operation of the ISF Facility in accordance with the ISF Facility policies and programs and the NRC license. The ISF Facility Manager shall hold line managers, including direct reports, accountable for implementing necessary controls for safe performance of work in their area of responsibility. The ISF Facility Manager provides direct oversight and exercises upper-level management control over the operations activities through direction and oversight of the shift managers.

The ISF Facility Manager or designee has the following responsibilities:

- establish and implement policies, programs, and procedures to ensure the safe, legal, and efficient operation of the ISF Facility,
- establish and implement policies, programs, and procedures to ensure that the quality requirements of the QAP are achieved,
- ensure that regulatory requirements, commitments, and required notifications to NRC and other agencies are satisfied,
- cease work activities associated with the ISF Facility and/or initiate emergency procedures in an emergency or abnormal condition, and authorize resumption of work activities when the initiating condition has been determined and corrective action has been taken to prevent recurrence,
- certification of personnel to operate ITS equipment and controls in accordance with Section 9.3 Training Program,
- review and approve proposed facility modifications, procedural changes, and tests to ensure they do not require prior NRC approval in accordance with IO CFR 72.48,
- ensure that subordinate or delegated responsibilities, assignments, and authorities are understood and implemented by JSF Facility staff,

- ensure that adequate resources, staffing, and training are available to safely operate the JSF Facility,
- safe daily JSF Facility operations and maintenance,
- cessation of work activities associated with the ISF Facility and/or initiation of emergency procedures in an emergency or abnormal condition,
- adherence to applicable local, state, and Federal regulations and Technical Specifications,
- implementation of policies, programs, and procedures by shift operators,
- identification and resolution of shift crew performance weaknesses, and
- development and implementation of operating procedures.

The ISF Facility Manager has responsibility and oversight of the following positions:

- Shift Managers that have overall responsibility to ensure that shift operations of the ISF Facility are safely conducted in accordance with ISF Facility procedures, policies, and Technical Specifications. The Shift Operating Organization retains full authority and responsibility for the safety of the SNF. When the ISF Facility Manager is not on site, the Shift Manager is the onsite senior management representative for matters pertaining to safe operation of the ISF Facility, with authority and responsibility to cease work activities and/or initiate emergency procedures in an emergency or abnormal condition.
- Certified Operators that report to the Shift Manager and have responsibility to safely conduct fuel movement activities in accordance with ISF Facility procedures, policies, and Technical Specifications. The Certified Operators conduct applicable surveillances to meet the requirements of the Technical Specifications.
- Equipment Operators that report to the Shift Manager and have responsibility to safely conduct operations of support systems and components under the direction of a Certified Operator in accordance with ISF Facility procedures, policies, and Technical Specifications. The Equipment Operators conduct applicable surveillances to meet the requirements of the Technical Specifications. The Equipment Operators monitor operation of systems and components at the ISF Facility and performs switching and safety tagging operations to support maintenance activities.

Facility Safety Officer

The Facility Safety Officer reports to the ISF Facility Manager and provides oversight and direction of engineering activities associated with ISF Facility design, maintenance, and operation, fire protection, licensing, configuration management, and fuel accountability. The Facility Safety Officer oversees and directs onsite engineering and technical staff for the following functions and activities for support of ISF Facility operation and maintenance activities.

The Facility Safety Officer has responsibility for, oversees and directs matrixed administrative and training functions at the ISF Facility.

The Facility Safety Officer supports the ISF Facility Manager in day-to-day operations but reports to the ESH&Q Manager for issues involving personnel health or safety. This direct line to the ESH&Q Manager ensures appropriate independence from line management in health safety functions, including sufficient independence from cost and schedule issues.

The Facility Safety Officer is responsible for environmental, health and safety, emergency planning, security, and administers radiation safety at the ISF Facility. The Facility Safety Officer, like all employees, has the authority to cease work activities not in compliance with environmental, safety, or radiation protection programs or procedures. The Facility Safety Officer oversees and directs the following ISF Facility activities.

- developing and implementing industrial health and safety procedures,
- complying with applicable Occupational Safety and Health Administration (OSHA) standards,
- ensuring compliance with environmental permit requirements,
- planning and direction of radiation protection and ALARA programs,
- development and implementation of radiation protection procedures,
- packaging, storing, and shipping of radioactive waste,
- advising and informing the ISF Facility Manager on matters pertaining to radiological safety, including the status of radiological health aspects of facility operation and maintenance and the identification of potential radiological concerns,
- maintaining radiation protection-related records and monitoring for trends that may affect ISF Facility operation,
- ensuring that the ISF Facility is maintained in a state of readiness for effective emergency response in accordance with the *ISF Facility Emergency Plan* (Ref. 9-3),
- ensuring adequacy of the *ISF Facility Emergency Plan* implementing procedures, including that the ISF Facility staff is adequately trained in emergency response, and that emergency response facilities and equipment are adequate and properly maintained in a state of readiness, and
- establishing and maintaining physical security in accordance with the *ISF Facility Physical Protection Plan* (Ref. 9-2).

The Facility Safety Officer is also responsible for implementing the Radiological Protection Program and, like all employees, has the authority to cease work activities not in compliance with radiation protection or ALARA program requirements. The

Facility Safety Officer supervises radiation protection technicians in performance of their assigned duties, which include:

- monitoring radiological and environmental conditions,
- determining and evaluating radiation hazards in relation to prescribed limits,
- developing and recommending control and protective measures for radiological conditions,
- performing radiation surveys of ISF Facility areas and equipment to define existing and potential hazards,
- monitoring worker practices to ensure compliance with radiation protection and ALARA program requirements,
- packaging and storing radioactive waste associated with radiation protection operations in accordance with applicable requirements,
- calibrating survey and analytical instruments,
- developing and implementing personnel monitoring activities, including maintenance of personnel exposure records and environmental survey records,
- maintaining radiation protection logs, and
- performing investigations of personnel overexposure and excessive contamination and reporting the findings and corrective action recommendations to the ISF Facility Manager.

The Facility Safety Officer is also responsible for the development and maintenance of the auditing and verification functions of the QAP. The Facility Safety Officer, through performance of QA audits and surveillance of project performance, ensures compliance with QAP requirements. The Facility Safety Officer responsibilities include:

- initiating a work cessation action when necessary, to ensure implementation of the QAP,
- overseeing implementation of the QAP to meet the requirements of 10 CFR, Part 72, Subpart G,
- overseeing effective implementation of QAP procedures,
- verifying, through monitoring of ongoing activities and reviews of records, that ITS activities are performed correctly and in compliance with governing procedures, standards, policies, and regulations,
- coordinating ISF Facility quality activities to ensure appropriate oversight, in accordance with the required frequency,
- developing, maintenance, and implementation of audit programs and schedules, and
- timely and appropriate feedback to functional area managers of the results of audits, surveillance, inspections, and monitoring activities.

The Facility Safety Officer will notify the Shift Manager of any significant adverse to quality condition pertaining to ITS SSCs, including operating and maintenance activities in progress.

9.1.2.4 ISFSI Safety Review Committee

Reporting to and chartered by a senior executive for operations is the ISFSI Safety Review Committee. This committee is comprised of senior technical personnel and management personnel with extensive nuclear experience in various areas.

The purpose of this committee is to evaluate the performance of staff level safety review committees, to review performance indicators (such as audit findings, reportable events and conditions, Technical Specification violations); to review 10 CFR 72.48 evaluations (and associated procedure or design changes); to review changes to the Technical Specification Bases, SAR, Emergency Response Plan, and Physical Protection Plan; to approve license amendment requests; and to review preparations for major changes in operation (such as removing fuel from the ISFSI). The ISFSI Safety Review Committee shall also perform special reviews at the direction of the DOE-IDISF Facility Director.

Core members, appointed in writing by the chartering senior executive, provide the needed technical expertise in engineering, radiological control, criticality safety, nuclear facility operations, and nuclear quality assurance; their technical qualifications are described in section 9.1.3 below. Other members may be appointed as considered appropriate by the chartering senior executive.

A quorum shall include three core members, the technical disciplines appropriate for the matters under review, and the DOE-ID (ISF Facility Director). The ISF Facility Director is informed of all appointments to the Safety Review Committee.

9.1.2.5 Succession of Operation Authority and Responsibilities

The ISF Facility Manager has overall responsibility and authority for the ISF Facility. To ensure continuity of operation and organizational responsiveness to off-normal situations, a normal order of succession and delegation of authority will be established. The ISF Facility Manager will designate in writing personnel qualified to act as ISF Facility Manager in their absence.

The ISF Facility Manager is the senior management representative on site with authority and responsibility for matters pertaining to safe receipt, packaging, and storage of SNF; as well as compliance with Technical Specifications. When the ISF Facility Manager is off site, the on-duty Shift Manager will assume these responsibilities.

9.1.3 Personnel Qualification Requirements

9.1.3.1 Minimum Qualification Requirements

The following DOE-ID positions require minimum qualifications and training for the management and oversight of the ISF Facility:

- ISFSI QA Program Manager
- ISF Facility Director and designated alternate

Both positions have direct access to the licensee on an as-needed basis and shown in Figure 9.1-1. The DOE-ID ISFSI QA Program Manager shall have a minimum of a Baccalaureate degree in an engineering or physical science field and five years of experience in nuclear quality assurance and certification as lead auditor. The minimum training for this position shall include the 10 CFR 72.48 process, QA program indoctrination, NRC requirements, and the ISF Facility License Basis (consisting of the identification of and orientation to the license and design basis documents).

The DOE-ID ISF Facility Director shall have a minimum of a Baccalaureate degree in an engineering or physical science field and five years of experience in nuclear facility operations. The minimum training for this position shall include the 10 CFR 72.48 Process, QA program indoctrination, Technical Specifications, NRC requirements, and the ISF Facility License Basis. The designated alternate for the ISF Facility Director shall meet the same minimum qualifications and training requirements.

The following contractor positions require minimum qualifications and training for the operation of the ISF Facility:

- ISFSI Safety Review Committee members
- ISFSI Program Manager
- ISF Facility Manager and designated alternate
- ISF Facility Safety Officer and designated alternate
- Certified ISFSI Operators
- Quality Assurance Manager assigned to ISF Facility

The Chair, Members, and Alternates of the ISFSI Safety Review Committee (SRC) shall have a minimum of a Baccalaureate degree in an engineering or physical science field and five years of experience in one or more of the following technical areas at nuclear facilities:

- Radiological Safety
- Nuclear Safety (with at least two years of experience in criticality safety analysis)
- Nuclear Facility Operations

- Nuclear Quality Assurance
- Engineering

The minimum training for the Chair, Members, and Alternates of the ISFSI SRC shall include the 10 CFR 72.48 process, QA program indoctrination, Technical Specifications, NRC requirements, and the ISF Facility License Basis.

The ISFSI Program Manager shall have a minimum of a Baccalaureate degree in an engineering or physical science field and five years of supervisory experience in nuclear facility operations. No minimum training requirements are associated with this position.

The ISF Facility Manager shall have a minimum of a Baccalaureate degree in an engineering or physical science field and five years of supervisory experience in nuclear facility operations or equivalents for education and experience as approved by the ISFSI Program Manager. The minimum training for this position shall include 10 CFR 72.48 process, ISF Facility License Basis, Radiation Worker, Emergency Response, and ISF Facility Qualification training. The designated alternate for the ISF Facility Manager shall meet the same minimum qualifications and training requirements.

The ISF Facility Safety Officer shall have a minimum of a Baccalaureate degree in an engineering or physical science field and five years of supervisory experience in radiation protection for nuclear facility operations. The minimum training for this position shall be the ISFSI Radiation Protection Program. The designated alternate for the ISF Facility Safety Officer shall meet the same minimum qualifications and training requirements.

The minimum qualifications for the position of Certified ISFSI Operators are successful completion of the biennial medical examination, training, and certification in accordance with the requirements in Section 9.3.

The minimum qualifications for the QA manager assigned to the ISF Facility are a Baccalaureate degree in an engineering or physical science field and five years experience in nuclear operations quality assurance. No minimum training requirements are associated with this position.

9.1.3.2 Qualification of Personnel

The resumes or other appropriate documentation of personnel occupying the positions listed above will be kept on file to demonstrate compliance with the minimum requirements described.

9.1.4 Liaison with Outside Organizations

Despite the fact that the ISF Facility is a DOE-owned facility located on the INL with several other DOE- owned facilities and DOE-managed programs, the external regulation by the NRC of the ISF Facility sets this facility apart in some respects. The INL is a large, remotely located site and has its own large security police force, a fire department, medical staff, emergency response teams, and full-time shift plant supervision. Thus, the INL infrastructure will be considered to serve equivalent functions as independent local agencies (similar to local city or county) do for typical commercially-licensed sites.

9.2 PREOPERATIONAL TESTING AND OPERATION

The purpose of the pre-operational testing at the ISF Facility is to ensure that the facility can safely receive, package, and load spent fuel into the ISF canister and place the loaded canisters in storage.

The pre-operational test program starts with acceptance testing of safety-significant components (SSCs). This acceptance testing is performed by the construction organization and involves testing to verify compliance with construction specifications, procurement documents, and design requirements. This acceptance testing includes a functional test of the SSCs for proper system/component operation (e.g., testing of interlocks, load testing of cranes, system flow verifications). After acceptance testing is completed, the systems are turned over to the startup test organization who is responsible for "dry-run" testing using mock fuel assemblies and canisters fabricated to the dimensions and weights of the actual components. Dry-run testing is an integrated test program that verifies system interface operations, procedure usage, and adequacy of personnel training before receipt of SNF. The main objective of the pre-operational test plan is to verify the integrity of the structures and equipment and to substantiate the safety analysis. The pre-operational testing includes off-normal operation scenarios with mitigation plans. Overall goals of the pre-operational dry run are to:

- demonstrate the functionality of equipment
- verify adequacy of procedures used for receipt, transfer, and storage of SNF
- verify adequacy of staff training and qualifications to safely operate the ISF Facility
- develop proficiency with procedures involving radiation exposures to determine likely exposures for specific procedures and to consider alternative procedures to minimize exposures

9.2.1 Administrative Procedures for Conducting Test Programs

Test procedures will be developed for the ISF Facility. Approval of procedures, performance of tests, evaluation of test results, and incorporation of any needed system modifications or procedural changes (based on the results of the tests) will be performed by the contractor using administrative controls existing at the INL.

ISF Facility administrative control procedures will be used for: 1) preparing, reviewing, approving, and conducting procedures and test instructions, and 2) documenting, evaluating, and accepting the test results. The minimum requirements for planning and conducting tests are contained in Section 11.11 of the SAR Chapter 11 (QAP). The pre-operational test program consists of two separate but integrated phases, 1) acceptance testing and 2) dry-run testing. Following completion of pre-operational testing, operations testing will be performed on initial receipt of each fuel type. The ISF

Facility Manager has overall authority and responsibility for both the pre-operational and operational testing.

