



## Department of Energy

Idaho Operations Office  
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Idaho Falls, ID 83415

June 4, 2015

U.S. Nuclear Regulatory Commission  
Attn: Document Control Desk  
Office of Nuclear Material Safety and Safeguards  
Director Division of Spent Fuel Storage and Transportation  
Washington, DC 20555-0001

SUBJECT: Submittal of the Fort Saint Vrain (Docket 72-9) Safety Analysis Update Report  
72-9/2015-01, SNM-2504 (EM-FMDP-15-032)

Dear Sir or Madam:

Materials license SNM-2504 to possess nuclear material and operate the Fort Saint Vrain (FSV) Independent Spent Fuel Storage Installation (ISFSI) was issued to Public Services Company of Colorado November 30, 1991. The license was transferred to the Department of Energy's Idaho Operation Office (DOE-ID) June 4, 1999. July 18, 2011, the license was extended for 20 years through November 30, 2031.

Pursuant to 10 CFR 72.70, the Department of Energy, Idaho Operations Office (DOE-ID) has effected changes to the Safety Analysis Report (SAR) for the FSV ISFSI. The DOE-ID ISFSI Facility Director certifies that the changes described in the enclosure accurately represent the FSV ISFSI SAR changes made since the previous update submitted June 4, 2013.

Per 10 CFR 72.48(d) (2) and FSV ISFSI Technical Specifications 5.5.1 and 5.5.2, the enclosures report the changes, tests or experiments that were enacted since the previous biennial report submitted June 4, 2013. There were no changes that required NRC approval.

If you have any questions, please contact me at (208) 526-8888.

Sincerely,

Steven R. Ahrendts  
NRC Licensed Facilities Director

Enclosures  
Update Report 72-70/2015-01  
FSV ISFSI SAR Ch. 9 & 11

cc:

Lee Brookhart, NRC-Region IV  
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HMSS26

## Update Report 72-9/2015-01

### Introduction

Materials license SNM-2504 to operate the Fort St. Vrain (FSV) Independent Spent Fuel Storage Installation (ISFSI) was transferred to the Department of Energy's Idaho Operations Office (DOE-ID) from Public Service Company of Colorado on June 4, 1999. This update report addresses the following reporting requirements which were last implemented in May 2013.

- The biennial Safety Analysis Report (SAR) update pursuant to 10 CFR 72.70, Safety Analysis Report Updating.
- The biennial 72.48 evaluations report pursuant to 10 CFR 72.48.
- The biennial Technical Specifications Bases evaluations report pursuant to Technical Specification (TS) 5.5.1.
- The biennial essential program evaluations report pursuant to TS 5.5.2. Note: The 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.
- The biennial Natural Gas and Oil Monitoring Program report pursuant to TS 5.5.3.

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, TS 5.5.2 and TS 5.5.3. TS 5.5.1 requires 72.48 evaluations to be performed for any change to the Technical Specification Bases. TS 5.5.2 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 contained in the FSV ISFSI SAR. TS 5.5.3 requires that new natural gas and oil infrastructure installed within one-half mile of the FSV ISFSI and bounded by the analysis done for Amendment 1 be reported with the periodic SAR updates.

### Changes to the Safety Analysis Report

There were no changes made to the proprietary appendices in the FSV ISFSI SAR during this reporting period. Changes were made to Chapters 9 and 11 during this reporting period as follows:

- Figure 9.1-1, DOE-ID Organization was revised to reflect DOE-ID position title changes.
- A position title change was also reflected in a revision to Section 11.1.3 along with minor format and footer changes.

The changes to the SAR resulted in no change in the Technical Specifications and no exemption from the regulations. Facility design and operation parameters were not changed.

### Changes, Tests, and Experiments

The previous report of changes made pursuant to 10 CFR 72.48 was provided in May 2013. There were no changes made pursuant to 10 CFR 72.48 during this period. However, two evaluations were performed pursuant to 10 CFR 72.48 associated with an application for a specific exemption. Resulting changes are pending NRC approval.

### Changes to the Technical Specifications Bases

The previous update of the Technical Specifications Bases made pursuant to TS 5.5.1 was provided in May 2013. There were no changes made to the Technical Specifications Bases during this period.

### Radiological Environmental Monitoring Program Changes

The previous update of the Radiological Environmental Monitoring Program made pursuant to TS 5.5.2 was provided in May 2013. There were no changes made to the Radiological Environmental Monitoring Program during this period.

### Training Program Changes

The previous update of the Training Program made pursuant to TS 5.5.2 was provided in May 2013. There were no changes made to the Training Program during this period.

### Quality Assurance Program Changes

The previous update of the Quality Assurance Program made pursuant to TS 5.5.2 was provided in May 2013. There was one change made to the Quality Assurance Program during this period; a DOE-ID position title change was reflected in a revision to Section 11.1.3 along with minor format and footer changes.

### Natural Gas and Oil Infrastructure Changes

The previous update of the Natural Gas and Oil Infrastructure made pursuant to TS 5.5.3 was provided in May 2013. There was one change made to the Natural Gas and Oil Infrastructure during this period; a clarifying reference to a 2009 license evaluation (FSV-09-001) was added to LST-278, FSV Oil and Gas Database on May 28, 2013.

### Attachments

1. FSV ISFSI SAR Chapter 9, Conduct of Operations
2. FSV ISFSI SAR Chapter 11, Quality Assurance

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## **9. CONDUCT OF OPERATIONS**

This chapter describes the organization and general plans for operating the FSV ISFSI. The organization section includes a brief description of the responsibilities of key personnel. The training program for the facility staff is described. The Emergency Plan, Decommissioning Plan and the Physical Protection Plan are 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**

#### **9.1.1. Corporate Organization**

The Manager of DOE-ID is authorized to be the license holder for the FSV ISFSI (materials license SNM-2504). This authority was delegated and responsibility was assigned to the DOE-ID Manager by the Secretary of Energy pursuant to 10 CFR 72.16(b) (Ref.1) in Delegation Order No. 10CFR72.512.1. As the facility owner and licensee, DOE retains ultimate responsibility for the safe operation of the facility and for compliance with all license conditions.

