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## Quality Assurance Program Plan

# ISFSI Management

Idaho Cleanup Project

The Idaho Cleanup Project is operated for the
U.S. Department of Energy by CH2M•WG Idaho, LLC

| QUALITY ASSURANCE PROGRAM PLAN FOR ISFSI MANAGEMENT | Identifier: PLN-466<br>Revision*: 21<br>Page: **1** of 23 |
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# BACKGROUND

In the performance of the NRC licensed facilities activities at the Fort St. Vrain (FSV) Independent Spent Fuel Storage Installation (ISFSI), the Three Mile Island Unit-2 (TMI-2) ISFSI, and the Idaho Spent Fuel Facility (ISFF), the licensee (DOE-ID) and the contractor for the Idaho Clean-Up Project, are required to comply with NRC licenses SNM-2504, SNM-2508, and SNM-2512. The NRC licenses specify the use of applicable portions of DOE/RW-0333P, *Quality Assurance Requirements and Description* (QARD), revision 10, as the baseline standard for developing and implementing a quality assurance program for the NRC licensed activities to confirm that essential technical and quality requirements are achieved and documented, for structures, systems, and components that are important to safety.

This Quality Assurance Program Plan (QPP) describes how the DOE/RW-0333P requirements are implemented by CH2M-Washington Group Idaho, LLC (CWI) for the FSV, the TMI-2, and the ISFF ISFSIs, within the Idaho Cleanup Project. Activities of DOE-ID are addressed separately unless otherwise described in this QPP.

# 1. PURPOSE AND SCOPE

## 1.1 Purpose

The Quality Assurance Programs (QAPs) forming the bases for this Quality Program Plan (QPP) are the QAPs for the Fort St. Vrain (FSV) Independent Spent Fuel Storage Installation (ISFSI), the Three Mile Island Unit 2 (TMI-2) ISFSI, and the Idaho Spent Fuel Facility (ISFF) ISFSI. Each ISFSI QA Program is defined in Chapter 11 of the respective Safety Analysis Report (SAR) and, incorporate by reference into the SAR several sections of DOE/RW-0333P Quality Assurance Requirements and Description (QARD) Revision 10.

This QPP describes how the FSV QAP, the TMI-2 QAP, and the ISFF QAP are implemented by the ISFSI Management department. Because the QAP for the TN-FSV cask, as defined in QAP Approval 71-0786, is also QARD Revision 10 and because the ISFSI Management manages the TN-FSV cask, this QPP also describes how the TN-FSV cask QAP is implemented by the ISFSI Management department.

Section 5 documents the QARD requirements that must be used in the development of implementing procedures and in the flow-down of requirements to matrix organizations (through intra-company agreements) or to subcontractors (through contracts). QARD clarifications and statements of applicability and exception are also documented in Section 5.

Section 6 provides a matrix listing the requirement sections of the QARD and the corresponding implementing documents.

It is the policy of DOE-ID and the ISFSI Management department to ensure that the ISFSIs and their components are designed, constructed, handled, shipped, stored, cleaned, assembled, inspected, tested, operated, maintained, modified, and decommissioned in a manner that assures the health and safety of workers and the public and protects the environment. It is the policy of ISFSI Management to comply with the ISFSI QA Program as directed in POL-110, "Quality Assurance Policy."

## 1.2 Scope

This QPP applies to systems, structures, and components (SSCs) and associated activities that are important to safety for the FSV ISFSI, the TMI-2 ISFSI, and the ISFF ISFSI. 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 associated with items that are important to safety. SSCs which are not important to safety have the QAP applied in a graded approach commensurate with their importance to safety.

This QPP also applies to the TN-FSV cask as described in Certificate of Compliance 71-9253 and in the SAR and drawings identified on the Certificate.

## 1.3 Change Control

Changes to the FSV or the TMI-2 QAPs, or revision of the QARD incorporated therein shall be evaluated for change in program effectiveness in accordance with TS 5.5.2 and company implementing procedure. (The Technical Specification number is the same for both ISFSIs.) Changes determined not to be a decrease in effectiveness may be made without NRC approval. Changes determined to be a decrease in effectiveness or changes to the ISFF QAP will require NRC review and approval before they are incorporated into the respective QAPs.

The program owner for the FSV, TMI-2, and ISFF ISFSIs QAPs is the DOE-ID ISFSI QA Manager. The DOE-ID ISFSI QA Manager is responsible for interpreting and approving QAP requirements as they apply to the ICP contractor's scope of work. Therefore, changes to this QPP shall be approved by the DOE-ID ISFSI QA Manager.

Section 2.2.1.C.3 of the QARD requires updates to the implementing procedures matrix. The ISFSI Management department is responsible for maintaining the implementing procedures matrix and has agreed to review and update it at least annually.

## 1.4 Interfacing Programs

The Part 21 program for evaluating deviations and violations and reporting defects and failures to comply interfaces with the QA Program in Procurement Document Control, Nonconformances, and Corrective Action.

The 72.48 Program for screening and evaluating changes to the licensed facilities and their procedures interfaces with the QA Program in Design Control and Document Control.