The ISF Facility Manager is responsible for ensuring that acceptance tests prior to and during the pre-operational testing are identified, acceptance test procedures are developed, and testing personnel qualifications are identified and met. These acceptance test procedures at the ISF Facility will be reviewed and approved by the ISF Facility technical staff, and test performance will be coordinated with the Construction Manager. Test procedures performed off site by equipment suppliers or contractors will be controlled in accordance with the QAP. The administrative process for conducting the initial test procedures will include provisions for review of the activities to identify and incorporate lessons learned into dry-run procedures.

The ISF Facility Manager is responsible for ensuring dry-run tests are identified, developed, and performed by qualified and trained personnel. Dry-run testing is performed, using mock fuel assemblies and canisters, to ensure that facility operations can be performed using the proposed operating procedures with qualified personnel before initial fuel receipt. The technical staff will review test procedures for technical accuracy. The dry-run test procedures will be verified and validated by table-top reviews or plant walk-downs by personnel qualified to perform the test and approved by the ISF Facility Manager. Pre-operational test procedures performed at the ISF Facility will contain the following minimum requirements.

- personnel qualifications
- objective(s)
- prerequisites
- applicable design, procurement, and/or facility license requirements
- description of test configuration
- test instructions
- QA inspection hold points (if required)
- acceptance criteria
- measuring and test equipment requirements
- test requirements and acceptance limits

Completed preoperational testing will be documented by test reports that will include as a minimum:

- item/system tested
- date of test
- test results and acceptability
- identification and signature of test personnel
- identification of measuring and test equipment used during test

- evaluation of test results for acceptability
- actions taken regarding any nonconformance noted

Following completion of pre-operational testing, test reports will be reviewed to determine the need to incorporate system modifications or procedure changes, based on lessons learned. When changes to the system design or procedures are necessary, they will be reviewed to ensure that they do not require prior NRC approval in accordance with 10 CFR 72.48. In addition, a fuel acceptance readiness review (FARR), as described in Section 9.2.3, will be performed to ensure that the ISF Facility equipment, procedures, programs, and staffing are in place before receipt of the first fuel assemblies and commencement of startup testing.

Startup testing will be performed during initial fuel receipt for each fuel type to verify compliance with calculated dose projections and heat removal aspects evaluated in the SAR. The startup test plan will include the following elements as a minimum:

- test procedures and confirmation of exposure times involving actual radioactive sources
- direct radiation monitoring of Transfer Cask, canister trolley shielding, and facility shielding (including plugs, covers, shield windows, doors, etc.) for radiation dose rates, streaming, and surface "hot spots"
- verification for the effectiveness of the passive heat removal features associated with the storage system
- plans and preparations for controlling radiological activities include, as a minimum:
 - ALARA reviews and planning
 - radiation work permits
 - hot particle controls
 - contamination, exposure, and airborne controls
 - alarms and monitoring systems
 - contingency plans to restore plant to a safe condition if unexpected results are obtained

The administrative process for conducting operational test procedures will include provisions for review of the activities to identify and incorporate lessons learned into facility design and operating procedures. In addition, design and operator training deficiencies will be identified, reviewed, and appropriate corrective actions taken. Changes to facility design or operations will be reviewed to ensure the change does not require prior NRC approval in accordance with 10 CFR 72.48. The ISF Facility Manager or designee approval of the changes is required prior to implementation.

9.2.2 Test Program Description

This section describes the pre-operational test objectives and the general methods for achieving those objectives, and discusses the bases for selection of acceptance criteria that will be used to evaluate the test results.

Pre-operational tests will closely simulate actual operations involving fuel receipt, fuel packaging, canister closure, and canister storage, to ensure that qualified ISF Facility staff using the operational procedures can safely perform these operations. The testing program will be conducted using mock fuel assemblies, rods, or modules to simulate the different types of fuels to be handled in the Fuel Packaging Area of the Transfer Area. Either a Transfer Cask (Peach Bottom cask and canister/basket) or mock cask will be used to simulate receipt operations. Mock ISF canisters (i.e., canisters similar in configuration and construction but not to final QA or QC standards) will be used to test handling equipment (fuel repackaging process) and canister closure operations (i.e., welding, nondestructive examination [NDE], vacuum drying, and helium backfilling). These mock ISF canisters will be used to pre-operationally test Cask Handling Machine operations including insertion of mock canisters into a storage tube. Verification of ALARA practices, which are not completely achievable during dry runs, will take place during the initial fuel loading.

Before pre-operational test performance, test personnel shall have a clear understanding of their duties and responsibilities. The following shall be completed before pre-operational testing:

- Personnel training and qualification per the approved training program.
- A pre-job briefing for affected staff.
- Hold and inspection points are clearly identified.
- Stop-work criteria and contingency plans are established to place the spent fuel in a safe configuration. (e.g., established guideline for how long a cask or canister may remain suspended from a crane).
- Personnel are aware of compensatory measures.
- Oversight command and control responsibilities are clearly established, including notification requirements.
- Specific radiological hazards are identified and controls are implemented.
- Radiation dose rates will be verified during initiation of start-up testing to ensure that actual values are within prescribed limits.

The methods for accomplishing the objectives and the acceptance criteria that will be used to evaluate the test results will be included in the procedures and test instructions. In addition, the general prerequisites for performing the tests, including special conditions to simulate normal and off-normal operating conditions, will be included in the procedures and test instructions.

9.2.3 Physical Facilities

This section discusses the type of tests and inspections to be performed on the ISF Facility safety significant components (SSCs) before receipt of SNF.

During construction, testing or inspections will be used to verify configuration, materials, performance, and quality for SSCs ITS (see Section 3.4 for a list of ITS items). The purpose of testing and inspections during construction is to verify that design requirements, specifications, and applicable code criteria are satisfied. Construction, materials, operations, or quality items that are found not to satisfy requirements will be identified as nonconforming and resolution/corrective action will be taken as required by the QAP.

Vendor-supplied SSCs are procured, tested/inspected, and received in accordance with the QAP. Quality oversight of this process requires the use of pre-approved vendors with conforming QA programs. Purchased items will be accompanied by documentation of conformance with requirements specified by DOE.

The construction organization will acceptance test and inspect SSCs (e.g., testing of interlocks, load testing of cranes, system flow verifications) before turnover to the ISF Facility operations organization for pre-operational testing, to ensure that individual systems and components operate properly and will perform as designed. The ISF Facility Manager is responsible for development of acceptance test/inspection procedures, and for review and approval of testing/inspection requirements provided by vendors before implementation. Table 9.2-1 lists the SSCs that will be acceptance tested/inspected.

Satisfactory completion of the test/inspection will require conformance with the acceptance criteria specified in the test/inspection procedure. Section 9.2.1 presents the administrative process for conducting the test program.

9.2.4 Operations

This section discusses those operations to be tested. Operations testing begins after completion of the construction and functional testing of SSCs. This section discusses the dry-run testing. Startup testing is described in Section 9.2.3.

Dry-run testing is the integrated system testing performed before initial fuel receipt to verify that the ISF Facility can be safely operated by individuals, qualified in accordance with the training program described in Section 9.3, using facility operating procedures. Mock fuel assemblies and canisters are used to simulate actual operations. Dry-run testing will verify that these activities can be performed:

- Receipt Operations. Activities related to receipt of spent fuel at the ISF Facility, including unloading of the receipt cask from the transporter through transport to the Fuel Processing Area (FPA) fuel receipt port.
- Packaging Operations. Activities performed in the FPA of the Transfer Area, where spent fuel is removed from the receipt containers (baskets or canisters), inspected, and placed in an ISF basket/canister in preparation for canister closure operations.
- Canister Closure Operations. Activities performed to prepare new ISF Facility canisters and baskets for SNF loading, and activities associated with receipt of loaded canister from the FPA through closure of the ISF Facility canister (lid weld, vacuum drying, helium backfill, and leak test). Special emphasis will be placed on verifying ability to satisfactorily perform the final closure weld.
- Loading Operations. Activities related to transferring sealed ISF Facility canisters from the Canister Closure Area (CCA) to the Storage Area and loading them into storage tubes in the dry vault storage system.
- Unloading Operations. Activities relating to retrieving an ISF facility canister from an individual storage tube in the modular dry-vault storage system and transferring it either back into the FPA or into a licensed transportation device.
- Waste Processing Operations. Activities involving handling and processing of radioactive waste (e.g., liquid, compactable, contact, and non-contact waste types).

Pre-operational testing will be completed, results reviewed, and required corrective actions (e.g., procedure and equipment modifications) will be completed before receipt of fuel. The FARR is discussed in Section 9.2.3. Once the operational readiness is completed, the startup test program can commence.

9.2.5 Test Discussion

After pre-operational testing is complete, a FARR will be performed before receipt of SNF, to verify the ability of the ISF Facility and staff to safely receive, repackage, and store fuel. The FARR will consist of a programmatic and procedure review, equipment and staffing review, and a performance assessment of operators, support staff, and management. The FARR will cover the following areas:

Construction

Construction activities complete (as required), as-built drawings updated and available in document control system, open items resolved, non-conformances corrected, acceptance construction test completed and approved, and inspections performed and accepted.

Engineering and Technical Support

Onsite technical staffing is adequate and available. Design control procedures are written and approved, required vendor information and manuals, design bases calculations, and as-built drawings are available as approved documents through the document control system.

Operations

Operating, off-normal, surveillance, and emergency response procedures are approved, operationally tested, and available in the document control system. Pre-operational testing including corrective actions for identified deficiencies and non-conformances, as required, are complete. Operational staffing is trained and adequate to support operations.

Training

Training procedures are written and approved. ISF Facility staff have completed required training.

Radiological Controls

Radiation protection procedures are approved, health physics personnel are trained, required radiation posting is completed; and radiological monitoring equipment has been tested and is operational.

Maintenance and Surveillance

Maintenance and surveillance procedures are approved, required spare parts is identified and available, post maintenance testing is complete as required, surveillances necessary to receive fuel are completed and current.

Organization and Management

Procedures affecting organization and management are approved and available through document control, adequately trained and qualified personnel available.

Security

Security procedures are approved, adequately trained and qualified personnel are available. Security equipment has been tested and is operational.

Fire Protection

Procedures are approved, fire detection/suppression systems have been tested and are operational, and adequate fire personnel are trained and available.

Emergency Response

Emergency plan implementing procedures are approved, agreements for support organizations are in place, required emergency equipment has been tested and is operational, and emergency response staff is trained and qualified.

Nuclear Safety

Criticality controls and fuel accountability control procedures, and procedures for fuel acceptance verification, are approved and available through document control.

The FARR team will consist of a team leader and support personnel with experience in operations, engineering and technical support, maintenance and surveillance, document control, security, fire protection, emergency response, and nuclear safety. The FARR team will develop a written report to document the results of their findings. Before commencement of startup testing, the FARR report will be presented to the DOE ISF Facility Director, who has approval authority for receipt of SNF.

A startup test plan and implementing procedures will be written and approved before receipt of SNF. These documents will verify that the ISF Facility design bounds the calculated dose projections and the heat generation and removal aspects evaluated and presented in the SAR. Section 9.2.1 presents the elements of the startup test program. Startup testing will be performed on the first two fuel receipt shipments for each of the various fuel types to be handled by the ISF Facility.

9.3 TRAINING PROGRAM

This section of the SAR comprises DOE's ISF Facility Training Program and is submitted pursuant to Subpart I of 10 CFR Part 72. The requirements of this training program are implemented by contractor procedures providing for the administration of training programs. Changes which do not decrease the effectiveness of this program will be documented in annual SAR updates.

The objective of this training program is to use a systematic approach to training (SAT) to provide competent contractor personnel to perform all functions related to the operation of the ISF facility. The application of the SAT process will use a graded approach, with the training modules for the operation and maintenance of ISF structures, systems, and components identified as important-to-safety subject to the most rigorous application.

9.3.1 Administration

This training program ensures that qualified individuals will be available to perform planned and unplanned tasks while protecting the health and safety of plant personnel and the public. DOE, through its contractor, commits to maintain additional training to support the emergency plan, physical protection plan, quality assurance plan, and administrative and safety requirements, as required. Procedures and lesson plans used to implement this training program will be developed and maintained by the contractor.

The Training Manager is responsible for the administration of training programs and for maintaining up to date records on the status of contractor and DOE-ID trained personnel, training of new employees, and refresher or upgrade training of present personnel.

The ISF Facility Manager is responsible for ensuring that training requirements are specified for personnel assigned to support the ISF. In this role, the ISF Facility Manager or designee will approve all ISF Facility specific lesson plans, applications for exceptions of training requirements, and extensions of retraining and requalification requirements. Training material for ISF Facility support functions (such as radiation protection, ESH&QA, emergency response/emergency plan, and security/physical protection plan) may be developed and approved by the appropriate support organization.

The ISF Facility Manager is responsible for ensuring that training requirements have been satisfied for personnel assigned to the ISF Facility.

9.3.2 Records

The following records on the status of trained personnel will be maintained for a minimum of five years in accordance with the Records Section 9.4.2 below:

- a. Results of each Certified ISF Operator's biennial medical examination.
- b. The completed records of operator certification.

9.3.3 Instructor Qualifications and Development

The DOE contractor shall provide for and document the qualification and training of the Training Staff. Instructors designated to teach the Certified ISF Facility Operator Program shall possess subject matter expertise for a particular subject or topic. Instructors initially qualified shall maintain qualifications by instructing classes, and administering or grading examinations and On-the-Job Training (OJT) guides, and preparing, reviewing, or revising Certified ISF Facility Operator instructional material.

9.3.4 Development of Training Material

The DOE contractor shall maintain procedures providing for the analysis of jobs, design of initial and continuing training, development of instructional material, implementation (conduct of training), and evaluation (examinations, performance demonstration, program effectiveness, etc.). The development of training material shall be performed by trained and qualified staff. The DOE contractor shall maintain academic lesson plans and On-the-Job training (OJT) guides developed in accordance with this training program.

Because of varied complexity and scope of job functions, the degree of analysis (needs analysis, job analysis, task analysis) necessary to define training program content will vary. For example, a job and needs analysis may be appropriate for operations and maintenance personnel, whereas a less formal broad-based assessment of training needs is appropriate for technical staff personnel. Job analyses need not be conducted for technical support staff personnel. Consensus-based content guides should be used to assist with the determination of technical support staff training program content.

9.3.5 Training Improvement

The DOE contractor shall provide for and document the evaluation of training programs in order to ensure the continued improvement of training material and the conduct of training. A DOE assessment of the contractor's implementation of this training program shall be performed biennially.

9.3.6 Frequency of Training

Training requirements must be completed within the period specified in the sections below for General Employee Training and Certified ISFSI Operator Training; however, a grace period of 25% is allowed. Not completing the retraining requirements within the specified frequency will require completion of the initial training course in order to have qualification reinstated.