#### **9.1.2. Corporate Functions, Responsibilities, and Authorities.**

The Manager of DOE-ID is the authorized DOE representative having direct authority and responsibility for compliance with the FSV ISFSI License. The Manager of DOE-ID is responsible for overall executive management of the Idaho Operations Office, has signature authority for the FSV ISFSI license, and is the person ultimately responsible for compliance with the facility's license conditions and overall facility nuclear safety. The Manager of DOE-ID 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 Manager of DOE-ID, as depicted in Figure 9.1-1, are described below.

The responsibility of the Deputy Manager for Idaho Cleanup Project (ICP) is the overall execution of EM-funded programs and operations at the INL, under which spent nuclear fuel storage (including NRC-licensed ISFSI operations) falls. The actual day-to-day execution of programs and operations associated with the NRC-licensed ISFSIs is performed by a contractor. The Deputy Manager for ICP and staff provide management direction and oversight of contractor performance in accordance with DOE-ID's Quality Assurance Program and commitments herein.

The Deputy Manager for Operations Support is independent of facility line management and is responsible for environmental protection, safety, health, quality assurance, and security. This Office provides DOE-ID oversight of the contractor for licensed activities, independent of the ICP organization.

The responsibility for developing the appropriate revisions to the contract is delegated to the Assistant Deputy Manager for Administration Services Administrative Support.

##### **9.1.2.1. Applicant's In-House Organization.**

This section continues the description of DOE-ID's organization, as depicted in Figure 9.1-1. 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. Oversight of the EM owned spent fuel management facilities and activities, including the NRC-licensed ISFSIs, is

delegated by the Deputy Manager for ICP to the Assistant Manager for Facility and Material Disposition.

Reporting directly to the Assistant Manager for Facility and Material Disposition through the Facility Demo and Fuels Disposition Team Supervisor is the FSV Facility Director, who is responsible for the oversight of the contractor to ensure that approved requirements and performance objectives are met for the FSV ISFSI. The FSV Facility Director has an alternate, designated in writing, who meets the training and qualification requirements specified below for the Facility Director. The FSV Facility director has direct access to the Manager of DOE-ID on issues affecting the safety and surety of ISFSI operations.

Also reporting to the Assistant Manager for Facility and Material Disposition through the Facility Demo and Fuels Disposition Supervisor Materials Disposition Project Team Leader is the NRC Licensing Manager. 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 FSV Facility Director.

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

#### **9.1.2.2. Interrelationships with Contractors and Suppliers.**

The DOE utilizes a contractor for the FSV ISFSI activities. The authority for the management and operation of the facility is contractually delegated and the responsibility for compliance with license requirements and applicable regulations is contractually assigned to the contractor. To exercise DOE's ultimate responsibility, DOE will: (1) retain responsibility for and perform independent audits of the contractor's FSV ISFSI Quality Assurance program (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 DOE-ID's FSV Facility Director, TMI/FSV Licensing Manager, and ISFSI QA Manager and its contractor are also depicted in Figure 9.1-1.

##### **9.1.2.2.1. ISFSI Oversight Program**

The Facility Director is the day-to-day management DOE-ID employee responsible for the compliance of FSV ISFSI operations. Although not in residence at the FSV ISFSI, the FSV Facility Director shall maintain routine electronic and verbal communication with the facility staff.

The FSV Facility Director shall visit the FSV ISFSI at least twice a year for the purpose of verification or audit of FSV ISFSI compliance with regulatory requirements and license basis commitments, to communicate in person with facility staff, and to apprise DOE-ID management of FSV ISFSI status based on observations.

The FSV Facility Director or alternate shall be present during significant operational or maintenance evolutions, emergency exercises, and announced NRC inspections. Surveillances of these activities will be performed. During prolonged evolutions, the FSV Facility Director shall be present during initial activities and at least monthly thereafter.

The DOE-ID FSV Facility Director or alternate shall perform surveillances of the contractor's ALARA Committee and the ISFSI Safety Review Committee and shall be an ex officio member (and is a quorum requirement) of these committees when they meet to review ISFSI matters to ensure these committees' functions are satisfactory and to report to DOE-ID management as needed. (See Section 9.1.3.1.1 for the duties of the ISFSI Safety Review Committee.)

The DOE-ID FSV 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 DOE-ID FSV Facility Director or alternate shall review and concur with all of the following:

- All 10 CFR 72.48 evaluations and TS Basis evaluations (TS 5.5.1) for the FSV ISFSI
- 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 which are not submitted by the Manager of DOE-ID.

#### **9.1.2.3. Applicant's 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 activities at the FSV ISFSI. 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 FSV Facility Director.

#### **9.1.3. Operating Organization, Management, and Administrative Control System**

The operating organization, 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 FSV ISFSI, personnel, and records that NRC considers necessary to carry out its responsibilities.

DOE-ID has assigned responsibility and delegated authority for the management and operation of the facility to the contractor. DOE-ID policy requirements for operating the FSV ISFSI are assigned to the contractor through the contract. Specifically, the contract requires the contractor to conduct work at the FSV ISFSI in compliance with all applicable:

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

DOE-ID commits to providing a contractor with management and staff for routine operation and maintenance of the FSV ISFSI and support organizations to implement DOE's program commitments in quality assurance, security, training, radiological protection, environmental monitoring, and spent fuel accountability.

#### **9.1.3.1. Onsite Organization.**

The contractor corporate structure provides the necessary organizations for operating the FSV ISFSI. The contractor organization supports the missions at the INL, not all of which are applicable to the management and operation of the ISFSI. The following organizational descriptions document the organizations necessary to manage the FSV ISFSI.

The contractor's chief executive officer is responsible for overall management of contractor activities and is accountable for complying with the contract conditions. Authorities are delegated and resources are provided to manage the FSV ISFSI in the areas of emergency preparedness, engineering, environmental management, operations, maintenance, quality assurance, radiological control, safety and health, training, and transportation. In addition to the interfaces shown on Figure 9.1-1 contractor personnel assigned to the above functions maintain interfaces with their functional counterparts at DOE-ID.