# 2. QA PROGRAM CODES, STANDARDS, AND REGULATIONS

The FSV ISFSI QAP (in Chapter 11 of the FSV ISFSI SAR), the TMI-2 ISFSI QAP (in Chapter 11 of the TMI-2 ISFSI SAR), the ISFF ISFSI QAP (in Chapter 11 of the ISFF ISFSI SAR), and the QAP for the TN-FSV cask (as identified in QAP Approval 71-0786) incorporate substantial portions of the QARD for quality assurance requirements. All implementing procedures and documents used for activities within the scope of this QPP must meet the program requirements.

The ISFSI QAPs are required to meet the requirements of 10 CFR Part 72, Subpart G, "Quality Assurance." The TN-FSV cask QAP is required to meet the requirements of 10 CFR Part 71, Subpart H, "Quality Assurance."

Revisions of the QARD to be incorporated into the ISFSI QAPs shall be reviewed and evaluated for changes in program effectiveness as described in Section 1.3. Revisions of the QARD to be incorporated into the TN-FSV QAP must be approved by the Nuclear Regulatory Commission in a revision to QAP Approval 71-0786.

Codes, standards, and regulations related to the design and construction of the FSV ISFSI and the TMI-2 ISFSI are identified in the respective ISFSI SARs.

# 3. ORGANIZATIONAL RESPONSIBILITIES

The ISFSI Management organization is responsible for all activities at the FSV, TMI-2, and ISFF ISFSIs. Lines of authority, responsibility, and communication shall be defined and established by the Manager, ISFSI Management with the use of organizational charts or descriptions and employee position descriptions. Changes to the organizational chart are issued by the Manager, ISFSI Management.

## 3.1 Manager, ISFSI Management

The Manager, ISFSI Management has overall responsibility for implementing quality assurance requirements (QAP execution) for the FSV, TMI-2, and ISFF ISFSIs. The Manager, ISFSI Management has delegated work to positions described in this section and to other organizations. The Manager, ISFSI Management retains overall responsibility for the delegated work.

ISFSI Management personnel have specific quality program responsibilities cited below.

### 3.1.1 FSV ISFSI Manager

Reports to the Manager, ISFSI Management and is responsible for implementing quality assurance requirements for the FSV ISFSI and the TN-FSV cask.

### 3.1.2 TMI-2 ISFSI Manager

Reports to the Manager, ISFSI Management and is responsible for implementing quality assurance requirements for the TMI-2 ISFSI.

### 3.1.3 ISFF ISFSI Manager

Reports to the Manager, ISFSI Management and is responsible for implementing quality assurance requirements for the ISFF ISFSI.

### 3.1.4 ISFSI Management Staff

Quality program responsibilities are assigned to ISFSI Management staff, both direct and matrixed. Organizational positions may be filled by more than one person. Qualifications and training shall be ensured before quality-affecting work is accepted by the ISFSI Management organization. Personnel performing quality affecting work for the ISFSIs will be identified; the qualifications and training for quality affecting positions will be determined and implemented in accordance with the procedures identified in the matrix.

Personnel outside the ISFSI Management organization may participate in quality-affecting activities. However, the ISFSI Management organization retains overall responsibility for the delegated work. Some of these personnel performing quality-affecting work are part of the companywide infrastructure involved in establishing QAP-implementing administrative procedures, document control, records, and procurement. These positions may be determined to be quality-affecting without needing training or qualification specific to NRC operations or the QAP.

The individuals who train the operating staff, carry out health physics, or perform quality assurance functions may report to the ISFSI Manager or the ISFSI Management department manager; however, these individuals have sufficient organizational freedom to ensure their independence from operating pressures.

## 3.2 QA Manager

The QA Manager has responsibility for development, management, and implementation of the company QAP. As part of this responsibility, the QA Manager ensures that other subtier QAPs meet all applicable requirements of the QARD for their scope of work. The QA Manager assigned to the FSV ISFSI, the TMI-2 ISFSI, and the ISFF ISFSI is assigned this responsibility.

The QA Manager assigned to the FSV ISFSI, the TMI-2 ISFSI, and the ISFF ISFSI reports to a level equal to or above the reporting level of the Manager, ISFSI Management. The QA Manager also reports to the DOE-ID ISFSI Management QA Manager. The QA Manager is responsible for establishing the QAP and for assuring QA program requirements performed by quality assurance management and staff are achieved. These responsibilities are associated with maintenance of the QA Program, QA Program information management, and qualification and training of QA Program personnel.

The QA Manager:

A. Is at the same organizational level as the Manager, ISFSI Management

B. Is sufficiently independent from cost and schedule considerations

C. Has organizational freedom to effectively communicate with other senior management positions

D. Is responsible for interpreting and approving QA program requirements as they apply to ISFSI Management's scope of work

E. Has no other assigned responsibilities unrelated to the QA program that prevents full attention to QA matters

F. Is responsible for identifying quality problems, initiating, recommending, or providing solutions to quality problems, and verifying solutions to quality problems

G. Is responsible for verifying the proper establishment and execution of the QA Program

H. Has the authority to stop work when significant conditions adverse to quality warrant such action.

Item (D) above is also the responsibility of the DOE-ID ISFSI QA Manager. Interpretations of QAP requirements shall be performed as part of the QA Manager's interface with the DOE-ID ISFSI QA Manager.