9.3.7 General Employee Training

Personnel requiring unescorted access to the ISF Facility must successfully complete General Employee Training (GET). The GET training program will be composed of topics derived through analysis (e.g., needs, job, or task analysis). Refresher training is required annually in order to convey pertinent modifications, procedure changes, regulatory changes, or other significant material as applicable.

9.3.8 Certified ISF Facility Operator Training

The training for Certified ISF Facility Operators and supervisors shall provide for initial training and testing of personnel who operate equipment identified as important to safety and will also provide for retraining, proficiency testing, and requalification as required based on job function analysis. Certified ISF Facility Operators will be actively maintained during transport and loading and unloading operations. During extended storage periods, qualifications will be required for ISF Facility monitoring activities.

ISF Facility equipment and controls that have been identified as important to safety in this SAR and in the license shall be operated by either personnel who have been trained and certified in accordance with this section or who are under the direct visual supervision of a trained, certified individual. Personnel who are in-training shall not independently make decisions or take actions that could affect facility safety, nor shall personnel who are in-training be placed in such positions. However, they may independently perform specific tasks or job assignments for which they are qualified.

Qualification and Certification is contingent upon meeting and maintaining the following criteria: obtaining a score of >80% on all academic examinations; and satisfactory performance of all OJT practical evaluations. A score of < 80% on any academic examination or failure to demonstrate satisfactory performance of an OJT practical evaluation shall result in the removal of the qualification or certification associated with the examination or evaluation. Following a failure, the qualification or certification is regained through successful completion of remedial training and retesting.

The physical condition and general health of certified personnel shall be verified by physical examination before initial certification and biennially thereafter. These physical examinations consider conditions which might cause impaired judgment or motor coordination. In addition, if an employee's behavior or condition creates a hazard to health or safety, then stop work may be imposed.

Each individual shall be given instructions regarding the hazards and safety precautions applicable to the type of work to be performed, general workplace hazards, and the procedures for protecting themselves from injury. These instructions are normally given during pre-job briefs prior to operations.

The certified operator continuing training programs shall be structured using a graded approach of the SAT process commensurate with specific position needs, and shall be administered on a biennial cycle.

9.3.9 Technical Support Positions

Technical support staff personnel are typically involved in surveillance, testing, analyzing facility data, planning modifications, program review, and technical problem resolution in their area of expertise (e.g., electrical, mechanical, instrumentation and control, chemistry, radiation protection, safety, quality assurance, facility engineering, security, emergency response).

The DOE contractor shall develop a list of specific technical staff positions that have a direct impact on employee, facility, or public safety.

Training for the applicable support positions shall include administrative and management controls associated with ensuring compliance with the ISF facility license conditions.

9.4 NORMAL OPERATIONS

This section describes the procedure controls associated with ITS operations, and the management system for maintaining records related to the operation of the ISF Facility.

9.4.1 Procedures

Procedures are used to document the performance of ITS activities and compliance with regulatory requirements. The format and content of written procedures include:

- Introduction (includes purpose and scope)
- precautions and limitations prerequisites
- instructions (sequence, forms to be completed, acceptable conditions, actions if conditions aren't acceptable, approvals)
- records

ISF Facility procedures are to be followed verbatim to ensure that activities are conducted safely and in accordance with regulatory requirements. If a procedure cannot be performed as written, the person performing the activity will stop the activity and, if necessary, place the system or component in a safe condition. The Shift Manager will be notified of procedure inadequacies and the activity will not resume until corrective actions have been implemented.

ITS activities and activities affecting quality are accomplished in accordance with approved and documented instructions, procedures, and drawings. Detailed written procedures developed, reviewed, and approved in accordance with ISF Facility requirements are used to perform operations, maintenance, surveillance, and testing activities. The following are the categories, criteria, and attributes of the types of procedure that will be implemented and maintained at the ISF Facility.

Administrative Procedures are instructions to ISF Facility personnel to provide an understanding of operating philosophy and management policies. These procedures include instructions for personnel conduct and procedures to develop, review, change, and approve facility procedures. Administrative procedures describe activities to ensure that personnel safety, working environment, procurement, and other general activities of the ISF Facility are conducted with quality and in a safe manner.

Radiation Protection Procedures are used to implement the radiation control program and ensure compliance with 10 CFR 20 and ALARA principles (Ref. 9-1). The procedures describe the methods for:

- use of environmental monitoring and measurement equipment
- qualifications and training of radiation protection personnel

- performance of surveys, measurements, and assessment of radiological conditions
- control of radiation hazards
- generation, review, and control of radiation work permits

Maintenance Procedures are used to implement the preventative and corrective maintenance program. Preventative maintenance procedures, including calibrations, are performed at a specified frequency to preclude degradation of ISF Facility SSCs. Corrective maintenance procedures are used to repair broken or degraded equipment. These maintenance procedures identify the level of qualification necessary for performance and provide a record of the activities performed, the date performed, and the person(s) performing the activity. In addition, prerequisites to perform the maintenance are identified, as well as post-maintenance testing requirements. Prerequisites include such things as facility operation mode, equipment configuration, or verification of alternate equipment availability.

Surveillance Procedures are used to implement the surveillance requirements of the ISF Facility operating license, which includes the Technical Specifications, to verify that plant operations and equipment operability comply with the conditions of the ISF Facility operating license. Surveillance procedures are performed periodically and before return to service after equipment maintenance or modification. Surveillance procedures will identify the level of qualification necessary for performance and will establish requirements for methods used to provide a record of the activities performed, the date performed, and the person(s) performing the activity. These procedures will also identify the source requirement for the surveillance, period for performance, acceptance criteria, and actions necessary if the acceptance criteria are not satisfied.

Operating Procedures provide instructions for normal and off-normal operations, including receiving, handling, repackaging, and storing spent fuel, and other operations ITS, such as those identified in the Technical Specifications. Procedures for operating equipment ITS include specification of certification/qualification requirements for personnel performing the procedure. Operating procedures also provide instructions for operation of equipment such as the storage area monitoring equipment and other plant equipment.

QA Procedures prescribe necessary elements of quality oversight to ensure that activities ITS are conducted in a controlled manner in accordance with the QAP.

Review, Change, and Approval Process

Written administrative procedures control the approval of new procedures and subsequent revisions. Administrative procedures specify the format, review process, and approval requirements. The ISF Facility Manager is responsible for ensuring that the administrative procedures for facility processes are implemented. New procedures and subsequent revisions to procedures are reviewed by appropriate subject matter experts on the facility staff and by affected

organizations. Before implementation, the ISFSI Operations Safety Board (OSB) will review new procedures and subsequent changes. The ISF Facility Manager or designee must approve new procedures and subsequent revisions before issue. The procedure reviews and approval process will be documented in accordance with the QAP.

9.4.2 Records

Administrative procedures have been implemented to ensure that quality records are identifiable and retrievable. Information Management Services will maintain records of historical operation of the ISF Facility. ISF Facility personnel are responsible for ensuring that QA records are legible, accurate, complete, and identifiable to the item or activity to which they apply. In addition to QA records, the following records will also be maintained in accordance with the regulatory reference(s) provided:

- records of spills or other abnormal occurrences involving the spread of radiation in and around the facility, equipment, or site, in accordance with 10 CFR 72.30(d)(1)
- as-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes, in accordance with 10 CFR 72.30(d)(2)
- a list contained in a single document and updated no less than every 2 years of the following, in accordance with 10 CFR 72.30(d)(3):
 - areas designated and formerly designated as restricted areas as defined under 10 CFR 20.1003
 - Areas outside of restricted areas that require documentation under 10 CFR 72.30(d)(1)
- records of cost estimate performed for the Proposed Decommissioning Funding Plan, in accordance with 10 CFR 72.30(d)(4)
- records of receipt, inventory, disposal, acquisition, and transfer of all spent fuel and high-level radioactive waste in storage, as required by 10 CFR 72.72(a)
- records of physical inventories and current material control and accounting procedures as required by 10 CFR 72.72(b) and 10 CFR 72.72(c)
- records of changes in the facility design, of changes in procedures, and of tests and experiments made pursuant 10 CFR 72.48(c)(1). These records must include a written evaluation that provides the bases for the determination that the change, test, or experiment does not require a license amendment pursuant to 10 CFR 72.48 (c)(2), pursuant to the requirements of 10 CFR 72.48(d)(1).
- records of employee certification as required by 10 CFR 72.44
- QA records as required by 10 CFR 72.174

- radiation protection program records as required by 10 CFR 20 Subpart L which includes:
 - program contents, audits, and reviews
 - radiation surveys
 - determination of prior occupational dose
 - planned special exposures
 - individual (worker) monitoring results
 - dose to individual members of the public
 - test of entry control devices for very high radiation areas
- records of changes to the *Physical Protection Plan* as required by 10 CFR 72.44(e) and 72.186, and other physical protection records required by 10 CFR 73.21 and 10 CFR 73.70
- records of occurrence and severity of natural phenomena as required by 10 CFR 72.92
- record copies of:
 - SAR and updates per 10 CFR 72.70
 - Safety Review Committee records
 - reports of accidental criticality or loss of special nuclear material as required by 10 CFR 72.74 and 10 CFR 73.71
 - material status reports per 10 CFR 72.76
 - nuclear material transfer reports per 10 CFR 72.78
 - *Physical Protection Plan* per 10 CFR 72.180
 - Other records and report per 10 CFR 72.82

The following records will be maintained as QA records in accordance with the QAP:

- operating records, including maintenance records on significant equipment
- records of off-normal occurrences and events associated with radioactive releases
- environmental survey records and environmental reports
- radiation monitoring readings and/or records (e.g., strip charts)
- report of preoperational test acceptance criteria and test results
- written procedures

The above records will be stored in accordance with the QAP. Security records, including security training and qualification records, will be maintained in accordance with the *Physical Protection Plan* (Ref. 9-2).

9.5 EMERGENCY PLANNING

The ISF Facility will repackage and store SNF; therefore, the *Emergency Plan* was written to meet the requirements of 10 CFR 72.32(b) (Ref. 9-3). In accordance with 10 CFR 72.32(b), the *Emergency Plan* provides for two classifications of accidents: "alerts" and "site area emergencies." The *Emergency Plan* developed emergency action levels for postulated accidents in each of the following areas:

- transfer cask accidents
- fuel packaging accidents
- fuel storage accidents
- external events (loss of power, earthquake, flood, extreme wind, lightning, accidents at nearby sites, volcanism, and aircraft impacts)

Because the ISF Facility site is remote, the DOE or its support contractors primarily provide emergency support services described in the *Emergency Plan*.

The ISF Facility Manager, or in the manager's absence, the Shift Manager(s) provide the onsite management and interface with the DOE INL infrastructure to respond to an event requiring implementation of the *Emergency Plan*.

9.6 DECOMMISSIONING PLAN

The *Proposed Decommissioning Plan* describes the proposed ISF Facility decontamination and decommissioning activities and funding method (Ref. 9-4), to demonstrate that it can be safely and effectively, decommissioned. If DOE does not request and receive an exemption from the decontamination and decommissioning provisions of the NRC regulations, DOE-ID will provide a final decommissioning plan prior to the start of decommissioning work.

The *Proposed Decommissioning Plan* was developed in accordance with NRC Regulatory Guide 3.6S and discusses the following topics (Ref. 9-5):

- plans for safely and efficiently decommissioning the ISF Facility
- ISF Facility design features to facilitate decommissioning
- estimate of decommissioning costs and financing method
- tentative selection and description of the plan decommissioning method
- basis for tentative selection of decommissioning method

If DOE does not request and receive an exemption from the decontamination and decommissioning provisions of the NRC regulations, to facilitate decommissioning, the records required by 10 CFR 72.30(d)(1) through 72.30(d)(4) will be maintained as quality records until decommissioning is complete and the ISF Facility license is terminated.

9.7 PHYSICAL PROTECTION PROGRAM

The purpose of the physical protection program is to establish and maintain the physical protection of the SNF stored in the ISF Facility in accordance with 10 CFR 72 Subpart H, *Physical Protection*, and applicable portions of 10 CFR 73 (Ref. 9-6).

The ISF Facility Physical Protection Program is described in the *Physical Protection Plan* (Ref. 9-2). The plan includes as appendices the *Security Personnel Training and Qualification Plan* and the *Safeguards Contingency Plan*.

Because the *Physical Protection Plan* contains safeguards information and is controlled and protected in accordance with 10 CFR 73.21 and 10 CFR 2.390, it has been submitted for NRC review under separate cover (Ref. 9-7).

9.8 REFERENCES

- 9-1 Title 10, Code of Federal Regulations, Part 20, Standards for Protection Against Radiation, Office of the Federal Register, Washington, D.C.
- 9-2 PLN-2215, ISF Facility Physical Protection Plan
- 9-3 PLN-2214, ISF Facility Emergency Plan
- 9-4 SAR-221, Appendix B, Proposed Decommissioning Plan
- 9-5 U.S. Nuclear Regulatory Commission, Regulatory Guide 3.65, Standard Format and Content of Decommissioning Plans/or Licenses Under 10 CFR Parts 30, 40, 70 (August 1989)
- 9-6 Title 10, Code of Federal Regulations, Part 73, Physical Protection of Plants and Materials, Office of the Federal Register, Washington, D.C.
- 9-7 Title 10, Code of Federal Regulations, Part 2, Rules of Practice for Domestic Licensing Proceedings and Issuance of Others, Office of Federal Register, Washington, D.C.
- 9-8 Title 10, Code of Federal Regulations, Part 72.16(b), Filing of Application for Specific License, Office of the Federal Register, Washington, D.C.