Reporting to the Manager of ISFSI Management are the FSV ISFSI Manager, the TMI-2 ISFSI Manager, and the Compliance Engineering Lead. Support staff for essential positions within the ISFSI Management department report to the FSV ISFSI Manager for services provided for the FSV ISFSI. The Manager of ISFSI Management also reports to the DOE-ID FSV Facility Director. This interface is the primary operations interface between DOE-ID and its contractor for the FSV ISFSI.

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

##### **9.1.3.1.1. ISFSI Safety Review Committee**

Reporting to and chartered by a senior executive 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 the 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 evaluations for the oil and gas program; to review evaluations in response to leaking FSCs; to review changes to the Technical Specification Bases, SAR, Emergency Response Plan, and Physical Protection Plan; to approve license amendment requests; and to review changes to the 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-ID 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 9.1.4.1 below. Other members may be appointed as considered appropriate by the chartering senior executive.

A quorum shall include 3 core members, the technical disciplines appropriate for the matters under review, and the DOE-ID FSV Facility Director

The DOE-ID FSV Facility Director is informed of all appointments to the Safety Review Committee.

#### **9.1.3.2. Personnel Functions, Responsibilities, and Authorities.**

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

Personnel on site at the FSV ISFSI report to the ISFSI Manager to ensure clear lines of authority. The ISFSI Manager, Facility Safety Officer (FSO), and the Security personnel are routinely stationed at the ISFSI. Other support personnel from the INL are periodically sent to the ISFSI and are either matrixed directly to the ISFSI Manager or the FSO while on site. The ISFSI Manager is responsible for maintaining the Operations log; this log will be used to note the performance of all significant on site activities and conditions not included in the Alarm Station log.

FSV 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.

#### **9.1.4. Personnel Qualification Requirements**

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

- ISFSI QA Manager
- FSV Facility Director and designated alternate

The following contractor positions require minimum qualifications and training for the operation of the FSV ISFSI:

- ISFSI Safety Review Committee members

- Manager of ISFSI Management
- FSV ISFSI Manager and designated alternate
- FSV Facility Safety Officer and designated alternate
- Security personnel
- Certified Fuel Handler
- Quality Assurance manager

#### **9.1.4.1. Minimum Qualification Requirements.**

In all of the positions below where an academic degree is required, the requirement for a degree may be replaced with an additional five years experience in the technical area (but not necessarily at supervisory level) specified for that position (for a total of ten years experience).

The ISFSI QA Manager shall have a minimum of a Baccalaureate degree in an engineering or physical science field and five years experience in nuclear quality assurance and certification as lead auditor. The minimum training for this position shall include 72.48 process, QA program indoctrination, NRC requirements, and the FSV ISFSI License Basis (consisting of the identification of and orientation to the license and design basis documents).

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

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 experience in one or more of the following technical areas at nuclear facilities:

- Radiological Safety
- Nuclear Safety (with at least two years 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 72.48 process, QA program indoctrination, Technical Specifications, NRC requirements, and the FSV ISFSI License Basis.

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

The FSV ISFSI Manager shall have a minimum of a Baccalaureate degree in an engineering or physical science field and five years supervisory experience in nuclear facility operations. The minimum training for this position shall include 72.48 Process, FSV ISFSI License Basis,

Radiological Control Technician, Certified Protection Officer, Emergency Response, and Certified Fuel Handler. The designated alternate for the FSV ISFSI Manager shall meet the same minimum qualifications and training requirements.

The FSV Facility Safety Officer shall have a minimum of a Baccalaureate degree in an engineering or physical science field and five year supervisory experience in nuclear facility operations. The minimum training for this position shall include 72.48 Process, FSV ISFSI License Basis, Radiological Control Technician, Certified Protection Officer, Emergency Response, and Certified Fuel Handler. The designated alternate for the FSV Facility Safety Officer shall meet the same minimum qualifications and training requirements.

Security personnel shall meet the employment suitability and training requirements described in the FSV ISFSI Physical Protection Plan and its addendum, Security Training and Qualification Plan. Security personnel training includes implementation of emergency response duties.

The minimum qualifications for the position of Certified Fuel Handlers are successful completion of required medical examination and training and certification in accordance with the requirements in section 9.3. The minimum qualifications for the position of Certified Fuel Handlers are a high school diploma and successful completion of the biennial medical examination. The position of Certified Fuel Handler requires training and certification in accordance with the requirements in section 9.3.

The minimum qualifications for the QA manager assigned to the FSV ISFSI 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.

#### **9.1.4.2. Qualifications of Personnel.**

The resumes or other appropriate documentation of personnel occupying the positions listed in section 9.1.4.1 will be kept on file to demonstrate compliance with the minimum requirements described in section 9.1.4.1.

#### **9.1.5. Liaison with Outside Organizations**

Arrangements have been made with the following local agencies to provide support services related to ISFSI operations, security, environmental monitoring, and emergency response:

- Platteville Gilcrest Fire Protection District, Platteville, CO (Fire Protection/Ambulance Service)
- North Colorado Medical Center, Greeley, CO (Medical Treatment, Decontamination and Air Ambulance Service)
- Weld County Sheriff's Department, Greeley, CO (Security Assistance)
- Weld County Paramedic Service, Greeley, CO (Ambulance Service)