The individuals who perform quality assurance functions may report to the appropriate operations manager; however, these individuals shall have sufficient organizational freedom to ensure their independence from operating pressures.

## 3.3 Company Organizational Interfaces

Authorities are delegated from, and resources are provided by DOE contractor senior management to manage the FSV ISFSI, the TMI-2 ISFSI, and the ISFF ISFSI for emergency preparedness, environmental protection, operations, maintenance, quality assurance, radiological control, safety and health, security, training, and transportation. The DOE contractor organizational structure provides the necessary independence for quality assurance. The company organizational interfaces are indicated in organizational descriptions maintained by the company.

## 3.4 DOE Organizational Interfaces

The **FSV, TMI-2, and ISFF Facility Director** interfaces directly with the Manager, ISFSI Management.

The **DOE-ID ISFSI Quality Assurance Manager** interfaces directly with the QA Manager assigned to the FSV ISFSI, the TMI-2 ISFSI, and the ISFF ISFSI.

## 3.5 NRC Interfaces

The Nuclear Regulatory Commission interfaces with the DOE contractor ISFSI Management department through DOE personnel. However, this interface expectation is not intended to interfere with NRC inspector access to facilities, records, and workers; and this interface expectation is not intended to interfere with company worker access to NRC inspectors. (Reference 10 CFR 19.14 and 19.15.)

# 4. ASSOCIATED PROGRAM DOCUMENTS

None

# 5. QUALITY PROGRAM ELEMENTS

## 5.1 QARD Clarifications and Statements of Applicability and Exception

Certain QARD clarifications and statements of applicability and exception are necessary. Many of the clarifications and statements of applicability and exception are due to organization differences between the Yucca Mountain project (with the goal to construct and operate a geologic repository) and the ISFSI Management department (with the goal to operate NRC regulated ISFSIs). All clarifications and statements of applicability and exception are described and justified below.

Only selected "Requirements" subsections of the QARD are incorporated into the three ISFSI QAPs. Therefore, only clarifications and statements of applicability and exception to the "Requirements" subsections are provided within this QPP.

## 5.2 Stop-Work Authority and Dispute Resolution

### 5.2.1 Stop-Work Authority

The ICP contractor maintains a process for stopping work or shutting down an operation or facility whenever a safety, environmental, radiological, operational, or quality deficiency is noted which warrants such action. Every employee has the obligation to stop work for safety-related reasons, and the responsibility to perform work in a quality manner at all times. During routine activities the QA professionals resolve issues with the ISFSI Management organization. Formal independent stop-work authority for significant conditions adverse to quality related to ISFSI Management activities is assigned to the ICP QA Manager. This authority and the process are defined in the ICP contractor's implementing documents listed in Section 6.

**Clarification:** DOE/RW-0333P Section 16, Paragraphs 16.2.4.C.2 describes lifting and closing stop work orders. **If DOE issues a stop work order, DOE concurrence will be obtained prior to restart.**

### 5.2.2 Dispute Resolution

Differences of opinion involving QA program requirements or activities are brought to the attention of appropriate management and, if not resolved, are elevated to successively higher levels of management until resolution is obtained. During routine activities the quality assurance professionals resolve issues within their organization structure; however, quality assurance professionals have direct access to ICP QA management for issue resolution when necessary. Employees also have access to DOE-ID for dispute resolution as necessary. This policy is consistent with the company policy implementing the requirements of 10 CFR 72.10, Employee Protection.

## 5.3 Specific Requirements

The FSV ISFSI SAR Chapter 11, the TMI-2 ISFSI SAR Chapter 11, and the ISFF ISFSI SAR Chapter 11 incorporate by reference the same sections of the QARD. Quality assurance for the FSV ISFSI and the TMI-2 ISFSI comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. The Implementing Documents matrix in Section 6 only lists those QARD sections incorporated by reference in the ISFSI SARs as clarified or modified in the subsections below.

### 5.3.1 Organization

The ISFSI Management organization is responsible for all activities at the FSV, TMI-2, and ISFF ISFSIs. Lines of authority, responsibility, and communication shall be defined and established by the Manager, ISFSI Management with the use of organizational charts and position descriptions. Changes to the organizational chart are issued by the Manager, ISFSI Management. Changes to position descriptions are approved by the Manager, ISFSI Management.

**Clarification:** QARD 1.2 requires the OCRWM Office of Quality Assurance to accept the organization. The DOE contractor organization described in Section 3 of this QPP does not require this acceptance by OCRWM.

**Statement of Applicability:** QARD 1.3 contains references to the Office of Civilian Radioactive Waste Management. The description refers to the Office of Civilian Radioactive Waste Management (OCRWM) direct-support organization activity. The description also refers to affected organizations performing work in accordance with Memoranda of Understanding, Memoranda of Agreement or Program Guidance Memoranda. The description and statements do not apply to the ICP contractor. DOE-ID delegates to the ICP contractor the responsibility for the execution of the QA functions described in the QARD (Contract DE-AC0705ID14516).

### 5.3.2 Quality Assurance Program

Implementing procedures provide positive control of internal organizational interfaces and contracts, purchase orders, and memoranda of agreement provide positive control of external interfaces.