Table 9.2-1 Acceptance Tests

Structure, System, or Component	Summary of Test
Cask receipt crane	Functional test of controls and interlocks and load test (NUREG-0554 criteria)
Cask trolley	Functional test of controls and interlocks, load testing (NUREG-0554)
FHM	Functional test of controls and interlocks and load test (includes power manipulator system), Test criteria based on NUREG-0554, ANSI/ASME 830.2, and CMAA Specification 70.
MSMs	Functional test per vendor recommendation
Decanning machine	Functional test using mock cans
Worktable system	Functional testing to verify capability to tip, rotate, and cut canisters and cans
Canister trolley	Functional test of controls and interlocks, load testing (NUREG-0554)
CCA	Testing in accordance with ASME 830.2 and DOE-STD-1090 Section 7.3
Canister welding equipment	Functional/demonstration test on mock canister weld areas
Vacuum drying system	Functional test per vendor recommendation
Helium back fill system and leak test system	Functional test per vendor recommendation
CHM	Functional test of controls and interlocks and load test (NUREG-0554 criteria)
Storage tube	Fit test to verify shield plug and cover plate fit up
Special lifting fixtures	Load test, functional test to verify grapple/load engagement
Transfer Tunnel doors	Functional test of controls and interlocks
HVAC system	Functional test to include controls and interlocks, ventilation flow and balance, and HEPA filter efficiency
Instrumentation and controls	Channel functional tests and channel calibrations
Fire protection equipment	Testing will be performed to satisfy the following: NFPA 25 (1998) - water suppressions NFPA 72 (1999) - detection and alarms
Normal and emergency lighting	Functional test

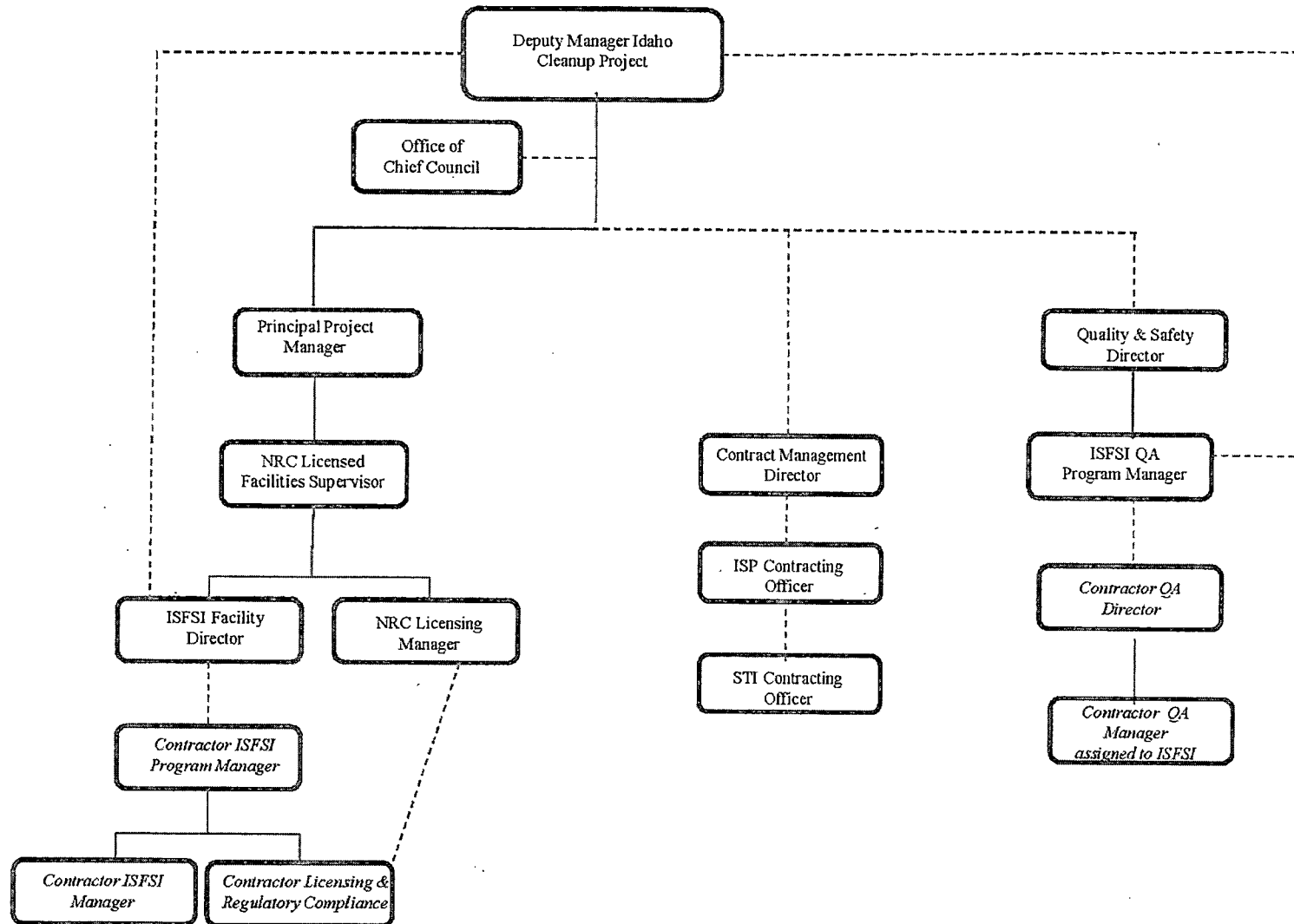


Figure 9.1-1 DOE-ID ISF Facility Organization

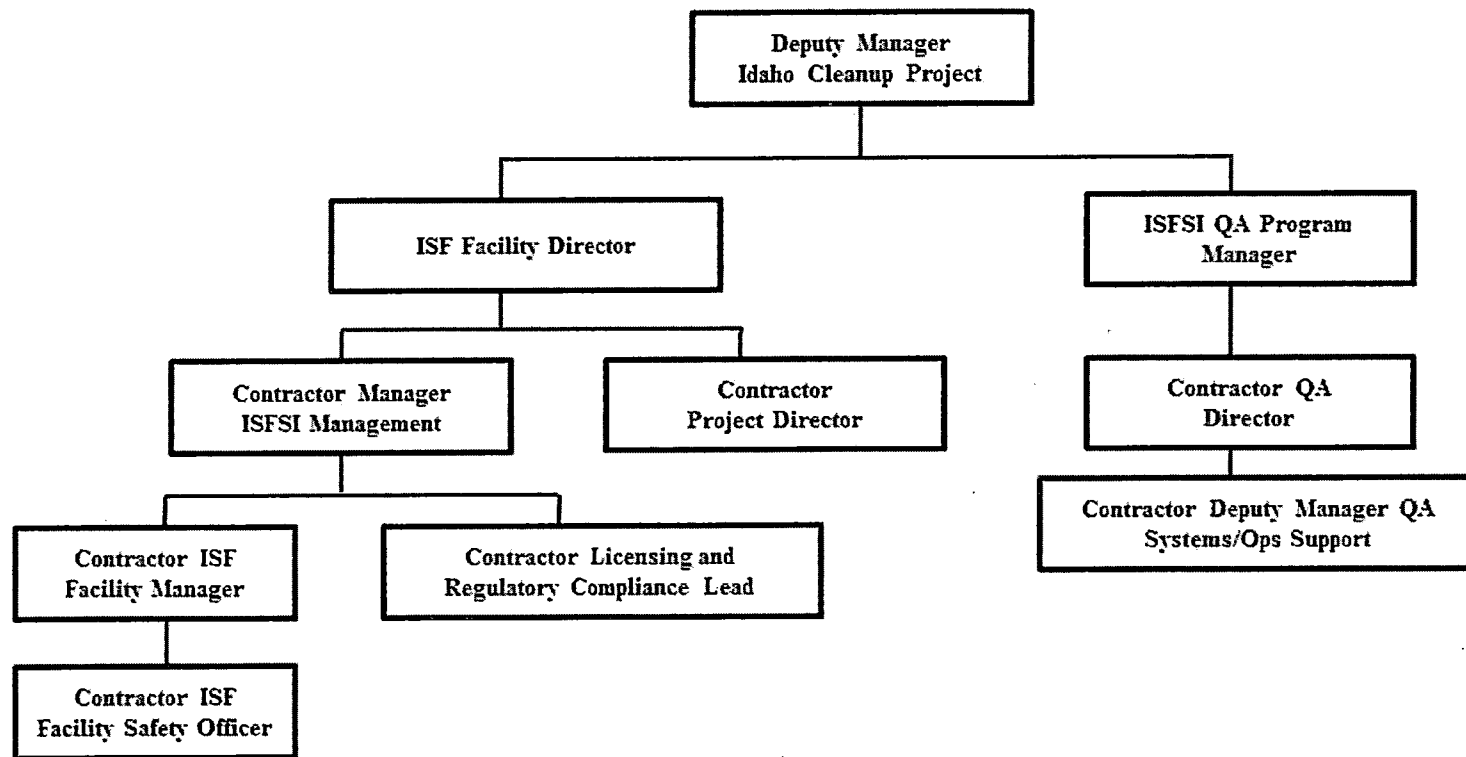


Figure 9.1-2 DOE ID ISF Facility Organization and Contractor Interfaces

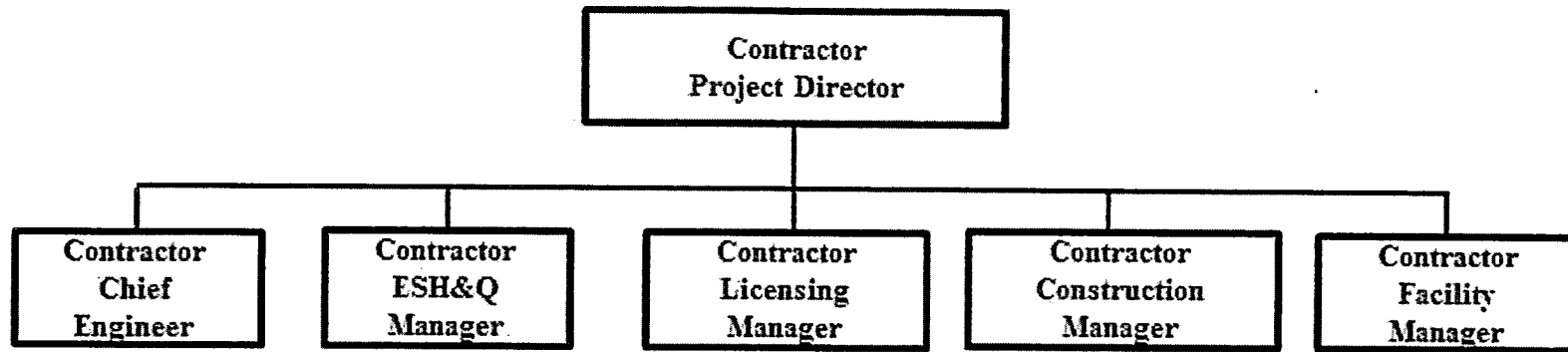


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11.0 QUALITY ASSURANCE

Beginning with accepting responsibility for the design of the ISF Facility ISFSI through to its completed decommissioning, it is the policy of DOE-ID to ensure that the facility is designed, constructed, handled, shipped, stored, cleaned, assembled, inspected, tested, operated, maintained, modified and decommissioned in a manner that assures the health and safety of workers and the public and protects the environment. The Quality Assurance Program is developed to confirm that essential technical and quality requirements for structures, systems, and components are achieved and documented.

DOE-ID maintains full responsibility for the development and execution of the ISF Facility ISFSI Quality Assurance Program. This program applies to design; purchase; fabrication; handling; shipping; storing; cleaning; assembly; inspection; testing; operation; maintenance; repair; modification of structures, systems, and components; and decommissioning activities that are important to safety. The ISF Facility ISFSI Quality Assurance Program is maintained to satisfy the requirements established in 10 CFR 72, Subpart G, "Quality Assurance."

The proposed quality assurance program for the ISF Facility is the same as the currently approved Quality Assurance Program (DOE/RW-0333P, Revision 10 [11.1]) for the TMI-2 and FSV ISFSIs (SNM-2508 and SNM-2504 respectively) and is included as part of the ISF Facility ISFSI license transfer application. The contents of the Quality Assurance Requirements and Description (QARD) are listed in Table 11.0-1. For ISF Facility ISFSI activities, DOE-ID and its contractor will apply applicable portions of the QARD to items important to safety. The purpose of this chapter of the SAR is to define the implementation and application of those applicable QARD requirements for the ISF Facility ISFSI, including the relationship and integration of DOE-ID and contractor quality assurance responsibilities. To facilitate this description, this chapter is written and developed following the format of the QARD. The quality assurance program described in this chapter shall be implemented by DOE-ID and its contractor through the use of approved, controlled implementing documents.

Changes that reduce the effectiveness of quality assurance program commitments and represent a change per 10 CFR 72.48, "Changes, Tests, and Experiments," will be submitted to the NRC for its review and acceptance prior to implementation.

The ISFSI Quality Assurance Program provides for a graded approach to the implementation of the QARD Elements, Supplements, and Appendices.

The remaining sections of this chapter describe how each of these Elements, Supplements, and Appendices will be implemented for the ISF Facility ISFSI.

All structures, systems, and components are analyzed to determine whether their functions or physical characteristics are essential to the safety function. Those items determined to be important to safety are subject to the applicable requirements of the QARD and identified in Table 3.4-1 in the ISF Facility SAR Structures, systems and components which are not important to safety have the QAP applied in a graded approach.

11.1 ORGANIZATION

The following is the organizational philosophy of the ISF Facility ISFSI Quality Assurance Program.

DOE, as facility owner and licensee, retains ultimate responsibility for the safe operation of the facility and compliance with all license conditions. The management and operation responsibility of the facility is delegated to the contractor. To exercise its ultimate responsibility, DOE-ID will:

1. Retain responsibility for and perform independent assessments of the contractor's ISFSI quality assurance program;
2. Ensure that the license conditions for the facility are included in the contractor's contract;
3. Assess the performance of the contractor against the terms of their contract;
4. Retain the responsibility to budget funds necessary and sufficient to safely operate the facility; and
5. Retain the authority to revise the contract in the even contract deficiencies are found relative to proper implementation of license conditions.

The primary role of DOE-ID is management oversight rather than daily, direct management. Therefore, a strong assessment function is retained by DOE-ID. The contractor's Quality Assurance (QA) Director has responsibility for development, management, and implementation of the contractor's quality assurance program. As part of this responsibility, the QA Director ensures that other sub-tier contractor Quality Assurance Programs meet all applicable requirements of the QARD for their scope of work.

The Quality Assurance Program is implemented by trained personnel with adequate resources so that cost and scheduling considerations do not override the Quality Assurance Program's function. Quality shall be achieved and maintained by those who have been assigned responsibility for performing work. Quality achievement shall be verified by persons and organizations not directly responsible for performing the work. Positions or organizations responsible for establishing and executing the quality assurance program may delegate work to other organizations. However, the positions or organizations making the delegation shall retain overall responsibility for the delegated work. Differences of opinion involving quality assurance requirements shall be brought to the attention of the appropriate management, and, if not resolved, shall be elevated progressively to successively higher levels of management. Stop work authority for significant conditions adverse to quality is assigned to the Deputy Manager for ICP. Contractor stop work authority resides with the INTEC QA Manager.

Stop work requests and actions are described in the DOE-ID and contractor's implementing documents.

DOE-ID and contractor Quality Assurance personnel have the necessary authority, resources, and organizational freedom to implement the Quality Assurance Program, including the ability to identify quality problems; to initiate, recommend and provide solutions; and to verify implementation of solutions. QA personnel also have written authority and responsibility to

stop unsatisfactory work, controlling further processing, delivery, installation, or use of nonconforming items.

QA personnel ensure that assessments of the Quality Assurance Program and its effectiveness are reported to the appropriate levels of management. Specific quality assurance responsibilities for the ISF Facility ISFSI are provided below.