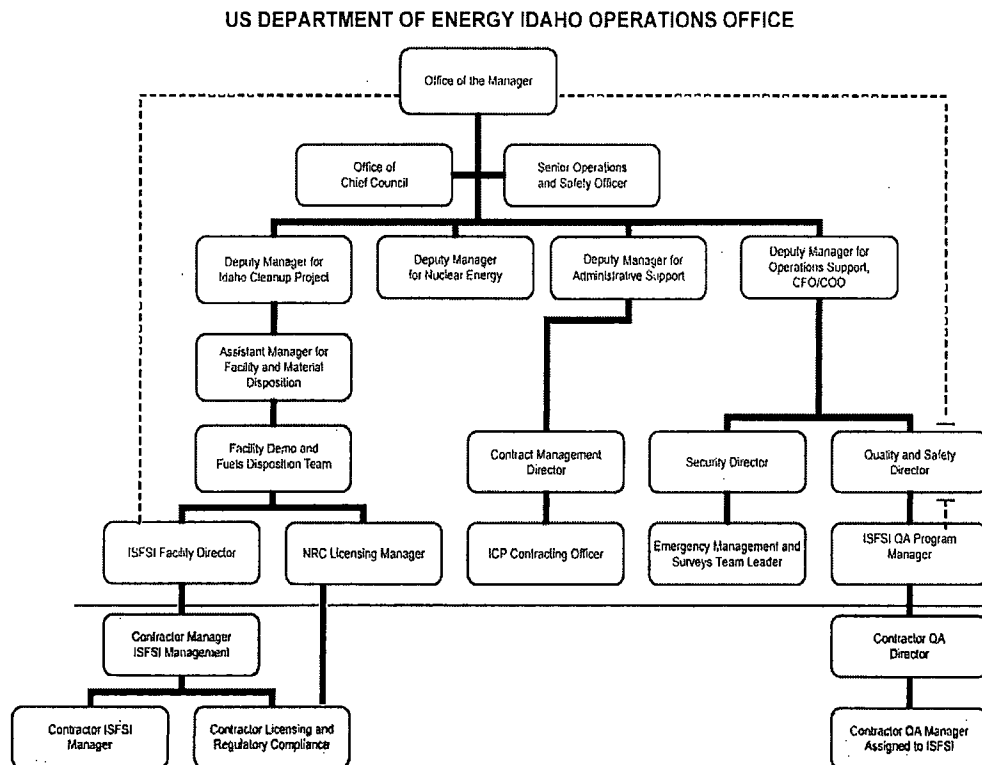


Figure 9.1-1 DOE-ID Organization

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## **9.2 Preoperational Testing Activities**

For the existing, loaded FSV ISFSI, the only preoperational testing will be for the fuel movement.

### **9.2.1. Administrative Procedures for Conducting Fuel Movement**

Training of selected INL personnel will be performed under the direction of FSV ISFSI staff as part of the FSV ISFSI fuel movement preparation program. Approval of procedures, performance of tests, evaluation of test results, and incorporation of any identified improvements (based on the results of the tests) will be performed by the FSV ISFSI contractor.

### **9.2.2. Fuel Movement Program Description**

All maintenance and operations procedures will be used in the training effort to ensure assigned personnel are qualified to commence fuel movement operations. Table top exercises and drills will be used to ensure the technical staff and management are qualified to respond to credible emergencies and security events. An operational demonstration will be used to ensure the operability of FSV ISFSI equipment needed for responding to off-normal operations and accidents.

### **9.2.3. Fuel Movement Discussion**

Implementation of the fuel movement program is discussed in the paragraphs which follow.

All routine maintenance and operation activities will be performed by assigned personnel under the direction of FSV ISFSI staff as a training exercise.

The FSV ISFSI staff will demonstrate spent fuel and container handling capabilities. A shipping cask will be used to remove an empty FSC. These demonstrations will require operation of the MVDS crane, the CHM, and other selected tools and fixtures

### **9.2.4. Component Operational Testing**

To ensure continued operability of the FSV ISFSI MVDS and equipment, procedures describing inspections and functional checks have been developed and approved as procedures in accordance with the FSV ISFSI Quality Assurance Program. Procedures implementing FSV ISFSI Technical Specifications reference the appropriate Technical Specifications. Inspections and functional tests are performed by following these procedures.

Table 9.2-1 lists the component operational tests and when these tests are needed. The vendor specifications for testing of components, systems, and sequences are retained for future use as appropriate for equipment or components replaced. An operational test has been added for Fuel Storage Container to list the requirement to purge and/or sample and analyze the air over the fuel for hydrogen before removing lids or before moving Fuel Storage Containers containing spent fuel.

Table 9.2-1 Component Operational Tests

Component	Test
MVDS Crane	Function check of controls and interlocks for long travel, cross travel, and hoist travel before each day of use.
	Weekly visual check of seismic restraint system to ensure engagement of restraint system.
Standby storage wells	Leak check of containment integrity before use.
SPHD 1	Function check of correct positioning on isolation valve before use.
SPHD 2	Function check of correct positioning on isolation valve before use.
CLUP and charge face isolation valve	Function check of controls and interlocks in conjunction with container handling machine and shield plug handling device before use.
Fuel storage container	Leak test of selected fuel storage containers when in storage position using special shield plug and MVDS leak test equipment every 5 years.
	Purge and/or sample/analyze the gas over the spent fuel to check the concentration of hydrogen before moving a fuel storage container or before removing a lid.



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## **9.3 Training Program**

This section of the SAR comprises DOE's FSV ISFSI Training Program and is submitted pursuant to Subpart I of 10 CFR Part 72. The requirements of this FSV ISFSI Training Program are implemented by contractor procedures providing for the administration of training programs. A management assessment of the contractor's implementation of this training program shall be performed biennially. Changes which do not decrease the effectiveness of this program will be documented with annual SAR updates. Records will be retained for three years when changes are made to this training program without prior NRC approval.

The objective of this FSV ISFSI Training Program is to use a systematic approach to training to provide competent contractor personnel to perform all functions related to the operation and maintenance of the FSV ISFSI. The application of the systematic approach to training will use a graded approach, with the training of Certified Fuel Handlers subject to the most rigorous application.

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.

### **9.3.1. Administration**

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

The FSV ISFSI Manager is responsible for ensuring that training requirements are specified for personnel assigned to support the FSV ISFSI. In this role, the ISFSI Manager or designee will approve all FSV specific lesson plans.

The FSV FSO is responsible for ensuring that training requirements have been satisfied for personnel assigned to the FSV ISFSI.

### **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 Section 9.4.2 below:

- Results of each Certified Fuel Handler's (CFH) biennial medical examination.
- The completed records of certification.

### **9.3.3. Instructor Qualifications and Development**

The contractor shall provide for and document the qualification and training of Training Staff.

### **9.3.4. Development of Training Material**

The 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, boards, performance demonstration, etc.) The development of

training material shall be performed by qualified and trained staff. The contractor shall maintain all training materials, both academic lesson plans and On-the-Job training (OJT) guides, developed in accordance with this training program.