All ISFSI Management quality-affecting activities must conform to the procedures listed in Section 6.

**Clarification:** QARD 2.2.1.C.2 requires approval of the matrix by the Office of Quality Assurance (OQA) and review of changes to the matrix through audits and surveillance by OQA. **The DOE-ID ISFSI QA Manager shall review the matrix in lieu of the OQA.**

**Clarification:** QARD 2.2.2.A requires inclusion of items important to safety on a Q-list. **Those items important to safety and to which the QA program applies are listed on Table 3.4-1 of the FSV SAR, Table 3.4-1 of the TMI-2 SAR, and Table 3.4-1 of the ISFF ISFSI SAR. These tables meet the requirement for a Q-list.**

**Statement of Applicability:** QARD 2.2.2.A.1 and 2.2.2.A.2 require application of 10 CFR 60. **10 CFR 60 is not applicable to ISFSI Management activities. 10 CFR 60 only applies to disposal of high-level radioactive waste in geological repositories.**

**Statement of Applicability:** QARD 2.2.2.A.3, 2.2.2.B, 2.2.2.A.4, and 2.2.2.A.6 require the inclusion on the Q-List of "... items required for the control and management of site-generated radioactive waste other than spent fuel and high-level waste...," "items required for the protection of items important to safety and waste isolation from the hazards of fire," "items required for physical protection as defined by 10 CFR Part 73," and "items required to control occupational radiological exposure." **A Part 60 facility is postulated to include repackaging of spent fuel and high-level waste, unknown future activities that could cause fire hazards not existing at a Part 72 facility, a facility design requiring the assured physical protection after facility closure, and occupational radiological hazards associated with unknown future handling of large quantities of spent fuel and high-level waste. Therefore, while these items may be important for an ISFSI, they are not required to be on a Q-List.**

**Statement of Applicability:** QARD 2.2.3.A, 2.2.3.C, 2.2.3.D, 2.2.3.E apply to activities associated with site characterization, dispersion of radioactive materials from the licensed facility, high-level waste form development, and characterization and conditioning DOE spent nuclear fuel. **These activities are not applicable to the FSV ISFSI, the TMI-2 ISFSI, or the ISFF ISFSI. The drying records for the TMI-2 core debris will be retained as quality records even though TMI-2 core debris drying was not performed for Part 60 acceptance.**

**Clarification:** QARD 2.2.7 states that OCRWM shall perform or direct the performance of management assessments. This requirement is expected to be performed by DOE-ID instead of OCRWM and is not performed by the DOE contractor.

**Clarification:** QARD 2.2.8 states that the management of DOE-ID (as an Affected Organization) shall determine the need for readiness reviews of major scheduled or planned work. The Manager, ISFSI Management as the primary company interface with DOE-ID management, is assigned the company responsibility for these requirements.

**Clarification:** QARD 2.2.9 states that peer reviews may be performed to qualify certain data. There is no need for peer reviews for ISFSI Management work and peer reviews are not a prerequisite for other work unless unqualified data is used for design input. Therefore, this requirement will not be implemented until it is needed.

**Clarification:** Regarding QARD 2.2.12, the graded approach is applied to indoctrination and training commensurate with the scope, complexity, and nature of the activity.

**Clarification:** Regarding QARD 2.2.13, the graded approach is not applied to the qualification and certification of inspectors, NDE personnel, lead auditors and auditors.

### 5.3.3 Design Control

The requirements of QARD, Section 3.0-Design Control will be followed with the following clarifications.

**Clarification:** Design control requirements ensure that designs as specified in the license application (including the ISFSI Safety Analysis Reports) are correctly defined, controlled, and verified.

**Clarification:** 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.

**Clarification:** 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.

### 5.3.4 Procurement Document Control

The requirements of QARD, Section 4.0-Procurement Document Control will be followed with the following clarification.

**Clarification:** The graded approach for applying QAP requirements on suppliers depends on type and end-use of the item or activity affecting quality being procured.

### 5.3.5 Implementing Documents

The requirements of QARD, Section 5.0-Implementing Documents will be followed with the following clarification and statement of exception.

**Clarification:** 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.

**Statement of Exception:** QARD 5.2.2.H addresses identification of lifetime and nonpermanent quality records in implementing documents. **The Records Type List will identify whether the record is Quality Lifetime or Quality Nonpermanent. The definition for Quality Lifetime records is contained in QARD 17.2.1.A. The document types listed as numbers (3), (4), (5), and (6) are not applicable to the FSV ISFSI, the TMI-2 ISFSI, or the ISFF ISFSI because they provide records of activities not applicable to the FSV ISFSI, the TMI-2 ISFSI, or the ISFF ISFSI.**

**The definition for nonpermanent quality records is contained in QARD 17.2.1.B.**

**Justification:** The system of determining records types and retention under the records management process is effective and meets the intent of this requirement.

### 5.3.6 Document Control

The requirements of QARD, Section 6.0-Documents Control will be followed with the following clarification and statement of exception.

**Clarification:** The document control system provides for identification, preparation, review, approval, and distribution of documents in a graded manner.