11.1.1 The Office of the Manager

The Deputy Manager for ICP is responsible for overall executive management of the Idaho Operations Office. The Deputy Manager for ICP has signature authority as the NRC Licensee. (See Figure 9.1-1)

11.1.2 The Office of Administration Services

The responsibility for developing the appropriate revisions to the contractor's contract with DOE-ID is delegated to the DOE-ID ICP Contracting Officer.

11.1.3 The Office of Environmental Management

The responsibility for the licensee's role of providing program direction to the contractor lies with the Assistant Manager, Office of Environmental Management (EM). Oversight of the EM owned spent fuel management facilities and activities, including the NRC-licensed ISFSIs is delegated by the Assistant Manager for EM to the Facility and Material Disposition Project Director.

DOE-ID personnel performing quality affecting activities are responsible for:

1. Planning and meeting product quality requirements and implementing the Quality Assurance Program in their work.
2. Retaining responsibility for delegated work.
3. Notifying the immediate supervisor to resolve differing staff opinions related to safety issues and quality issues and if not resolved elevating disputes to successive levels of management until resolved.
4. Recommending work to be stopped when significant conditions adverse to quality are identified.

11.1.4 Office of Operational Support

The DOE-ID NE Director, Quality and Safety Division, is responsible for oversight of the contractor as stated in Section 9.1.2. The responsibility for oversight of both the contractor's Quality Assurance Program for the ISFSI as well as the DOE-ID oversight program of the contractor's performance in ISFSI operations is delegated through the NE Director, Quality and Safety Division. The Quality and Safety Division Director delegates the responsibility for QA oversight of the ISFSIs to the ISFSI Quality Assurance Program Manager. The management responsibilities of the ISFSI Quality Assurance Program Manager are herein defined.

The ISFSI Quality Assurance Program Manager is at the same or higher organization level as the highest Program Manager/Team Leader responsible for performing work subject to the requirements of the QARD, has knowledge and experience in quality assurance and management, and has no other duties or responsibilities that could compromise the required independence. The ISFSI Quality Assurance Program Manager has the organizational freedom to communicate with senior management and is sufficiently independent from cost and schedule considerations.

The ISFSI Quality Assurance Program Manager is responsible for providing guidance and direction to the DOE-ID line organization and its contractor on quality assurance matters relating to NRC Licensing activities, developing DOE-ID's Quality Assurance Program implementation of the QARD, and effectively assuring conformance to quality requirements. The ISFSI Quality Assurance Program Manager also is responsible for the overview of work subject to QARD requirements. This overview includes verifying achievement of quality of work by DOE-ID's line organization and its contractor through assessments, surveillances, or other means of verification, as appropriate.

The ISFSI Quality Assurance Program Manager and the contractor's QA Director, respectively, are responsible and accountable for coordinating with the responsible managers to ensure that acceptable QARD requirement implementation is developed and established and for documenting and promulgating Quality Assurance policies, goals and objectives.

Also, the ISFSI Quality Assurance Program Manager is kept current through various reports and verifies the implementation, adequacy, and effectiveness of the overall Quality Assurance Program while maintaining a continual involvement in Quality Assurance matters (See Figure 9.1-1).

The ISFSI Quality Assurance Program Manager is responsible for developing and implementing the Quality Assurance Program. This includes the following activities:

1. Developing, reviewing, approving, issuing, and maintaining DOE-ID's implementing procedures
2. Verifying that the Quality Assurance Program is properly established and executed
3. Ensuring that quality is verified by an organization not responsible for the work and ensuring that the Quality Assurance Program is adequate and being effectively implemented
4. Ensuring Quality Assurance training and qualification programs are developed for DOE-ID and contractor personnel who perform quality affecting activities.
5. Develop, manage, update, and implement a Quality Assurance Audit Plan and schedule, and coordinate NRC participation in audit activities
6. Identifying quality problems; initiating, recommending, or providing solutions to quality problems; and verifying the implementation of solutions to quality problems
7. Determining the cause of significant conditions adverse to quality and ensuring that corrective action is initiated for all conditions adverse to quality

8. Accepting final resolution for all DOE-ID audit findings and proposed corrective actions
9. Initiating stop work orders within the license oversight program, when required
10. Receiving and compiling Quality Assurance information and forwarding Quality Assurance program status reports to management
11. Interfacing with NRC to coordinate and clarify NRC Quality Assurance requirements, the Quality Assurance Program, and to resolve Quality Assurance issues to NRC requirements
12. Interfacing with NRC to coordinate plans and schedules relevant to Quality Assurance for NRC overview of licensing activities
13. Being responsible for interpreting and approving Quality Assurance Program requirements as they apply to the contractor's scope of work.
14. Assignment of the Quality Assurance Specialist (QAS) staff.

11.1.5 Contractor Personnel

DOE and its contractor personnel perform work subject to the requirements of the QARD per the controls established in their respective implementing documents. The QARD requirements for the contractor are identified in the appropriate procurement documents. The ISFSI Quality Assurance Program Manager provides overviews of the contractor's work subject to QARD requirements by using appropriate verification methods.

Quality control functions that are performed as part of the line organization's activities will have surveillances performed by the Quality Assurance organization to confirm that there is sufficient independence from the individuals that actually performed the activity.

Quality-related activities are performed by the various contractor departments and contractors of DOE-ID. The DOE-ID contractor is responsible for development of its Quality Assurance Program which shall be consistent with the requirements of the QARD. All contractor personnel have the authority to stop work pending resolution of any quality problem. If a member of another area disagrees, that individual is instructed to take the matter to appropriate management. The disagreement may either be resolved at this level or at any level up to and including the Deputy Manager for ICP.

The topics from Section 1.0, Organization, that are implemented from the QARD are:

1.2 Requirements

Requires preparation of controlled documents describing internal and external interfaces.

1.2.1 Line Management

Requires identification of responsibilities and authorities of organizations responsible for achieving quality.

1.2.2 Quality Assurance Management

Describes appropriate knowledge and experience for those performing the Quality Assurance function.

1.2.3 Responsibility For Quality

Assigns responsibility for achieving quality in work and the verification of quality.

1.2.4 Delegation of Work

Discusses the delegation of the execution of the Quality Assurance program and maintenance of overall responsibility.

1.2.5 Resolution of Quality Disputes

Process for resolution of quality disputes.

1.3.3 Other OCRWM Affected Organizations

Section "A" and "C" only

Describes DOE EM as an agent of OCRWM. Also requires that appropriate technical and quality requirements applicable to this scope of work be incorporated into the associated work documents.

11.2 QUALITY ASSURANCE PROGRAM

DOE-ID has overall responsibility and program implementation authority for all Quality Assurance Program requirements. Quality Assurance Program elements that are implemented and discharged by DOE-ID are those identified as Organization, Quality Assurance Program, Implementing Documents, Document Control, Corrective Action, Quality Assurance Records, and Audits. Implementation of the entire QARD is delegated to the contractor for its scope of work.

The ISFSI Quality Assurance Program Manager has the assigned responsibility for ensuring that required DOE-ID quality assurance program implementing documents are established at the earliest practical time consistent with the schedule for accomplishing quality affecting activities. Instructions to DOE-ID personnel for implementation of quality activities including performance of verification activities are described by implementing documents.

Specific DOE-ID performance and verification activities include, but are not limited to:

- Reviews and approvals of various DOE-ID and contractor documents
- Surveillances, assessments, and evaluations of the DOE-ID and contractor's quality assurance program
- Readiness evaluations with the contractor
- Verification and validation of DOE-ID's personnel training and qualification records.

Authority for implementing Quality Assurance Program elements applicable to activities related to important to safety items is delegated by DOE-ID to the contractor. The contractor may pass functional activities to approved subcontractors. Overall responsibility for adequate implementation and performance by DOE-ID's contractor and its subcontractors is retained by DOE-ID. DOE-ID requires its contractor to document its Quality Assurance Program in appropriate descriptions, plans and implementing documents.

The ISFSI Quality Assurance Program Manager and the contractor initiate management assessments of the Quality Assurance program. All pertinent correspondence, checklists, and reports related to assessments are placed in the Quality Assurance files.

The graded approach for performing management assessments is commensurate with the risk associated with the item or activity affecting quality being assessed. Any identified corrective actions as a result of management assessments shall be tracked to completion.

Delegation of authority for implementation of Quality Assurance Program requirements is accomplished through contracts between DOE-ID and its contractor and/or technical direction given by DOE-ID. Contracts and technical direction specify that the applicable QARD requirements are to be established and functioning before initiating any activities affected by the contractor's Quality Assurance Program. These documents additionally require that 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 testing be taken into account for the scope of work.

Proficiency of personnel performing quality-affecting activities is maintained by training, examination, and/or certification. The graded approach is applied to indoctrination and training commensurate with the scope, complexity, and nature of the activity. The graded approach is not applied to the qualification and certification of inspectors, NDE personnel, and auditors. Specific documentation of completed training and qualifications will be described in the implementing documents. Qualified personnel are certified per applicable codes and standards.

Nuclear safety related activities are accomplished under controlled conditions. Preparations for such activities include confirmation that prerequisites, identified in the implementing documents, have been satisfied.

The contractor's Quality Assurance Program is monitored by DOE-ID on a continuing basis through review, surveillance, and assessment to evaluate its adequacy and to verify compliance with QARD requirements.

The topics from Section 2.0, Quality Assurance Program, that are implemented from the QARD are:

2.2.1.1 QA Program Documents

Discusses the role of the Policy Statement, Implementing Documents, and Requirements Matrix in the quality program.

2.2.2 Classifying Items

Identifies quality program applicability to systems, structures and components.

2.2.3 Controlling Activities

Identifies controls for activities related to quality affecting items.

2.2.4 Applying QA Controls

Describes graded approach application.

2.2.5 Planning Work

Provides planning elements for documentation of work under suitable controlled conditions.

2.2.6 Surveillances

Describes quality evaluations for selected work subject to QARD requirements.

2.2.7 Management Assessment

Describes the conduct and criteria for management assessments of Quality Assurance program effectiveness

2.2.8 Readiness Reviews

Identifies the need for and how readiness reviews shall be conducted for major work.

2.2.9 Peer Reviews

Identifies the need for peer reviews and how they shall be conducted.

2.2.10 Document Review

Describes the basic review process for technical and quality requirements in documents and implementing documents.

2.2.11 QA Program Information Management

Describes how management shall be apprised of Quality Assurance program information on a continuing basis.

2.2.12 Personnel Qualification

Describes the established program for the evaluation, selection, indoctrination, training, and qualification of personnel performing work subject to the QARD.

2.2.13 Qualification of Personnel Who Perform Inspection, Nondestructive Examination, Testing and Auditing.

Describes amplified requirements for personnel performing Quality Assurance functions like auditing, inspecting, examining and testing.

11.3 DESIGN CONTROL

The Quality Assurance Program requires procedures and instructions for implementation and assurance of design control during the various design phase activities. Design control requirements ensure that designs as specified in the license application are correctly defined, controlled, and verified. Appropriate provisions of design control include:

1. Specifying design inputs
2. Correct translation of inputs in design documents
3. Sufficient documentation which entails verification that design outputs relate to design inputs
4. Verification of design by persons other than the originator
5. Assurance that changes to the design are properly reviewed, controlled, and documented.

Designs are reviewed to ensure that the design characteristics can be controlled, inspected, and tested. Inspection and test criteria are identified. Implementing documents ensure that the design is performed per approved criteria which include appropriate regulatory and quality requirements and standards, and that deviations and nonconformances are controlled.

Design control practices provide appropriate attention to design error and deficiency control, design changes, technical reviews, control of experimental and developmental activities, qualification of data, and modification control. Practices shall be established to include the use of valid industry standards and specifications for the selection of suitable materials, parts, equipment and processes for important to safety structures, systems, and components. Modifications that affect licensing parameters are evaluated per 10 CFR 72.48, "Changes, Tests, and Experiments".

Provisions are specified for the control of design analyses such as criticality physics, stress, thermal, hydraulic, and accident; compatibility of materials; accessibility for in service inspection; maintenance and repair; and delineation of acceptance criteria for inspections and tests.

Revisions of controlled documents, including design documents, are reviewed for adequacy and approved for release by the same organization that originally reviewed and approved the documents or by some other designated organization that is qualified and knowledgeable.

Design verification methods include, but are not limited to design reviews, alternate calculations, and qualification testing or a combination thereof. When a test program is to be used to verify the adequacy of a design, a qualification test of a prototype unit under adverse design conditions shall be used. Independent design verification is completed before relying on the item to perform its function. Confirmation that the correct computer code has been used is part of the design verification. Design verification shall require a level of skill at least equal to that of the original designer, design checking can be performed by less experienced persons. The Design Control activities and their implementing documents are required to be in compliance with the requirements of QARD Section 3.0, Design Control.

Appropriate design verification implementing documents are established and executed commensurate with the importance to safety of the structures, systems, or components and in compliance with requirements of QARD Section 3.0, Design Control.

The graded approach for design verification is a function of importance to safety and the complexity of design, the degree of standardization, the state of the art, and the similarity with previous designs.

When quality related structures, systems, and components are designed or require design modifications, controls are applied commensurate with the controls established for the original design, applicable regulatory requirements, and health and safety of operating personnel and the general public.

DOE-ID delegates implementation authority for QARD Section 3.0, Design Control to its contractor.

DOE-ID monitors its contractor's design control activities, by surveillance and assessment and periodically reviews the contractor's practices to ensure proper implementation and adequacy.

DOE-ID's contractor is assigned Design Control responsibility in support of program activities and is required to implement and maintain design control/verification practices and/or to delegate these quality assurance program requirements to its next lower tier contractor for their implementation.

The topics from Section 3.0, Design Control, that are implemented from the QARD are:

3.2.1 Design Input Control

Describes criteria that provides for adequate control of design inputs.

3.2.2 Design Process

Describes controls for an adequate design process.

3.2.3 Design Analyses

Describes criteria for adequate design analyses.

3.2.4 Design Verification

Provides additional document review criteria for completed design analyses and design output in support of QARD Section 2.2.10, Document Review.

3.2.5 Design Reviews

Describes how design reviews are controlled and performed.

3.2.6 Alternate Calculations

Describes the appropriateness of assumptions and checks required for other calculation methods.

3.2.7 Qualification Testing

Describes criteria for verification of design adequacy.

3.2.8 Design Change Control

Provides criteria for controlling design changes.

3.2.8.1 Design Interface Control

Provides criteria for controlling design interfaces.

11.4 PROCUREMENT DOCUMENT CONTROL

Implementing documents are established and executed to ensure that applicable regulatory and technical requirements, design bases, quality assurance program requirements, and other performance requirements necessary to ensure adequate quality are included or referenced in documents for procurement of material, equipment, and services. These implementing documents clearly identify the sequence of actions to be accomplished in the preparation, review, approval, and control of procurement documents.