#### **9.3.5. Training Improvement**

The 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.

#### **9.3.6. Waivers of Training Requirements**

Applications for waivers of training requirements shall be approved by the FSV ISFSI Manager or designee. Successful completion of equivalent training programs may be used as a basis for waiver from academic training requirements. This training should be comparable in content, performance criteria, and duration. Any information used in the evaluation for a waiver should be verified. Previous work experience may be used as a basis for waiver from OJT requirements.

#### **9.3.7. Frequency of Training**

Training requirements must be completed within the period specified in the sections below for General Employee Training and Certified Fuel Handlers 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.

#### **9.3.8. General Employee Training**

General employee training will be provided to ISFSI certified fuel handlers and their direct supervision. Topics required for certified fuel handlers may be included in the generalized training.

The GET training program is composed of an initial training course and required annual retraining.

A score of <80% on the examination will require a retest. Individuals who write or review lesson plans or tests are excused from taking GET exams.

The GET course shall consist of material dealing with:

- Physical description of the FSV ISFSI (structural characteristics).
- Heat transfer design considerations, including engineering principles of passive cooling.
- Applicable regulations and standards.
- Radiological shielding.
- General FSV ISFSI information on building alarms, and access control.
- Emergency response.
- 10 CFR 19.12.

The annual retraining for GET will be composed of the topics covered in the Initial GET course. Additional topics may be added as needed.

### **9.3.9. Certified Fuel Handler Training**

Detailed CFH and direct supervision training will be provided for the operations described in Section 5.1. CFH certifications are required for personnel performing and directly supervising fuel handling and transfers. (An exception is for uncertified personnel undergoing on-the-job training acting under the direct observation of certified personnel.)

The training for ISFSI personnel shall provide for initial testing of persons who operate equipment identified as Important to Safety and will also provide for retraining, proficiency testing, and requalification for ISFSI personnel as required. Certified Fuel Handlers will be actively maintained as necessary for the life of the ISFSI.

FSV ISFSI 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.

Instructors designated to teach the CFH Certification Program shall possess a current CFH certification or sufficient subject matter expertise for a particular subject or topic. Instructors initially qualified will maintain qualifications by instructing classes, and administering or grading examinations and OJT guides, and preparing, reviewing, or revising CFH instructional material.

The CFH Training Program will consist of lesson plans and associated examinations in, but not limited to, the following topics, as applicable to personnel job functions:

- Fuel Characteristics
  - elementary nuclear theory
  - fuel element description/identification
  - fuel storage configuration
- Equipment, Component, and Design Description
  - crane
  - transfer cask load/unload port
  - isolation valves
  - shield plug handling devices
  - charge face/standby storage wells
  - container handling machine
  - fuel storage containers
  - utility supplies and systems ventilation system
  - equipment operational interlocks
  - shipping cask
- Regulations, Procedures, and Limitations

- administrative control of CFH actions
- description of events and sequence of fuel handling operations
- identified applicable procedures and regulations including normal, emergency, and 10 CFR Part 72 related
- Technical Specifications
- Accident Analysis, Emergency Systems, and Safety Devices
  - accident analysis from the FSV ISFSI SAR for off normal operations and accidents.
  - confinement barriers/systems
  - FSV ISFSI cooling, equipment and instrumentation
  - criticality prevention
- Radiological Protection
- General Organization

The CFH Training Program will include operational training (OJT) involving actual and/or mock control manipulations of the following:

- Container handling machine
- Isolation valves
- Shield plug handling devices
- Cask load/unload port
- Crane.

Manipulations will include CFH responses, instrumentation, indications, abnormal situations, corrective measures, alarms and annunciators, prerequisites, and procedures. Actual manipulation and operations are preferred to mock manipulations to the extent practicable based upon equipment availability.

The content of the recertification program will be determined prior to each annual recertification training. All OJT will be repeated biennially and approximately half of the total will be performed annually for recertification. The classroom material and written examinations associated with the OJT will be presented and completed prior to the OJT. Based on a job and task analysis, some parts of the training are identified as [pre-train] items. Training on pre-train items is only completed prior to doing the task. Additionally, classroom material will be presented as needed in order to convey pertinent modifications, procedure changes, regulatory changes, or other significant material in a timely manner.

Certification as a FSV ISFSI CFH is contingent upon meeting the following criteria: obtaining a score of  $\geq 80\%$  on all CFH academic examinations; and satisfactory performance of all OJT practical evaluations. A score of  $< 80\%$  on any CFH academic examination will require retesting. A score of  $< 80\%$  on the retest will constitute cause for dismissal from the CFH Training Program. A score of  $< 80\%$  on any three initial academic examinations will constitute

cause for dismissal from the CFH Training Program. Failure to demonstrate satisfactory performance of the OJT practical examinations will require retesting. Failure to demonstrate satisfactory performance of a second OJT practical examination will constitute cause for dismissal from the CFH Training Program.

The evaluation criterion for initial certification of CFHs shall not be waived; nor shall the evaluation criterion be waived for two or greater consecutive recertification cycles.

The physical condition and general health of certified personnel will be verified by physical examination before initial certification and biennially thereafter. These physical examinations consider conditions which might cause impaired judgement 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.

#### **9.3.10. Technical Support Positions**

Training for the applicable support positions will include the administrative and management controls associated with ensuring compliance with the FSV ISFSI license conditions.

## **9.4 Normal Operations**

### **9.4.1. Procedures**

Detailed written procedures have been developed and maintained for the ISFSI operations, maintenance, surveillance, and testing described in Section 5.1. These procedures constitute the "procedures described in the SAR" associated with the requirements of 10 CFR 72.48.

The format and content of written procedures include

- purpose, scope, and applicability
- limitations and precautions
- prerequisites
- personnel (number and function) and equipment required
- detailed instructions (sequence, forms to be completed, acceptable conditions, actions if conditions aren't acceptable, records generated, approvals)

In addition, the periodic check of the metallic O-ring integrity incorporates the requirements of Section 11.11.