**Statement of Exception:** QARD 6.2.6D addresses documentation, maintenance, and review of document histories. **Document case files are maintained and contain all changes to implementing procedures. The DOE contractor process does not require review of the case file, but does review the procedure basis.**

**Justification:** The intent of Paragraph 6.2.6D is met. Histories of design documents are reviewed, and implementing procedures are reviewed against their procedure bases to ensure requirements continue to be met. Operations management does not see added value in reviewing historical document changes to implementing procedures. Past revisions are retained in historical files if reference is needed.

### 5.3.7 Control of Purchased Items and Services

The requirements of QARD, Section 7.0-Control of Purchased Items and Services will be followed with the following clarifications.

**Clarification:** 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.

**Clarification:** 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.

### 5.3.8 Identification and Control of Items

The requirements of QARD, Section 8.0-Identification and Control of Items will be followed with the following clarification.

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

### 5.3.9 Control of Special Processes

The requirements of QARD, Section 9.0-Control of Special Processes will be followed with the following clarifications.

**Clarification:** QARD 9.2.3B addresses qualifications to SNT-TC-IA, 1980 Edition for personnel performing nondestructive examination (NDE). The DOE Contractor will follow SNT-TC-IA, 1988 Edition.

**Clarification:** The graded approach is not applicable for special processes.

### 5.3.10 Inspection

The requirements of QARD, Section 10.0-Inspection will be followed with the following clarification.

**Clarification:** 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.

### 5.3.11 Test Control

The requirements of QARD, Section 11.0-Test Control will be followed with the following clarification and statement of applicability.

**Clarification:** QARD Section 11.2.3.A states that other testing documents (such as ASTM specifications, supplier manuals, etc.) may be used instead of preparing special test implementing documents. This is determined to be commonly accepted practice and is not required to be implemented in a program-implementing administrative procedure.

**Statement of Applicability:** QARD Section 11.0 applies to new or modified items on the ISFSI Q-Lists and not to periodic operability tests performed after an initial post-installation test.

### 5.3.12 Control of Measuring and Test Equipment

The requirements of QARD, Section 12.0-Control of Measuring and Test Equipment will be followed with the following clarification and statement of applicability.

**Clarification:** The graded approach is not applicable for measuring and test equipment used for activities affecting quality.

### 5.3.13 Handling, Storage, and Shipping

The requirements of QARD, Section 13.0-Handling, Storage, and Shipping will be followed with the following clarification.

**Clarification:** 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.

### 5.3.14 Inspection, Test, and Operating Status

The requirements of QARD, Section 14.0-Inspection, Test, and Operating Status will be followed with the following clarification.

**Clarification:** The graded approach is not applicable for inspection, test, and operating status.

### 5.3.15 Nonconformances

The requirements of QARD, Section 15.0-Nonconformances will be followed with the following clarifications.

**Clarification:** All nonconformances, including supplier generated upon receipt, and problem description reports will be forwarded to the DOE-ID ISFSI QA manager within 15 days and will be dispositioned within 30 days.

**Clarification:** A corrective action system is established and executed which promotes a "no fault" attitude toward identification of conditions that are adverse to quality.

**Clarification:** The graded approach is not applicable for the identification and control of nonconforming items.

### 5.3.16 Corrective Action

The requirements of QARD, Section 16.0-Corrective Action will be followed with the following statements of clarification.

**Clarification: In addition to the requirements of the QARD, all ISFSI Management responses to audits performed by external organizations shall be submitted within 30 days of receipt of the audit report.**

**Clarification:** A corrective action system is established and executed which promotes a "no fault" attitude toward identification of conditions that are adverse to quality.

**Clarification:** Corrective action to preclude recurrence of a nonconforming condition is commensurate with the item's importance.

**Clarification:** QARD 16.2.4.C.2 describes lifting and closing stop work orders. **If DOE issues a stop work order, DOE concurrence will be obtained prior to restart.**

**Clarification:** Corrective action documentation (for conditions and significant conditions adverse to quality) is provided to DOE-ID and the appropriate ISFSI Manager, and requires appropriate quality assurance organizational concurrence with proposed actions and verification of corrective actions.

**Clarification:** Quality trends and results of remedial actions are reported to the DOE-ID ISFSI QA Manager.

**Clarification:** Evaluations (of adverse quality trends) are performed to determine systemic root cause(s) and determine if a course of action for correction is required.

**Clarification:** Determination of the extent of an adverse condition is accomplished by completing the "Issue Categorization" portion of the "Screening" section of the electronic ICARE form. An extent of condition "evaluation" (when required) will be accomplished as described in MCP-598, "Corrective Action System," Appendix D.

### 5.3.17 Quality Assurance Records

The requirements of QARD, Section 17.0-Quality Assurance Records will be followed with the following clarifications and statements of applicability.

**Clarification:** The graded approach for Quality Assurance Records is as specified in design documents, procurement documents, test procedures, and operational procedures.