These actions include: evaluating qualifications of suppliers; ensuring qualified suppliers remain qualified; accepting purchased items or services and invoking applicable technical, regulatory, administrative, and reporting requirements, such as 10 CFR Part 21.

These implementing documents include provisions for ensuring that documentation for structures, systems, and components classified as important to safety provide objective evidence that those items conform to procurement requirements. Those implementing documents further ensure that inspection, test, and acceptance requirements have been used to monitor and evaluate the performance of the supplier and are satisfied before these items are placed in service.

Controls include specifying documents along with their revision level and change status that describe selection criteria, determination of suitability for intended use, evaluation, receipt inspection, and dedication of commercial grade items for use in structures, systems, and components classified as important to safety.

Implementing documents are established and executed to verify that the quality of purchased items and services is evaluated at appropriate intervals and to a depth consistent with the items' and services' importance to safety, complexity, quantity, and frequency of procurement. A review and concurrence of the adequacy of quality requirements stated in procurement documents is performed by qualified personnel. This review shall determine that:

1. Quality requirements are correctly stated, inspectable, and controllable
2. There are adequate acceptance and rejection criteria
3. The procurement document has been prepared, reviewed, and approved per quality assurance requirements.

DOE-ID delegates implementation authority for QARD Section 4.0, Procurement Document Control to its contractor.

The graded approach for applying Quality Assurance Program requirements on suppliers depends on type and end-use of the item or activity affecting quality being procured.

DOE-ID monitors its contractor's procurement document control practices that support program activities, or, by surveillance and assessment, periodically reviews its contractor's practices to ensure their proper implementation and adequacy.

The topics from Section 4.0, Procurement Document Control, that are implemented from the QARD are:

4.2.1 Procurement Document Preparation

Describes necessary provisions for issued procurement documents.

4.2.2 Document Review and Approval

Provides additional document review criteria in support of QARD Section 2.2.10, Document Review for procurement document review and approval.

4.2.3 Procurement Document Change

Describes change controls imposed on procurement documents of items and services that affect quality.

11.5 IMPLEMENTING DOCUMENTS

Implementing documents are instructions, procedures, drawings and other documents that prescribe an approved process for accomplishing work in compliance with Quality Assurance Program requirements. Activities affecting quality are prescribed and accomplished per documented implementing documents. Implementing document requirements ensure that work is prescribed by, and performed per written implementing documents. Methods for complying with each of the applicable Quality Assurance requirements are specified in the implementing documents. The graded approach for the direction of work processes, in the form of instructions, procedures, and drawings is commensurate with risk, complexity, and importance of the work. Document Control requirements provide guidance for the review, approval, and control of implementing documents.

Provisions are established which clearly delineate the sequence of actions to be accomplished in the preparation, review, approval, and control of implementing documents.

Contractor QA, as part of a multi-disciplined review team, reviews and concurs with inspection plans; test, calibration, and special processes; procedures; drawings and specifications; and their associated changes.

DOE-ID has a procedural control system for its implementing documents which assigns responsibility and provides instructions for preparation, review, approval, release, issuance, distribution, and control of changes to implementing documents.

The ISFSI Quality Assurance Program Manager participates in and monitors program execution of these implementing documents related to program quality affecting activities. Periodically the ISFSI Quality Assurance Program Manager performs surveillance or arranges for an independent assessment of DOE-ID Quality Assurance Program practices to document their level of implementation and adequacy.

DOE-ID monitors its contractor's procedural practices related to implementing documents, and, by surveillance or assessments, periodically reviews its contractor's practices to document their level of implementation and adequacy.

DOE-ID's contractor is assigned the authority for performing work activities affecting quality in support of program activities and is required to establish and implement a practice of prescribing those activities per documented instructions, implementing documents, and drawings.

The topics from Section 5.0, Implementing Documents, that are implemented from the QARD are:

5.2 Requirements

Specifies that work done per the QARD shall be performed per controlled implementing documents.

5.2.1 Types of Implementing Documents

Describes the type of document to be used to perform work per the QARD and what they include.

5.2.2 Content of Implementing Documents

Describes the information that implementing documents shall contain.

5.2.3 Review and Approval of Implementing Documents

Requires that implementing documents shall be reviewed and approved per QARD Section 6.0 Document Control.

5.2.4 Compliance With Implementing Documents

Requires individuals to comply with QARD requirements and describes what to do when work cannot be completed per QARD requirements.

11.6 DOCUMENT CONTROL

Document control requirements ensure that the preparation and issuance of documents including changes thereto, are reviewed for adequacy, approved for release, and distributed to and used at the location where the work is being performed. The document control system provides for identification, preparation, review, approval and distribution of documents in a graded manner. The review, approval, distribution and issue of documents and changes thereto, shall be procedurally controlled to ensure that documents are adequate and that Quality Assurance Program requirements are stated. Implementing documents and documents that specify technical and/or quality assurance requirements are controlled per requirements of the Quality Assurance Program.

The controlled documents include but are not limited to:

- a. Design specifications
- b. Design and fabrication drawings
- c. Procurement documents
- d. Quality Assurance Program manuals
- e. Design criteria documents
- f. Fabrication, inspection, and testing instructions
- g. Test procedures.

Implementing documents provide program guidance, technical and/or quality assurance requirements, or prescribe work processes that ensure proper execution of Quality Assurance Program activities. Compliance with the Quality Assurance Program's document control implementing documents ensures that the designated document holder and user of these implementing documents have the latest up-to-date information and data available which define technical and quality assurance requirements.

Distribution of new and/or revised controlled documents is in accordance with work processes that are established, approved, and documented in the Quality Assurance Program's implementing documents. Provisions shall be established which identify those individuals or groups responsible for reviewing, approving, and issuing documents and revisions thereto. Approved changes shall be included in implementing documents prior to the implementation of the change.

A master list (either hard-copy or electronic) shall be established and identify the current revision number of procedures, specifications, and drawings. This list shall be updated and distributed to pre-determined responsible personnel to preclude the use of superseded documents.

DOE-ID monitors its contractor's procedural practices related to document control, and, by surveillance or assessments, periodically reviews its contractor's practices to document their level of implementation and adequacy.

DOE-ID's contractor has established and implemented document control practices through their Quality Assurance Program and its associated implementing documents which are responsive to this Quality Assurance program.

The topics from Section 6.0, Document Control, that are implemented from the QARD are:

6.2.1 Types of Documents

Requires that implementing documents and documents that specify technical and quality requirements be controlled per this section.

6.2.2 Preparing Documents

Requires assignment for preparation and maintenance of documents to appropriate organizations.

6.2.3 Reviewing Documents

Requires that documents shall be reviewed per QARD Section 2.2.10, Document Review.

6.2.4 Approving Documents

Requires identification of the position which has approval authority for documents.

6.2.5 Distribution and Use of Documents

Provides criteria for distribution and use of documents.

6.2.6 Changes To Documents

Provides criteria governing changes to documents.

6.2.7 Expedited Changes

Provides criteria for initiating changes at the work location by responsible management.

6.2.8 Editorial Corrections

Describes the criteria for editorial changes to documents.

11.7 CONTROL OF PURCHASED ITEMS AND SERVICES

Control of purchased items and services requirements provide for planning and executing procurements assuring that purchased items and services meet specified requirements. Technical and quality assurance requirements specified in these documents are verified and incorporated into the program prior to starting work subject to the requirements of the Quality Assurance Program.

Qualified personnel evaluate the supplier's capability to provide acceptable quality services and products before the award of the procurement order or contract. The contractor's quality assurance, requesting organization and technical support as required participate in the evaluation of those suppliers providing important to safety items and services and the responsibilities for each group's participation are provided.

The evaluation of suppliers is based on one or more of the following:

- a. The supplier's capability to comply with the elements of the quality assurance criteria that are applicable to the type of material, equipment, and service being procured.
- b. A review of previous records and performance of suppliers who have provided similar articles of the type being procured.
- c. A survey of the supplier's facilities and quality assurance program to determine the capability to supply a product that meets the design, manufacturing, and quality requirements.

The results of supplier evaluations are documented and filed. Supplier's certificates of conformance are periodically evaluated by audits, independent inspections, or tests to ensure they are valid.

Receiving inspection of the supplier-furnished material, equipment, and services is performed to ensure that items accepted and released are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for installation or for further work.

Surveillance of suppliers during fabrication, inspection, testing, and shipment of materials, equipment, and components shall be planned and performed per written procedures to ensure conformance to the purchase order requirements. These procedures provide for: (a) instructions that specify the characteristics or processes to be witnessed, inspected, or verified, and accepted; the method of surveillance and the extent of documentation required; and those responsible for implementing these instructions, and, (b) assessments and surveillance which ensure that the supplier complies with the Quality Assurance Program requirements. Surveillance shall be performed on those items where verification of procurement requirements cannot be determined upon receipt. That verification documentation shall be available for the life of the NRC issued operating license for the operation of the ISFSI.

The supplier furnishes the following records as a minimum to the purchaser:

- a. Documentation that identifies the purchased material or equipment and the specific procurement requirements (e.g., codes, standards, and specifications) met by the items
- b. Documentation that identifies any procurement requirements which have not been met together with a description of those nonconformances dispositioned "accept as is" or "repair".

Items accepted and released are identified as to their inspection status prior to forwarding them to a controlled storage areas or releasing them for installation or further work.

The graded approach for verification of supplier activities, the selection of suppliers, and amount of supplier documentation, including planning is applied based on the relative importance, complexity, and quantity of the item or activity being procured.

DOE-ID delegates implementation authority for QARD Section 7.0, Control of Purchased Items and Services, to its contractor.

DOE-ID monitors its contractor's control of purchased items and services practices in support of program activities, and, by surveillance and assessments, periodically reviews its contractor's practices to document their level of implementation and adequacy.

DOE-ID's contractor is assigned authority for implementing QARD Section 7.0, Control of Purchased Items and Services, for procurement of items (structures, components and systems) and services in support of program activities and is required to establish and implement a system for control of the procurement activity that is responsive to the requirements of the QARD. It is required that supplier Quality Assurance Programs be reviewed and accepted before initiation of program activities affecting quality.

The topics from Section 7.0, Control of Purchased Items and Services, that are implemented from the QARD are:

7.2.1 Procurement Planning

Describes criteria for adequate procurement planning and documentation.

7.2.2 Source Evaluation and Selection

Provides criteria for determining supplier selection and supplier capability in providing items and services that affect quality.

7.2.3 Proposal/Bid Evaluation

Provides criteria for the proposal/bid evaluation process and who shall participate in that evaluation.

7.2.4 Supplier Performance Evaluation

Provides criteria for interfacing with suppliers and verifying their performance.

7.2.5 Control of Supplier Generated Documents

Establishes criteria for controlling, processing and accepting procurement documents.

7.2.6 Acceptance of items and Services

Provides criteria for objective evidence used in the acceptance of procured items and services.

7.2.7 Certificate of Conformance

Provides criteria for when a Certificate of Conformance is used for acceptance of an item or service.

7.2.8 Source Verification

Provides criteria where various methods of source verification may be used. Includes description of the process involved to control and personnel qualifications for source verification.

7.2.9 Receiving Inspection

Establishes the criteria for when receiving inspection is used to accept an item.

7.2.10 Post-installation Testing

Establishes that QARD Section 11, Test Control and that post-installation testing criteria are mutually established by purchaser and supplier.

7.2.11 Control of Supplier Nonconformances

Establishes requirements for both purchaser and supplier to document the process for disposition of items that do not meet procurement document requirements.

7.2.11.1 Commercial Grade Items

Establishes an acceptable alternative for commercial grade items when and where specified by the design.

11.8 IDENTIFICATION AND CONTROL OF ITEMS

Consistent with the importance to safety, implementing documents shall be established and implemented to identify and control materials, parts, and components including partially fabricated sub-assemblies to ensure that only correct and accepted items are used and installed.

Identification requirements are determined during generation of specifications and design drawings. Correct identification of materials, parts, and components is verified and documented prior to release for fabrication, assembly, shipment, and installation.

The graded approach for identification and control of items, and traceability requirements are specified in applicable codes, standards, or specifications.

DOE-ID delegates implementation authority for QARD Section 8.0, Identification and Control of items, to its contractor.

DOE-ID monitors its contractor's identification and control of item practices and, by surveillance and assessments, periodically reviews its contractor's practices to ensure proper implementation and adequacy.

DOE-ID's contractor is assigned responsibility for implementing QARD Section 8.0, Identification and Control of items, for items which support program activities and is required to establish and implement identification and control practices that are responsive to the requirements of the Quality Assurance Program.

The topics from Section 8.0, Identification and Control of Items, that are implemented from the QARD are:

8.2.1 Identification

Establishes the requirements for maintenance of identification of items.

8.2.2 Physical Markings

Establishes physical marking requirements for item identification.

8.2.3 Traceability

Provides requirements for the established and maintenance of traceability criteria to items.

8.2.4 Conditional Requirements

Establishes controls for item identification to be specified in specifications.

11.9 CONTROL OF SPECIAL PROCESSES

Implementing documents are established and implemented to control special processes such as welding, heat treating, and nondestructive examination. Implementing documents are used to ensure that process parameters are controlled and that the specified environmental conditions are maintained.

Special processes are accomplished by qualified personnel using qualified implementing procedures and equipment per applicable codes, standards, specifications or other special program requirements. The graded approach is not applicable for special processes. Special processes are performed by qualified personnel and accomplished per written process sheets or equivalent, with recorded evidence of verification per Quality Assurance Program requirements. Qualification records of procedures, equipment, and personnel associated with special processes shall be established, filed, and kept current.

DOE-ID delegates implementation authority for QARD Section 9.0, Control of Special Processes, to its contractor.

DOE-ID monitors its contractor's special processes control practices related to program activities, and, by surveillance and assessments, periodically reviews its contractor's practices to ensure proper implementation and adequacy.

DOE-ID's contractor is assigned responsibilities for implementing QARD Section 9.0, Control of Special Processes, for activities where special processes in support of program activities are involved, and is required to establish and implement practices to ensure adequate performance and control of production special processes. DOE-ID's contractor's special process controls shall be responsive to the requirements of the QARD.

The topics from Section 9.0, Control of Special Processes, that are implemented from the QARD are:

- 9.2.1 Special Processes
Establishes requirements for control and verification of quality for special processes.
- 9.2.2 Personnel, Implementing Documents, and Equipment Qualifications
Establishes requirements that process parameters are controlled and environmental conditions are maintained.
- 9.2.3 Qualification of Nondestructive Examination Personnel
Establishes the requirements for the control and administration of training, examination, and certification of nondestructive examination personnel.

11.10 INSPECTION

The inspection program's implementing documents shall be established and implemented to describe the planning (performance and documentation) and execution of inspections. These inspections shall verify conformance of quality affecting activities with requirements. The inspection program shall be established, documented, and accomplished per written, controlled procedures.