Maintenance of the written procedures is in accordance with Sections 11.5 and 11.6 as implemented by established INL management control procedures. The INL document control system provides written requirements for review, approval, revision, and controlled distribution of the written procedures.

### **9.4.2. Records**

The following FSV ISFSI records are maintained:

- QA records relating to design, construction, testing, surveillance, operation, and maintenance of the ISFSI
- Decommissioning records
  - Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site.
  - As-built drawings and modifications of structures and equipment in restricted or inaccessible areas.
  - A list contained in a single document of all areas designated and formerly designated as restricted areas and all areas outside of restricted areas that require documentation due to spread of contamination.
  - Records of the cost estimate performed for decommissioning.
- Security records
  - Records of changes to the Physical Protection Plan made without prior NRC approval
  - The Physical Protection Plan and the Safeguards Contingency Matrix
  - Other security records as specified in the Physical Protection Plan

- Training and certification/qualification records as specified by minimum training requirements in (Section 9.1.4.1 and 9.3)
- Changes, Tests and Experiments made without prior NRC approval, including the safety evaluations
- Spent fuel material records, including current inventory and material control and accountability procedures
- Emergency preparedness records as specified in the FSV ISFSI Emergency Response Plan
- ISFSI Safety Review Committee records
- Environmental monitoring records as specified in the FSV ISFSI Radiological Environmental Monitoring Program
- Records required by the operating, maintenance, and testing procedures described in Section 9.4.1

Copies of selected records are maintained at the FSV ISFSI Administration Building to facilitate interface with outside organizations. The records are maintained at the INL Idaho Falls Records Center in accordance with storage requirements



## **9.5 Emergency Planning**

The FSV ISFSI Emergency Planning requirements are maintained in the FSV ISFSI Emergency Response Plan (ERP). The ERP does not cover detailed security related planning for the ISFSI. These events are accounted for in the FSV ISFSI Physical Protection Plan.

It has been determined that radiological consequences (see Section 8 for accident analyses) at the ISFSI will not exceed ALERT criteria. While no off-site emergency centers are necessary due to the projected radiological consequences, the following DOE resources are available in an emergency: (1) the INL WCC, (2) engineering and technical analysis personnel at the INL, and (3) radiation protection and dose assessment personnel from the INL or DOE Region 6 Radiological Assistance Program. Specific ISFSI emergency planning requirements have been identified in the ISFSI ERP.

Emergency plan exercises are conducted biennially at the FSV ISFSI, in accordance with the ERP.

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## **9.6 Decommissioning Plan**

The proposed Decommissioning Plan, developed in accordance with NRC Regulatory Guide 3.65 (Ref. 2) and NUREG- 1757 (Ref. 3), describes the FSV Facility decommissioning activities and funding method to demonstrate that it can be safely and effectively decommissioned. The DOE will provide funding for decommissioning.

To facilitate decommissioning, the records required by 10 CFR 72.30(d)(1) through 72.30(d)(3) will be maintained as quality records until decommissioning is complete and the FSV Facility license is terminated.

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## **9.7 Physical Protection Plan**

The purpose of the FSV ISFSI physical protection program is to establish and maintain a physical protection program that has the capabilities for the protection of spent fuel stored in the MVDS, in accordance with Subpart H, "Physical Protection," of 10 CFR Part 72 and applicable portions of 10 CFR Part 73.

The FSV ISFSI physical protection program is described in the Physical Protection Plan for the FSV ISFSI. This plan includes, as appendices, the FSV ISFSI Security Training and Qualification Plan, the Security Contingency Plan, and the Threat Analysis & Design for Physical Protection.

The FSV ISFSI Physical Protection Plan contains Safeguards Information, is controlled and protected in accordance with 10 CFR 73.21 (Ref. 4) and 10 CFR 2.790 (Ref. 5), and has been submitted for NRC review under separate cover.

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## 9.8 Aging Management Program

An assessment of the FSV ISFSI inspection and monitoring activities identified an existing activity necessary to provide reasonable assurance that a FSV ISFSI component within the scope of license renewal will continue to perform its intended functions consistent with the current licensing basis for the renewal period. The FSV ISFSI Aging Management Program involves monitoring the exterior surface of the MVDS concrete. It includes visual inspection of the accessible concrete (including below grade concrete, if exposed during excavation) and any exposed steel embedments and attachments. It also includes monitoring the area radiation and loose surface contamination levels at selected areas of the FSV ISFSI. Although this is primarily a condition monitoring program, it also includes preventive actions such as a weekly surveillance to ensure MVDS cooling inlet and outlet screens are not obstructed.

Subsequent to the aging management reviews conducted to support the license renewal application, a number of technical procedures used for the inspection and maintenance of several in-scope SSCs (FSC, SS, SSW, CHM Raise/Lower Mechanism, CHM FSC Grapple, CFS Structural Steel, CLUP, and MVDS Structural Concrete) have been enhanced to include more comprehensive inspection criteria, remote video inspection, tracking and trending of aging conditions, increased inspection frequencies, documentation, engineering evaluations and compliance with GEC Alstom specifications. DOE-ID will implement all measures and enhanced procedures recommended in the aging management reviews and as committed in the response to the Request for Additional Information (RAI) following the license renewal application (Ref. 6). Inaccessible areas of the vaults that can be remotely inspected will be visually inspected every 10 years to assess FSC, SS, CFS underside (vault ceiling), and vault wall and floor surfaces for signs of degradation.

Additional commitments in the response to the RAI include repair and/or additional inspection of concrete and metal conditions exceeding second tier-criteria, as well as development of a concrete inspector training and qualification program in accordance with ACI 349.3R-02 (Ref. 7). These additional commitments will be completed prior to the next MVDS concrete inspection scheduled for June 2014.

A Time Limited Aging Analysis for the SSW indicates a wall thickness of 0.372 inches will remain after 50 years of atmospheric exposure. This thickness exceeds the minimum wall thickness of 0.0095 inches specified in the GEC Alstom design calculation for SSW tube corrosion allowance. Although any further loss of material due to corrosion on the internal surfaces of the SSW is not an aging effect requiring management during the license renewal period, the seal integrity of the SSWs will be periodically tested.