**Clarification:** 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.

**Clarification:** QARD 17.2.1 provides the definition for QA lifetime and QA nonpermanent records for ISFSI Management.

**Statement of Applicability:** QARD 17.2.1 A contains a list of types of documents to be classified as lifetime quality assurance records. **The document types listed as numbers (3), (4), (5), and (6) are not applicable to the FSV ISFSI, the TMI-2 ISFSI, or the ISFF ISFSI because they provide records of activities not applicable to the FSV ISFSI, the TMI-2 ISFSI, or the ISFF ISFSI.**

**Clarification:** QARD 17.2.3 requires that a receipt control system be established for QA records according to established requirements. The records from Foster Wheeler for the Idaho Spent Fuel Facility ISFSI will be properly received and indexed at the time a decision is made by the licensee to go forward with construction of the facility. Until then the records will be stored in accordance with the QA program.

**Clarification:** QARD 17.2.3.G requires records to be submitted to storage after processing. **Because ISFSI Management records are processed and maintained in an appropriate SLF or in the INL Site Record Center, no additional implementing documents are needed to assure records storage after processing.**

**Clarification:** QARD 17.2.6.A requires records retrieval. The requirement for retrieval is based on the concept that records are not immediately retrievable while in storage. ISFSI Management records maintained in the records center are all rapidly retrievable. **Because ISFSI**

**Management records are maintained in the INL Site Record Center, no additional implementing documents are needed to plan and provide for records retrieval.**

**Clarification:** QARD 17.2.7.A states "OCRWM or its designee shall retain and preserve lifetime QA records for the operating life of the item or facility." **The DOE contractor retains lifetime QA records until the termination of the NRC licenses.**

**Statement of Applicability:** QARD 17.2.8 contains requirements for turnover of QA records to OCRWM. **QA records will be stored in facilities meeting the requirements of QARD 17.2.11 until they are transferred to another authorized organization.**

**Statement of Applicability:** QARD 17.2.9 contains requirements for OCRWM single storage facilities for lifetime QA records. **The INL Site Record Center (ISRC) in building IF-663 meets the requirement for single storage of lifetime QA records.**

**Clarification:** QARD 17.2.10 contains requirements for dual-storage facilities. **OCRWM is not responsible for the facilities used for dual storage of ISFSI records. If records are not stored in a facility approved for single storage, such as the ISRC, QA records must meet the requirements for dual storage. For ISFSI Management one of the storage media is electronic with the storage (server) located sufficiently remote from the other record copy until such a time as the Electronic Document Management System (EDMS) has been approved by DOE for dual storage of ISFSI records.**

**Clarification:** QARD 17.2.11.C contains a requirement for OCRWM or "the purchaser" to designate the maximum time limit for keeping QA records in temporary storage. **The DOE contractor has this responsibility for ISFSI Management QA records. QA records will be stored in facilities meeting the requirements of QARD 17.2.11. The maximum time limit for keeping QA records in temporary storage is 1 year from time receipt of records in Records Center.**

### 5.3.18 Audits

The requirements of QARD, Section 18.0-Audits will be followed with the following clarifications.

**Clarification:** QARD 18.2.2.A refers to OCRWM as the customer for work performed by suppliers. DOE-ID is the customer for ISFSI Management work.

**Clarification: QARD 18.2.2.B required audits are performed. If an audit is not performed a detailed justification will be documented.**

**Clarification:** QARD 18.2.2.E refers to annual performance of internal audits of work to verify QA program compliance. The annual audit of QA program compliance will be conducted under the direction of the DOE-ID ISFSI QA manager.

### 5.3.19 Software

The requirements of QARD, Supplement I.0-Software will be followed with the following clarification.

**Clarification:** Software activities subject to the QARD used for ISFSI Management work are limited to software used in engineering analyses.

### 5.3.20 Sample Control

**Statement of Applicability:** The requirements of QARD, Supplement II.0-Sample Control, are not applicable to the FSV ISFSI, the TMI-2 ISFSI, or the ISFF ISFSI.

### 5.3.21 Scientific Investigation

**Statement of Applicability:** The requirements of QARD, Supplement III.0-Scientific Investigations, are not applicable to the FSV ISFSI, the TMI-2 ISFSI, or the ISFF ISFSI.

### 5.3.22 Field Surveying

**Statement of Applicability:** The requirements of QARD, Supplement IV.0-Field Surveying, are not applicable to the FSV ISFSI, the TMI-2 ISFSI, or the ISFF ISFSI.

### 5.3.23 Control of the Electronic Management of Data

The requirements of QARD, Supplement V.0-Control of the Electronic Management of Data, will be followed with the following clarification.

**Clarification:** The management of electronic data subject to the QARD used for ISFSI Management work is limited to data used in engineering analyses.

### 5.3.24 High-Level Waste Form Production

**Statement of Applicability:** The requirements of QARD, Appendix A, High-Level Waste Form Production, are not applicable to the FSV ISFSI, the TMI-2 ISFSI, or the ISFF ISFSI.

### 5.3.25 Storage and Transportation

**Statement of Applicability:** The requirements of QARD, Appendix B, Storage and Transportation, are not applicable to the FSV ISFSI, the TMI-2 ISFSI, or the ISFF ISFSI because the ISFSI Management organization does not directly design or fabricate storage casks, transportation casks, or multi-purpose canisters. Appendix B is applicable to the ISFF.