Implementing documents address inspection planning, acceptance criteria, inspection techniques to be applied, establishment of hold points, documentation of inspection results, and actions to be taken when acceptance criteria are not met. Inspection implementing documents address source, in-process, final, receipt, maintenance, modification, operations, and eventually, decommissioning activities. Inspections are conducted by certified personnel who are independent of the inspected activity. Inspection results are documented by the inspector and reviewed by the cognizant quality assurance organization.

Inspection practices identify and verify conformance of items and services with the documented specifications, instructions, implementing documents and drawings for accomplishing the required activities. Documented inspection practices shall be responsive to the requirements of the Quality Assurance Program. Inspection personnel shall be sufficiently independent from the individuals performing the activity being inspected.

Inspection procedures, instructions, and checklists shall provide for the following:

- a. Identification of characteristics and activities to be inspected
- b. Identification of the individuals or groups responsible for performing the inspection operation
- c. Acceptance and rejection criteria
- d. A description of the method of inspection
- e. Recording evidence of completing and verifying a manufacturing, inspection, or test operation
- f. Recording inspector or data recorder and the results of the inspection operation.

The graded approach for inspection, verification and documentation is applied based on the importance or complexity of the item or activity affecting quality being inspected or tested. Modifications, repairs, and replacements are inspected per the original design and inspection requirements or acceptable alternatives.

The individuals or groups who perform receiving and process verification inspections are identified and shown to have sufficient independence and qualifications.

DOE-ID delegates implementation authority for direct inspection of items and work practices per QARD Section 10.0, Inspection, to its contractor.

DOE-ID monitors its contractor's inspection practices associated with program activities, and, by surveillance and assessments, periodically reviews its contractor's practices to ensure proper implementation and adequacy.

DOE-IP's contractor is assigned responsibility for performing procurement, manufacturing, fabrication and assembly, testing, constructing, and operational activities in support of program activities, and, is required to establish and implement inspection practices of sufficient scope to be fully effective.

The topics from Section 10.0, Inspection, that are implemented from the QARD are:

10.2.1 Inspection Planning

Establishes requirements for performing and documenting inspection planning.

10.2.2 Selecting Inspection Personnel To Perform Inspections

Establishes qualification requirements for inspection personnel.

10.2.3 Inspection Hold Points

Establishes criteria for mandatory hold points to control work.

10.2.4 Statistical Sampling

Requires that statistical sampling shall be based on recognized standard practices.

10.2.5 In-Process Inspections and Monitoring

Establish criteria for in-process inspection of items to verify quality. These criteria include those necessary for coordination and sequencing of work at established inspection points.

10.2.6 Final Inspection

Establishes criteria for final inspection of items.

10.2.7 Accepting Items

Establishes criteria for acceptance of items. QARD Section 14.0, Inspection, Test, and Operating Status governs the item's inspection status.

10.2.8 Inspection Documentation

Provides criteria that govern contents of inspection documentation.

10.2.9 Qualifications of Inspection and Test Personnel

Provides guidance for qualification, determination of initial capabilities, indoctrination and training of inspection and test personnel, and functional qualification levels and associated documentation.

11.11 TEST CONTROL

Written and controlled procedures are established and executed to verify conformance to specified requirements and demonstrate that items provide satisfactory performance. These procedures contain:

- a. Instructions and prerequisites to perform the test
- b. Use of proper test equipment
- c. Acceptance criteria
- d. Mandatory witness and hold point inspections
- e. Other specified technical and/or quality assurance requirements.

Written test procedures incorporate and reference:

- a. The requirements and acceptance limits contained in applicable design and procurement documents
- b. Instructions for performing the test
- c. Test prerequisites
- d. Mandatory inspection hold points
- e. Acceptance and rejection criteria
- f. Methods of documenting or recording test data results.

Test results shall be documented, evaluated, and their acceptability determined by a qualified, responsible individual or group. When practicable, testing will test the structure, system, or component under conditions which will be present during normal and anticipated off-normal operations.

DOE-ID delegates implementation authority for QARD Section 11.0, Test Control, to its contractor.

DOE-ID monitors its contractor's testing and test control practices related to program activities, and, by surveillance and assessments, periodically reviews its contractor's practices to ensure proper implementation and adequacy.

DOE-ID's contractor is assigned responsibilities for documenting, evaluating, and determining test result acceptability in support of program activities, and is required to establish, as

applicable, proof tests, pre-operational tests, product certification tests, and other testing activities that are responsive to the requirements of the QARD.

The topics from Section 11.0, Test Control, that are implemented from the QARD are:

11.2.1 Test Planning

Establishes criteria for effective test planning.

11.2.2 Performing Tests

Establishes criteria that implementing documents shall address for tests.

11.2.3 Use of Other Testing Documents

Establishes criteria for incorporation of test information directly from testing documents into the testing implementation documents.

11.2.4 Test Results

Establishes criteria for documentation and evaluation of test results.

11.2.5 Test Documentation

Establishes criteria for contents of test documentation.

11.2.6 Qualification of Test Personnel

Establishes criteria that test personnel shall be qualified per QARD Section 10, Inspection.

11.12 CONTROL OF MEASURING AND TEST EQUIPMENT

Implementing documents are established and executed to ensure that appropriate tools, gauges, instruments, and other measuring and testing devices used in activities which have quality assurance requirements or health and safety considerations are properly controlled, calibrated, adjusted, and maintained at specified intervals. The graded approach is not applicable for measuring and test equipment used for activities affecting quality.

Provisions, contained in procedures, describe the calibration technique and frequency, maintenance, and control of the measuring and test equipment (instruments, tools, gages, fixtures, reference and transfer standards, and nondestructive test equipment) which is used in the measurements, inspection, and monitoring of important to safety structures, systems, and components.

These implementing documents shall maintain equipment accuracy within necessary limits and maintain traceability to National Institute of Standards and Technology (NIST) or other known standards.

Calibration standards have an uncertainty requirement of no more than 1/4th of the tolerance of the equipment being calibrated. A greater uncertainty may be acceptable when limited by the "state of-the-art".

The complete status of all items under the calibration system shall be documented and maintained.

DOE-ID delegates implementation authority for QARD Section 12.0, Control of Measuring and Test Equipment, to its contractor.

DOE-ID monitors its contractor's measuring and test equipment control practices related to program activities, and, by surveillance and assessments, periodically reviews its contractor's practices to ensure proper implementation and adequacy.

DOE-ID's contractor is assigned responsibility for performing inspections, examinations, or tests which support program activities, and is required to establish and implement a system of calibration and control of measuring and test equipment that is responsive to the requirements of the QARD.

The topics from Section 12.0, Control of Measuring and Test Equipment, that are implemented from the QARD are:

12.2.1 Calibration

Provides criteria for calibration, adjustment and maintenance of measuring and test equipment.

12.2.2 Documenting the Use of Measuring and Test Equipment

Requires that use of M&TE be documented.

12.2.3 Out-of-Calibration Measuring and Test Equipment

Provides criteria for when MT&E shall be considered as out-of-calibration.

12.2.4 Lost Measuring and Test Equipment

Provides criteria for lost M&TE.

12.2.5 Handling and Storage

M&TE shall be properly handled and stored to maintain accuracy.

12.2.6 Commercial Devices

Provides criteria for rulers, tape measures, levels, and other commercial equipment.

12.2.7 Measuring and Test Equipment Documentation

Provide criteria for M&TE documentation information.

11.13 HANDLING, STORAGE, AND SHIPPING

Consistent with an item's or activity's importance to safety, procedures are established and executed to control handling, storage, shipping, cleaning, packaging, and preservation of material and equipment shall be accomplished by qualified individuals to prevent damage or loss, and to minimize deterioration.

Procedures shall be prepared which control the cleaning, handling, storage, packaging, shipping, and preservation of materials, components, and systems per design and specification requirements to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity.

Application of the graded approach for handling, storage, and shipping of items is specified in work and inspection instructions, and depends on how critical, sensitive, perishable, or high-value the item is.

DOE-ID delegates implementation authority for QARD Section 13.0, Handling, Storage, and Shipping to its contractor.

DOE-ID monitors its contractor's handling, storage, and shipping practices related to program activities, and, by surveillance and assessments, periodically reviews its contractor's practices to ensure implementation and adequacy.

DOE-ID's contractor is assigned the authority to develop special handling, preservation, storage, cleaning, packaging, and shipping practices which support program activities, and is required to establish and execute implementing procedures which control the cleaning, handling, storage, packaging, shipping, and preservation of materials, components, and systems per design and specification requirements which preclude damage, loss, or deterioration by environmental conditions. These practices shall be responsive to the requirements of the QARD.

The topics from Section 13.0, Handling, Storage, and Shipping that are implemented from the QARD are:

- 13.2.1 Controls
Provides criteria for handling, storage, cleaning, packaging, shipping, and preservation of items.
- 13.2.2 Special Equipment, Tools, and Environments
Provides criteria for special equipment and protective environments for particular items.
- 13.2.3 Marking and Labeling
Provides criteria for establishment of marking and labeling for packaging, shipping, handling and storage of items.

11.14 INSPECTION, TEST, AND OPERATING STATUS

Implementing documents are established and executed to identify the inspection, test, and operating status of items. The Quality Assurance Program has provisions to ensure that inspection, test, and operating status is verified before release, fabrication, installation, test, and use of items to preclude inadvertent bypassing of inspections and tests and to prevent accidental operation. Application and removal of status indicators, welding stamps, and other tags, markings, and labels shall be procedurally controlled.

The graded approach is not applicable for inspection, test and operating status. The status is identified either on the item or on documents to ensure the inspections and tests have been performed, and to ensure items are not inadvertently installed, used, or operated.

Bypassing of inspections, tests, and other critical operations shall be procedurally controlled under the cognizance of the contractor's quality assurance organization.

DOE-ID delegates implementation authority for QARD Section 14.0, Inspection, Test and Operating Status, to its contractor.

DOE-ID monitors its contractor's practices related to program activities for indicating inspection, test, and operating status, and, by surveillance and assessments, periodically reviews its contractor's practices to ensure implementation and adequacy.

DOE-ID's contractor is assigned authority for: (1) developing practices that identify the inspection and test status of structures, systems, and components throughout their fabrication; (2) documenting bypassed inspections, tests, and other critical processes that are under the purview of the Quality Assurance Program; (3) identifying the organization responsible for documenting and identifying the status of nonconforming, inoperative, or malfunctioning structures, components, and systems which support program activities; and (4) establishing and implementing those practices to be responsive to the requirements of the QARD.

The topics from Section 14.0, Inspection, Test and Operating Status, that are implemented from the QARD are:

14.2.1 Identifying Items

Provides criteria for identification of items passing or not passing required inspections and tests.

14.2.2 Indicating Status

Provides criteria for indicating status of required inspections and tests and authority of application and removal of status indicators.

11.15 NONCONFORMANCES

Nonconformance requirements shall establish control of items (material, components, and systems) that do not conform to requirements in order to prevent their inadvertent installation or use through written documents. The identification, documentation, tracking, segregation, review, disposition, and notification to affected organizations of nonconforming material, components, systems, services, or activities shall be procedurally controlled to prevent inadvertent test, installation, or use.

A corrective action system is established and executed which promotes a "no fault" attitude toward identification of conditions that are adverse to quality. Nonconforming items must be reviewed and accepted, rejected, repaired, or re-worked per implementing documents.

Documentation shall:

- a. Identify the nonconforming item
- b. Describe the nonconformance, the disposition of the nonconformance, and the inspection requirements
- c. Includes signature approval for the disposition.

Provisions shall be established identifying those individuals or groups delegated the responsibility and authority for the disposition and the close out of nonconformances.

The graded approach is not applicable for the identification and control of nonconforming items. All items that do not conform to the quality requirements shall be controlled to prevent their inadvertent installation or use. Nonconforming items shall be segregated from acceptable items and identified as discrepant until properly dispositioned and closed out.

Dispositions to nonconformances shall identify materials, components, and systems to be used-as-is, rejected, or re-worked. Dispositioned nonconformance reports shall be made part of the quality records.

Acceptability of re-work or repair of materials, parts, components, systems, and structures shall be verified by re-inspecting and re-testing the item as originally inspected and tested or by a method which is at least equal to the original inspection and testing method. Inspection, testing, re-work, and repair procedures shall be documented.

Nonconformance documentation is analyzed to identify adverse trends in the performance of the Quality Assurance Program. Results of these analyses are reported to DOE-ID's, and its contractor's, senior management.

DOE-ID also retains authority to identify and require that DOE-ID and contractor identified nonconformances be entered into its contractor's nonconformance control system.

DOE-ID monitors its contractor's nonconformance control practices related to program activity, and, by surveillance and assessments, periodically reviews its contractor's nonconformance practices to ensure implementation and adequacy.

DOE-ID delegates implementation authority to its contractor for developing procedurally controlled practices that identify, document, track, segregate, review, disposition, and notify affected organizations of nonconforming materials, components, and systems, and is required to establish and implement those practices for the control of nonconforming materials, components, and systems in support of program activities. These practices shall be responsive to the requirements of the QARD.

The topics from Section 15.0, Nonconformances, that are implemented from the QARD are:

15.2.1 Documenting and Evaluating Nonconforming Items

Provides criteria for nonconformance identification and describing nonconforming characteristics of an item. Corrective action criteria used for evaluation use the requirements of QARD Section 16.0, Corrective Action.

15.2.2 Identifying Nonconforming Items

Provides criteria for identification of nonconforming items through marking, tagging or other means.

15.2.3 Segregating Nonconforming Items

Provides criteria for segregation of nonconforming items to prevent inadvertent use.

15.2.4 Disposition of Nonconforming Items

Provides criteria of the use of "use-as-is", "reject", "repair", or "rework" dispositions for nonconforming items.

15.2.5 Quality Trending

Requires that nonconforming documentation shall be periodically analyzed to identify quality trends per QARD Section 16.0, Corrective Action.

11.16 CORRECTIVE ACTION

The corrective action system elements consist of prompt identification, documentation, classification, cause analysis, correction of condition, elimination of root cause factors for significant conditions, and follow-up activities. All conditions adverse to quality shall be promptly identified and corrected.

Procedures have been established and implemented for the identification and correction of conditions adverse to quality including the causes of significant conditions adverse to quality identified through internal DOE-ID surveillance and assessments or external surveillance and assessments performed on the program. Procedural instructions and policy guidance provide criteria for determining the existence of significant conditions adverse to quality. The ISFSI Quality Assurance Program Manager provides follow-up to verify timely and proper implementation of corrective action.

Corrective action is required for conditions adverse to quality such as failures, nonconformances, malfunctions, deficiencies, deviations, and defective material, components or systems. Significant conditions adverse to quality identified by DOE-ID overview or assessments of the contractor's activities requires corrective action by the DOE-ID contractor and DOE-ID's review and approval prior to the corrective action's implementation. Corrective action to preclude recurrence of a nonconforming condition is commensurate with the item's importance.