The gas inside one FSC in each of the six vault modules will be sampled for hydrogen no later than June 2015. The FSCs selected will be the same six FSCs scheduled for seal leak testing.

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## 9.9 References

1. 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste."
2. US Nuclear Regulatory Commission (2008), Regulatory Guide 3.65, "Standard Format and Content of Decommissioning Plans for Materials Licensees"
3. US Nuclear Regulatory Commission (2006), NUREG-1757, "Consolidated Decommissioning Guidance: Decommissioning Process for Materials Licensees," Revision 2
4. 10 CFR Part 73, "Physical Protection of Plants and Materials."
5. 10 CFR Part 2, "Rules of Practice for Domestic Licensing and Issuance of Orders."
6. Docket No. 72-79 Response to Nuclear Regulatory Commission Request for Additional Information on the Fort St. Vrain Independent Spent Fuel Storage Installation Site Specific License (EM-FMDP-10-055), June 9, 2010
7. American Concrete Institute, 349.3R-02, Evaluation of Existing Nuclear Safety Related Concrete Structures, 2002

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## **11. QUALITY ASSURANCE**

The Quality Assurance Program that was used for the design, construction, and initial fuel loading of the FSV ISFSI was based upon the NRC approved PSCo FSV Nuclear Generating Station Quality Assurance Program that was in effect at the time. This Quality Assurance Program was applicable for those systems, structures and components which were determined to be important to safety as defined in Section 3.4 of this SAR. In addition, PSCo extended certain aspects of the Quality Assurance Program, under the designation Enhanced Quality, to encompass systems, structures and components considered important to the operation of the ISFSI. These items also are defined in Section 3.4 of this SAR. PSCo implemented a modified ISFSI Quality Assurance Program, approved by the NRC, for long term operation of the ISFSI.

DOE-ID applies the Quality Assurance Program described in this chapter of the SAR to long-term ISFSI operations and decommissioning activities.

### **11.0. Quality Assurance**

It is the policy of DOE-ID to ensure that the FSV ISFSI and the spent nuclear fuel stored there is handled, shipped, stored, inspected, tested, operated, maintained, modified, and decommissioned in a manner that ensures the health and safety of workers and the public and protects the environment. The Quality Assurance Program for the FSV ISFSI is developed to confirm that essential technical and quality requirements for structures, systems, and components important to safety are satisfied and documented. The FSV ISFSI may optionally apply greater rigor to quality requirements implementation, in whole or in part, to non-quality related portions, as may be deemed appropriate, by DOE-ID, for the FSV ISFSI's continued reliable operation.

DOE-ID maintains full responsibility for the development and execution of the 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 FSV ISFSI Quality Assurance Program is maintained to satisfy the requirements established in 10 CFR 72, Subpart G, "Quality Assurance."

The quality assurance program for DOE spent fuel storage and transportation activities is the DOE's Office of Civilian Radioactive Waste Management's Quality Assurance Requirements and Description, DOE/RW-0333P, Revision 10 (QARD) (Ref. 1). The contents of the QARD are listed in Table 11.0-1. For FSV ISFSI activities, DOE-ID and its contractor will apply applicable portions of the QARD to systems, structures and components 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 FSV 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 significantly reduce the effectiveness of quality assurance program will be submitted to the NRC for its review and acceptance prior to implementation.

The FSV 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 FSV 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. Structures, systems and components which are not important to safety have the Quality Assurance Program applied in a graded approach.

**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	3-3-97
7.0	Control of Purchased Items and Services	4	4-28-97
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

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### 11.1. Organization

The following is the organizational philosophy of the FSV 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 contractor. To exercise its ultimate responsibility, DOE-ID will:

- Retain responsibility for and perform independent assessments of the contractor's ISFSI quality assurance program
- Ensure that the license conditions for the facility are included in the contractor's contract
- Assess the performance of the contractor against the terms of its contract
- Retain the responsibility to budget funds necessary and sufficient to safely operate the facility
- Retain the authority to revise the contract in the event 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, directs the contractor's quality assurance organization during the operation and decommissioning of the FSV ISFSI and 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 subtier 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 conditions adverse to quality is assigned to the Manager of DOE-ID. Contractor stop work authority resides with the CWI QA Director.

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. Quality Assurance 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 FSV ISFSI are provided below.

#### **11.1.1. The Office of the Manager**

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

#### **11.1.2. Deputy Manager for Idaho Cleanup Project**

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

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

- Planning and meeting product quality requirements and implementing the Quality Assurance Program in their work
- Retaining responsibility for delegated work
- 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
- Recommending work to be stopped when significant conditions adverse to quality are identified.

#### **11.1.3. Deputy Manager for Operations Support**

The responsibility for developing the appropriate revisions to the contractor's contract with DOE-ID is delegated to the Deputy Manager for Administrative Support.

The DOE-ID Deputy Manager for Operations Support 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 Deputy Manager for Operations Support to the Quality and Safety Director. The Quality and Safety Director delegates the responsibility for QA oversight of the ISFSIs to the ISFSI Quality Assurance (QA) Manager. The management responsibilities of the ISFSI QA Manager are herein defined.

The ISFSI QA 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 QA Manager has the organizational freedom to communicate with senior management and is sufficiently independent from cost and schedule considerations.

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

- Developing, reviewing, approving, issuing, and maintaining the DOE-ID's implementing procedures
- Verifying that the Quality Assurance Program is properly established and executed
- 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
- Ensuring Quality Assurance training and qualification programs are developed for DOE-ID and contractor personnel who perform quality affecting activities.
- Develop, manage, update, and implement a Quality Assurance Audit Plan and schedule, and coordinate NRC participation in audit activities
- Identifying quality problems; initiating, recommending, or providing solutions to quality problems; and verifying the implementation of solutions to quality problems
- Determining the cause of significant conditions adverse to quality and ensuring that corrective action is initiated for all conditions adverse to quality
- Accepting final resolution for all DOE-ID audit findings and proposed corrective actions
- Initiating stop work orders within the license oversight program, when required
- Receiving and compiling Quality Assurance information and forwarding Quality Assurance program status reports to management

- Interfacing with NRC to coordinate and clarify NRC Quality Assurance requirements, the Quality Assurance Program, and to resolve Quality Assurance issues to NRC requirements
- Interfacing with NRC to coordinate plans and schedules relevant to Quality Assurance for NRC overview of licensing activities
- Being responsible for interpreting and approving Quality Assurance Program requirements as they apply to the contractor's scope of work
- Assignment of the Quality Assurance Specialist (QAS) staff.