### 5.3.26 Mined Geologic Repository

**Statement of Applicability:** The requirements of QARD, Appendix C, Mined Geologic Repository, are not applicable to the FSV ISFSI, the TMI-2 ISFSI, or the ISFF ISFSI.

## 6. PROGRAM REQUIREMENTS IMPLEMENTATION

This section lists QA Program requirements paragraph identification in the left-hand column and the corresponding DOE contractor document(s) in the center and right hand columns. Only those company-level documents and selected lower level documents necessary to specify program requirements to workers are required to demonstrate implementation of the QA Program requirements.

The Implementing Documents listed implement the requirements of the applicable sections of the QARD where such applicability was described or clarified in Section 5.

## 6.1 Implementing Documents

| QARD Requirement Topics | PRD | Implementing Documents |
|---|---|---|
| **1-Organization** | PRD-5070, Organization | PLN-466, Quality Assurance Program Plan for ISFSI Management<br>MCP-1521, Differing Professional Opinions |
| **2-Quality Assurance Program** | See breakdown by subsection. | |
| 2.2.1-Quality Assurance Program Documents | PRD-5071, Quality Assurance Program | PLN-466, Quality Assurance Program Plan for ISFSI Management<br>MCP-561, Quality Program Plan/Quality Assurance Project Plan Development<br>POL-110, Quality Assurance Policy |
| 2.2.2-Classifying Items | | Table 3.4-1 of the FSV SAR, the TMI-2 SAR and the ISFF SAR |
| 2.2.3-Controlling Activities | | PLN-466, Quality Assurance Program Plan for ISFSI Management<br>MCP-540, Assigning Quality Levels |
| 2.2.4-Applying Quality Assurance Controls | | PLN-466, Quality Assurance Program Plan for ISFSI Management<br>MCP-540, Assigning Quality Levels |
| 2.2.5-Planning Work | | MCP-2811, Nuclear Facility Change<br>MCP-101, ICP Integrated Work Control Process<br>MCP-3562, Hazard Identification, Analysis and Control of Operational Activities |
| 2.2.6-Surveillances | | MCP-589, Quality Assurance Surveillance |
| 2.2.7-Management Assessments | N/A | |
| 2.2.8-Readiness Reviews | PRD-5071, Quality Assurance Program | MCP-3815, Major Work Preparation and Review |
| 2.2.9-Peer Reviews | N/A | |
| 2.2.10-Document Review | | MCP-135, Document Management |
| 2.2.11-Quality Assurance Program Information Management | PRD-5071, Quality Assurance Program | |
| 2.2.12-Personnel Selection, | PRD-5071, Quality | MCP-3043, ISFSI Management Department Training |

Implementing Documents (continued).

| QARD Requirement Topics | PRD | Implementing Documents |
|---|---|---|
| Indoctrination, Training, and Qualification | Assurance Program | |
| 2.2.13-Qualification of QA Personnel | PRD-5073, Audit Personnel Qualification and Certification | MCP-535, NDE Personnel Certification,<br>MCP-1309, Inspection Personnel Certification |
| **3-Design Control** | PRD-5074, Design Control | MCP-1308, Field Design Change<br>MCP-2374, Formal Analyses and Calculations<br>MCP-2377, Development, Assessment, and Maintenance of Drawings<br>MCP-2811, Nuclear Facility Change<br>MCP-3772. Commercial Grade Dedication<br>MCP-9185, Technical and Functional Requirements<br>MCP-9217, Design Verification<br>MCP-9359, Specifications and Statements of Work |
| **4-Procurement Document Control** | PRD-5075, Procurement Document Control | **NOTE:** Project personnel are to fill out FRM-1533 and provide to QA to assist QA with filling out Form 414.A92E. QA is to attach completed FRM-1533 to Form 414.A92E to become part of the procurement record.<br>FRM-1533, 10 CFR 21 Applicability Determination<br>Form 414.A92E, Selectable Quality Clauses<br>MCP-1185, Material Acquisitions<br>MCP-1186, Service Acquisitions |
| **5-Implementing Documents** | PRD-5076, Instructions, Procedures, and Drawings | MCP-135, Document Management<br>MCP-3562, Hazard Identification, Analysis and Control of Operational Activities<br>STD-8, Management Control Procedure Writing<br>STD-9, Technical Procedure Writing<br>MCP-101, ICP Integrated Work Control Process |
| **6-Document Control** | PRD-5077, Document Control | MCP-135, Document Management<br>MCP-9395, Releasing and Distributing Controlled Documents |
| **7-Control of Purchased Items and Services** | PRD-5078, Control of Purchased Items and Services. | MCP-591, Supplier Evaluation and Qualification<br>MCP-1185, Material Acquisitions<br>MCP-1186, Service Acquisitions<br>MCP-2489, Supplier Surveillance<br>MCP-3491, Acceptance of Procured Materials and Services<br>MCP-3772, Commercial Grade Dedication<br>TPR-4960, Receiving Inspection |

Implementing Documents (continued).