Corrective action documentation is provided to appropriate DOE-ID and its contractor is management, and requires appropriate quality assurance organizational concurrence with proposed actions.

DOE-ID monitors its contractor's corrective action systems related to program activities, and, by surveillance and assessments, periodically reviews its contractor's systems to ensure implementation and adequacy.

DOE-ID's contractor is required to establish and implement a corrective action system which supports program activities and is responsive to the requirements of the Quality Assurance Program. Quality information is promptly analyzed and examined for adverse quality trends. Trend analysis identifies adverse quality trends.

Quality trends and results of remedial actions are reported to the ISFSI Quality Assurance Program Manager who is responsible for corrective action tracking and providing appropriate DOE-ID upper management appraisal.

DOE-ID's contractor collects key information from program assessments, surveillance, and assessments reports. Analysis is performed to ensure prompt identification of adverse quality trends. Evaluations are performed to determine systemic root cause(s) and determine if a course of action for correction is required.

The topics from Section 16.0, Corrective Action, that are implemented from the QARD are:

16.2.1 Identifying Conditions Adverse To Quality

Provides criteria for identification of conditions adverse to quality.

16.2.2 Classification of Conditions Adverse To Quality

Provides classification criteria for conditions adverse to quality

16.2.3 Conditions Adverse To Quality

Provides criteria for documenting and reporting to appropriate levels of management conditions adverse to quality.

16.2.4 Significant Conditions Adverse To Quality

Provides criteria for determining, evaluating, investigating, and concurring of proposed remedial actions for significant conditions adverse to quality.

16.2.5 Follow-up and Closure Action

Requires Quality Assurance verify implementation of corrective actions and closed related corrective action documentation when complete.

16.2.6 Quality Trending

Provides criteria for determining adverse quality trends and the manner in which trend evaluation shall be conducted.

11.17 QUALITY ASSURANCE RECORDS

Quality Assurance records requirements ensure that Quality Assurance records are specified, prepared, maintained and retrievable. As identified in the implementing documents Quality Assurance records are classified as lifetime of the facility license or as nonpermanent. The graded approach for Quality Assurance Records is as specified in design documents, procurement documents, test procedures, and operational procedures. To aid in minimizing the retention of unnecessary records, the records program shall list records to be retained by "type of data" rather than by record title.

Implementing documents control records that document: design, design review and peer review reports, engineering, procurement, manufacturing, construction, inspections, tests, installation, pre-operation, start-up, operations, maintenance, modification, decommissioning, audits, manufacturer's records, proof, receipt, training and qualification records of personnel, procedures and equipment, operating logs, results of reviews, assessments, material analyses, monitoring of work performance, calibration procedures and reports, nonconformance reports and corrective action reports.

Implementing documents are established and executed to ensure that sufficient records of structures, components, systems and activities are generated and maintained to reflect completed work. These implementing documents provide for the administration, receipt, retrieval, and disposition of Quality Assurance records. All Quality Assurance records are retained in storage, and are identified and retrievable. DOE-ID delegates to its contractor the maintenance and control of the records storage facilities per the requirements of the QARD for the life of the ISFSI.

Established implementing documents assign responsibility for storage, filing system, transmittal verification, record access, retrieval and removal, filing supplemental information and for the disposition of superseded records.

DOE-ID monitors its contractor's records' practices related to program activities, and by surveillance and assessments, periodically reviews its contractor's practices to ensure implementation and adequacy.

Quality Assurance records generated by DOE-ID will be maintained in accordance with the QA program.

DOE-ID's contractor is assigned authority for performing work activities, and is required to establish and implement a practice of specifying, preparing, and maintaining records in a manner that is responsive to the requirements of the QARD.

The topics from Section 17.0, Quality Assurance Records, that are implemented from the QARD are:

- 17.2.1 Classifying Quality Assurance Records
Provides criteria for classification of quality assurance records.

17.2.2 Creating Valid Quality Assurance Records

Provides criteria for identification, creation, handling, and validating of quality assurance records.

17.2.3 Receiving and Indexing Quality Assurance Records

Provides criteria for establishment of a receipt control system for quality assurance records.

17.2.4 Correcting Information in Quality Assurance Records

Provides criteria for correction and approval of information changes to quality assurance records.

17.2.5 Storing and Preserving Quality Assurance Records

Provides criteria for storing and preserving methods for quality assurance records in predetermined storage facilities.

17.2.6 Retrieval of Quality Assurance Records

Provides for planned retrieval time of quality assurance records and provides criteria for controlling access to storage facilities.

17.2.7 Retention of Quality Assurance Records

Establishes criteria for retention and preservation of quality assurance records.
Provides criteria for disposal of nonpermanent quality assurance records.

17.2.8 Turnover of Quality Assurance Records

Section "A" only
Provides criteria for temporarily stored quality assurance records subject to records turnover requirements.

17.2.11 Temporary Storage Facility

Provides criteria for temporary storage of quality assurance records during processing, review, or use until turnover to DOE-RW for disposition.

17.2.12 Replacement of Quality Assurance Records

Provides criteria for replacement, restoration, or substitution of lost or damaged quality assurance records.

11.18 AUDITS

Quality Assurance audits are to be performed by the contractor in accordance with their DOE-ID approved Quality Assurance Program. DOE-ID retains responsibility for the development and implementation of an audit plan which will evaluate the performance of the contractor as well as the adequacy of DOE-ID's oversight of the contractor.

DOE-ID Quality Assurance audits and surveillances conducted under the direction of the ISFSI Quality Assurance Program Manager will be planned, performed, and reported by trained and qualified personnel in accordance with implementing procedures. All audits of the contractor related to NRC regulated activities will be led by an Audit Team Leader who is not an employee of the contractor or parent organizations. Subjects for Quality Assurance audits and surveillances shall include, but not be limited to:

- Compliance, implementation, and effectiveness of the DOE-ID and contractor's Quality Assurance programs,
- Compliance with the 10 CFR Part 21 reporting requirements,
- Personnel training, and
- The managerial and administrative controls used to ensure safe operation of the ISF Facility ISFSI.

Regularly scheduled audits are supplemented by special audits when conditions which warrant special audits exist or when requested by DOE-ID management.

DOE-ID's contractor has established and executed implementing documents to confirm that activities affecting quality comply with the Quality Assurance Program and that they have been effectively executed and responsive to the requirements of the Quality Assurance Program.

DOE-ID monitors its contractor's records practices related to audits, and by surveillance and assessments, periodically reviews its contractor's practices to ensure implementation and adequacy.

The topics from Section 18.0, Audits, that are implemented from the QARD are:

18.2.1 Scheduling Internal Audits

Provides criteria for scheduling internal quality audits.

18.2.2 Scheduling External Audits

Provides criteria for scheduling external quality assurance audits.

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- 18.2.3 Audit Schedule
- Provides criteria for development of an audit schedule.
- 18.2.4 Audit Planning
- Provides criteria for development of an audit plan and scope of the audit.
- 18.2.5 Audit Team Independence
- Provides criteria for audit team independence, authority, and organizational freedom.
- 18.2.6 Audit Team Selection
- Provides criteria for identification of audit team, team leader and technical specialists.
- 18.2.7 Performing Audits
- Provides performance criteria for the audit team leader to ensure that the audit team is prepared to perform the audit.
- 18.2.8 Reporting Audit Results
- Provides criteria for preparation, contents, and signing of the audit report.
- 18.2.9 Responding To Audits
- Provides criteria for management to respond to the audit report.
- 18.2.10 Evaluating Audit Responses
- Provides for audit responses to be evaluated per QARD Section 16, Corrective Action.
- 18.2.11 Follow-up Action
- Provides criteria for follow-up actions to be taken by the auditing organization to verify that corrective actions were accomplished per QARD Section 16, Corrective Action.
- 18.2.12 Technical Specialist Qualifications
- Provides criteria for the indoctrination and training of technical specialist personnel to QARD Section 2, Quality Assurance Program.

18.2.13 Auditor Qualifications

Provides criteria for appropriate training and orientation of auditors for developing their competency in performing audits.

18.2.14 Lead Auditor Qualifications

Provides criteria for lead auditor skills at organizing and directing personnel.

18.2.15 Lead Auditor Education and Experience

Provides criteria for certification of education and experience of lead auditors.

18.2.15.1 Lead Auditor Communication Skills

Requires that lead auditors have effective communications skills.

18.2.16 Lead Auditor Training

Provides criteria for training lead auditors to attain proficiency.

18.2.17 Lead Auditor Audit Participation

Requires lead auditors to participate in five (5) Quality Assurance audits with at least one (1) being nuclear-related within one-year prior to certification as a lead auditor.

18.2.18 Lead Auditor Examination

Provides criteria for examination that evaluates lead auditor comprehension and ability to apply audit knowledge.

18.2.19 Certification of Lead Auditor Qualifications

Provides criteria for certification of qualified lead auditors by the auditing organization.

18.2.20 Maintaining Lead Auditor Proficiency

Provides criteria for lead auditors to maintain proficiency, management evaluation of proficiency, and qualification requirements.

11.19 SUPPLEMENTS AND APPENDICES

11.19.1 Software (QARD, Supplement I)

This QARD Supplement establishes requirements for the development, modification, control, and use of software.

DOE-ID delegates implementation authority for QARD Supplemental I, Software for configuration management which supports program activities, such as design, to its contractor.

DOE-ID monitors its contractor's practices related to program activities for software configuration, and, by surveillance and assessments, periodically reviews its contractor's practices to assure implementation and adequacy.

DOE-ID's contractor is assigned authority implementation of QARD Supplement I, Software for construction, fabrication, assembly and/or operation functions which support program activities, and is required to establish and implement software configuration management practices for individual items throughout the program and operational status of structures, components or systems. These practices shall be responsive to the requirements of the Quality Assurance Program.

The topics from Supplement I, Software, that are implemented from the QARD are:

- 1.2.1 General Software Requirements
Provides requirements that apply generally to software.
- 1.2.2 Software Planning
Provides requirements for and contents of software plans.
- 1.2.3 Software Life Cycle Requirements
Provides software life cycle criteria for developed or modified software..
- 1.2.4 Software Configuration Management
Provides criteria for software configuration management to include configuration identification, configuration control, and status accounting.
- 1.2.5 Defect Reporting and Resolution
Provides criteria for software defect reporting and resolution which shall be integrated into the software configuration management system..
- 1.2.6 Software Procurement
Stipulated the flow down of software requirements to other organizations developing and supplying software under contract.

- 1.2.7 Software Previously Developed Not Using This Supplement
Provides criteria for use of software in which the history of the software is not known.
- 1.2.8 Control of the Use of Software
Provides criteria for controlling, documenting, and using released software.

11.19.2 Sample Control (QARD, Supplement II)

Sample control practices as described in the QARD are not applicable to the ISF Facility ISFSI. Scientific samples taken, handled, or recorded for any purpose in order for the ISF Facility ISFSI to perform its function are covered by other procedures.

11.19.3 Scientific Investigation (QARD, Supplement III)

Scientific investigation practices are not applicable to the ISF Facility ISFSI. The facilities only function is SNF packaging and passive interim storage.

11.19.4 Field Surveying (QARD, Supplement IV)

Field surveying practices are not applicable to the ISF Facility ISFSI. The facility construction location is pre-established and identified in existing documents. The ISF Facility ISFSI does not need the surveying controls as outlined for a mined geological repository in the QARD.

11.19.5 Control of the Electronic Management of Data (QARD, Supplement V)

This supplement applies to the controls on the electronic management of data used as the controlled source for information used in design analysis or process control.

DOE-ID delegates implementation authority for control of the electronic management of data activities which support program activities to its contractor.

DOE-ID monitors its contractor's practices related to program activities for control of the electronic management of data, and, by surveillance and assessments, periodically reviews its contractor's practices to assure implementation and adequacy.

DOE-ID's contractor is assigned implementation authority for QARD Supplemental V, Control of the Electronic Management of Data, for design, construction, fabrication, and assembly and/or operation functions which support program activities. The contractor is required to established implement practices which control electronic management of data as the controlled source of information used in design analysis or process control. These practices are responsive to the requirements of the QARD.

The topics from Supplement V, Control of the Electronic Management of Data, that are implemented from the QARD are:

V.2.1 Control of the Electronic Management of Data

Provides criteria for data input, subsequent changes to data input, security of data, including integrity of the data, and retrieval of data using a query language.

11.19.6 High-Level Waste Form Production (QARD, Appendix A)

High-Level Waste Form Production practices are not applicable to the ISF Facility ISFSI. The facility does not produce High-Level Waste in any form. The ISF Facility ISFSI is a packaging and passive interim storage facility.

11.19.7 Storage and Transportation (QARD, Appendix 8)

The Licensee and the contractor design or fabricate ISF standard canisters.

11.19.8 Monitored Geological Repository (QARD, Appendix C)

Monitored Geological Repository practices are not applicable to the ISF Facility ISFSI. The ISF Facility ISFSI is a packaging and passive interim storage facility and is not a disposal system.

11.20 REFERENCES

- 11.1 DOE/RW-0333P, Revision 10, Office of Civilian Radioactive Waste Management's Quality Assurance Requirements and Description (QARD)

Table 11.0-1, Contents of the QARD Revision 10

Section No.	Section Title	Rev. No.	Eff. Date
Intro.	Introduction	3	4-28-00
1.0	Organization	4	4-28-00
2.0	Quality Assurance Program	4	4-28-00
3.0	Design Control	3	6-2-97
4.0	Procurement Document Control	1	10-31-95
5.0	Implementing Documents	1	10-31-95
6.0	Document Control	2	2-3-97
7.0	Control of Purchased Items and Services	4	4-28-00
8.0	Identification and Control of Items	1	10-31-95
9.0	Control of Special Processes	1	10-31-95
10.0	Inspection	0	12-18-92
11.0	Test Control	0	12-18-92
12.0	Control of Measuring and Test Equipment	1	10-31-95
13.0	Handling, Storage, and Shipping	0	12-18-92
14.0	Inspection, Test, and Operating Status	1	10-31-95
15.0	Nonconformances	1	10-31-95
16.0	Corrective Action	1	10-31-95
17.0	Quality Assurance Records	2	3-3-97
18.0	Audits	1	10-31-95
Supplement I	Software	3	2-7-00
Supplement II	Sample Control	1	10-31-95
Supplement III	Scientific Investigation	4	2-7-00
Supplement IV	Field Surveying	0	12-18-92
Supplement V	Control of the Electronic Management of Data	1	2-7-00
Appendix A	High Level Waste Form Production	1	10-31-95
Appendix B	Storage and Transportation	4	2-7-00
Appendix C	Monitored Geologic Repository	4	2-7-00
Glossary		4	2-7-00