#### **11.1.4. 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 QA 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. 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 DOE-ID Office of the Manager.

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

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## 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 QA 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 QA 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 the QARD Section 2.0, Quality Assurance Program, that are implemented are:

2.2.1 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.

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### 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:

- Specifying design inputs
- Correct translation of inputs in design documents
- Sufficient documentation which entails verification that design outputs relate to design inputs
- Verification of design by persons other than the originator
- 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 the QARD Section 3.0, Design Control, that are implemented 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.

### 3.2.9 Design Interface Control

Provides criteria for controlling design interfaces.

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## 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:

- Quality requirements are correctly stated, inspectable, and controllable
- There are adequate acceptance and rejection criteria
- 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 the QARD Section 4.0, Procurement Document Control, that are implemented are:

### 4.2.1 Procurement Document Preparation

Describes necessary provisions for issued procurement documents.

### 4.2.2 Procurement 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 QA Manager participates in and monitors program execution of these implementing documents related to program quality affecting activities. Periodically the ISFSI QA 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 the QARD Section 5.0, Implementing Documents, that are implemented 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 can not 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:

- Design specifications
- Design and fabrication drawings
- Procurement documents
- Quality Assurance Program manuals
- Design criteria documents
- Fabrication, inspection, and testing instructions
- 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 instructions, procedures, specifications, drawings, and procurement documents. 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 the QARD Section 6.0, Document Control, that are implemented 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 and engineering groups participate in the evaluation of those suppliers providing critical 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:

- 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
- A review of previous records and performance of suppliers who have provided similar articles of the type being procured
- 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:

- Documentation that identifies the purchased material or equipment and the specific procurement requirements (e.g., codes, standards, and specifications) met by the items

- 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 the QARD Section 7.0, Control of Purchased Items and Services, that are implemented 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.

#### 7.2.12 Commercial Grade Items

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

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## 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 the QARD Section 8.0, Identification and Control of Items, that are implemented 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.

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## 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 the QARD Section 9.0, Control of Special Processes, that are implemented 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.

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## 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:

- Identification of characteristics and activities to be inspected
- Identification of the individuals or groups responsible for performing the inspection operation
- Acceptance and rejection criteria
- A description of the method of inspection
- Recording evidence of completing and verifying a manufacturing, inspection, or test operation
- 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-ID'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 the QARD Section 10.0, Inspection, that are implemented 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:

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

Written test procedures incorporate and reference:

- The requirements and acceptance limits contained in applicable design and procurement documents
- Instructions for performing the test
- Test prerequisites
- Mandatory inspection hold points
- Acceptance and rejection criteria
- 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 the QARD Section 11.0, Test Control, that are implemented 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 the QARD Section 12.0, Control of Measuring and Test Equipment, that are implemented 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 the QARD Section 13.0, Handling, Storage, and Shipping, that are implemented 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.

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### **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 the QARD Section 14.0, Inspection, Test and Operating Status, that are implemented 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.

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### 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:

- Identify the nonconforming item
- Describe the nonconformance, the disposition of the nonconformance, and the inspection requirements
- 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 the QARD Section 15.0, Nonconformances, that are implemented 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 DOE-ID ISFSI QA 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's 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 DOE-ID's ISFSI QA 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 the QARD Section 16.0, Corrective Action, that are implemented 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, personnel training and qualification records of 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 the QARD Section 17.0, Quality Assurance Records, that are implemented 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 QA Manager will be planned, performed, and reported by trained and qualified personnel in accordance with implementing procedures. 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 FSV 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 the QARD Section 18.0, Audits, that are implemented 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.

### 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.

#### 18.2.16 Lead Auditor Communication Skills

Requires that lead auditors have effective communications skills.

#### 18.2.17 Lead Auditor Training

Provides criteria for training lead auditors to attain proficiency.

#### 18.2.18 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.

#### 18.2.19 Lead Auditor Examination

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

#### 18.2.20 Certification of Lead Auditor Qualifications

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

#### 18.2.21 Maintaining Lead Auditor Proficiency

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

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## **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 ensure implementation and adequacy.

DOE-ID's contractor is assigned implementation authority 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 QARD.

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

#### **I.2.1 General Software Requirements**

Provides requirements that apply generally to software.

#### **I.2.2 Software Planning**

Provides requirements for and contents of software plans.

#### **I.2.3 Software Life Cycle Requirements**

Provides software life cycle criteria for developed or modified software.

#### **I.2.4 Software Configuration Management**

Provides criteria for software configuration management to include configuration identification, configuration control, and status accounting.

#### **I.2.5 Defect Reporting and Resolution**

Provides criteria for software defect reporting and resolution which shall be integrated into the software configuration management system.

#### **I.2.6 Software Procurement**

Stipulates the flowdown of software requirements to other organizations developing and supplying software under contract.

#### **I.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.

#### **I.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 FSV ISFSI. Scientific samples taken, handled, or recorded for any purpose in order for the FSV 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 FSV ISFSI. The facility is passive and its only function is SNF storage.

#### **11.19.4. Field Surveying (QARD, Supplement IV)**

Field surveying practices are not applicable to the FSV ISFSI. The facility construction location is pre-established and identified in existing documents. The FSV 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 ensure 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 establish and 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 the QARD Supplement V, Control of the Electronic Management of Data, that are implemented 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 FSV ISFSI. The facility does not produce High-Level Waste in any form. The FSV ISFSI is a passive facility.

#### **11.19.7. Storage and Transportation (QARD, Appendix B)**

The Licensee and the contractor do not directly design or fabricate storage casks, transportation casks, or multi-purpose canisters.

#### **11.19.8. Monitored Geological Repository (QARD, Appendix C)**

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

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## **11.20. References**

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

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