| QARD Requirement Topics | PRD | Implementing Documents |
|---|---|---|
| **8-Identification and Control of Items** | PRD-5079, Identification and Control of Items | MCP-2482, Inspection for Conformance<br>MCP-3491, Acceptance of Procured Materials and Services<br>MCP-9359, Specifications and Statements of Work<br>MCP-9436, Identification, Control, Storage, and Transfer of Item Traceability<br>STD-7006, Marking Methods for Equipment, Components, and Materials |
| **9-Control of Special Processes** | PRD 5080 Control of Special Processes | MCP-37, Control of Special Processes MCP-195, NDE Equipment and Procedure Qualification<br>MCP-535, NDE Personnel Certification<br>TPR-4975, Liquid Penetrant Examinations<br>TPR-4977, Magnetic Particle Examination<br>TPR-4978, Material Sorting Electronic Methods<br>TPR-4981, Visual Examination<br>TPR-4984, Ultrasonic Digital Thickness Measurement<br>TPR-6304, Small Volume Pressure Change Leak Test |
| **10-Inspection** | PRD-5081 Inspection | MCP-535, NDE Personnel Certification,<br>MCP-1309, Inspection Personnel Certification<br>MCP-2482, Inspection for Conformance<br>MCP-9151, Development and Control of Inspection Instructions |
| **11-Test Control** | PRD-5082, Test Control | MCP-3056, Test Control |
| **12-Control of Measuring and Test Equipment** | PRD-5083, Control of Measuring and Test Equipment | MCP-2391, Control of Measuring and Test Equipment |
| **13-Handling, Storage, and Shipping** | PRD-5084<br>Handling, Storage and Shipping | MCP-9436, Identification, Control, Storage, and Transfer of Item Traceability<br>MCP-6503, Inspection and Testing of Hoisting and Rigging Equipment |
| **14-Inspection, Test, and Operating Status** | PRD-5085, Inspection, Test, and Operating Status | MCP-538, Control of Nonconforming items<br>MCP-2482, Inspection for Conformance<br>MCP-3491, Acceptance of Procured Materials and Services<br>MCP-3056, Test Control |

Implementing Documents (continued).

| QARD Requirement Topics | PRD | Implementing Documents |
|---|---|---|
| **15-Nonconformances** | PRD-5086 Control of Nonconforming items<br>PRD-5095<br>Suspect/Counterfeit Items | MCP-538, Control of Nonconforming items<br>MCP-553, Step Back and Stop Work Authority<br>MCP-598 Corrective Action System<br>MCP-9110, Suspect/Counterfeit Item Identification and Control |
| **16-Corrective Action** | PRD-5087,<br>Corrective Action | MCP-190 Event Investigation and Occurrence Reporting<br>MCP-192, Processing Lessons Learned and Operating Experience Information<br>MCP-553, Step Back and Stop Work Authority<br>MCP-598, Corrective Action System<br>MCP-1269 Establishing, Monitoring, and Reporting ESH&QA Performance Objectives, Goals, and Measures<br>MCP-2924, NRC Licensee Event and Condition Reporting<br>STD-1113, Cause Analysis and Corrective Action Development |
| **17-Quality Assurance Records** | PRD-5088, Quality Assurance Records | Records Schedule Matrix<br>MCP-557, Records Management<br>MCP-2064 Implementing Records Management Processes |
| **18-Audits** | PRD-5089, Quality Assurance Audits<br>PRD-5090, Quality Assurance Surveillance<br>PRD-5091 Assessments | MCP-196, Qualification of Auditors and Lead Auditors<br>MCP-1539, Project Evaluation Board<br>MCP-9172, Developing, Integrating, and Implementing Assessment Schedules<br>MCP-9278, Quality Assurance Audits<br>MCP-589, Quality Assurance Surveillance<br>MCP-8, Performing Management Assessments and Management Reviews |
| **Supplement I-Software** | PRD-5092, Software Quality Assurance | MCP-550, Software Management |
| **Supplement II-Sample Control** | N/A | N/A |
| **Supplement III-Scientific Investigation** | N/A | N/A |
| **Supplement IV-Field Surveying** | N/A | N/A |

Implementing Documents (continued).

| QARD Requirement Topics | PRD | Implementing Documents |
|---|---|---|
| **Supplement V-Control of the Electronic Management of Data** | PRD-5092, Software Quality Assurance | MCP-550, Software Management<br>MCP-557, Records Management<br>MCP-2064, Implementing Records Management Processes<br>MCP-3933, Control of the Electronic Management of Data |
| **Appendix A-High-Level Waste Form Production** | N/A | N/A |
| **Appendix B-Storage and Transportation** | N/A | PLN-466, Quality Assurance Program Plan for ISFSI Management |
| **Appendix C-Mined Geologic Repository** | N/A | N/A |

# 7. QUALITY ASSURANCE RECORDS

The ISFSI Management Record Center will maintain the following quality assurance records:

- Documents that provide evidence of the quality of items important to safety.
- Documents that provide evidence of the quality of activities related to items important to safety.
- Personnel training and qualification documents for individuals executing QA program requirements.
- Documents that record activities performed with items important to safety.

The quality assurance records not meeting the criteria as Lifetime records (such as audit records, calibration records, document control records) may be retained by other company organizations if these actions are not performed by the ISFSI Management department.

Quality assurance records will be maintained until the quality assurance retention requirements are satisfied at which time such records may be transferred to satisfy additional records retention schedules.