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11. QUALITY ASSURANCE

11.0 Quality Assurance

Beginning with initial design of the TMI-2 ISFSI through to its completed decommissioning, it is the policy of DOE-ID to ensure that the facility is designed, constructed, handled, shipped, stored, cleaned, assembled, inspected, tested, operated, maintained, modified and decommissioned in a manner that assures the health and safety of workers and the public and protects the environment. The Quality Assurance Program is developed to confirm that essential technical and quality requirements for structures, systems, and components are achieved and documented. The TMI-2 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 TMI-2 ISFSI's reliable operation.

DOE-ID maintains full responsibility for the development and execution of the TMI-2 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 TMI-2 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) [11.1]. The QARD is included as part of the TMI-2 ISFSI license application. The contents of the QARD are listed in Table 11.0-1. For TMI-2 ISFSI activities, DOE-ID and its contractor will apply applicable portions of the QARD to items important to safety. The purpose of this chapter of the SAR is to define the implementation and application of those applicable QARD requirements for the TMI-2 ISFSI, including the relationship and integration of DOE-ID and contractor quality assurance responsibilities. To facilitate this description, this chapter is written and developed following the format of the QARD. The quality assurance program described in this chapter shall be implemented by DOE-ID and its contractor through the use of approved, controlled implementing documents.

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

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

The remaining sections of this chapter describe how each of these Elements, Supplements, and Appendices will be implemented for the TMI-2 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, NUHOMS Major Components and Safety Classification. Structures, systems and components which are not important to safety have the QAP 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	2-3-97
7.0	Control of Purchased Items and Services	4	4-28-00
8.0	Identification and Control of Items	1	10-31-95
9.0	Control of Special Processes	1	10-31-95
10.0	Inspection	0	12-18-92
11.0	Test Control	0	12-18-92
12.0	Control of Measuring and Test Equipment	1	10-31-95
13.0	Handling, Storage, and Shipping	0	12-18-92
14.0	Inspection, Test, and Operating Status	1	10-31-95
15.0	Nonconformances	1	10-31-95
16.0	Corrective Action	1	10-31-95
17.0	Quality Assurance Records	2	3-3-97
18.0	Audits	1	10-31-95
Supplement I	Software	3	2-7-00
Supplement II	Sample Control	1	10-31-95
Supplement III	Scientific Investigation	4	2-7-00
Supplement IV	Field Surveying	0	12-18-92
Supplement V	Control of the Electronic Management of Data	1	2-7-00
Appendix A	High Level Waste Form Production	1	10-31-95
Appendix B	Storage and Transportation	4	2-7-00
Appendix C	Monitored Geologic Repository	4	2-7-00
Glossary		4	2-7-00

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11.1 Organization

The following is the organizational philosophy of the TMI-2 ISFSI Quality Assurance Program.

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

- 1) Retain responsibility for and perform independent assessments of the contractor's ISFSI quality assurance program;
- 2) Ensure that the license conditions for the facility are included in the contractor's contract;
- 3) Assess the performance of the contractor against the terms of their contract;
- 4) Retain the responsibility to budget funds necessary and sufficient to safely operate the facility; and
- 5) Retain the authority to revise the contract in the 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 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 significant conditions adverse to quality is assigned to the Manager of DOE-ID. Contractor stop work authority resides with the INTEC QA Manager.

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

DOE-ID and contractor Quality Assurance personnel have the necessary authority, resources, and organizational freedom to implement the Quality Assurance Program, including the ability to identify quality problems; to initiate, recommend and provide solutions; and to verify implementation of solutions. QA personnel also have written authority and responsibility to stop unsatisfactory work, controlling further processing, delivery, installation, or use of nonconforming items.

QA personnel ensure that assessments of the Quality Assurance Program and its effectiveness are reported to the appropriate levels of management. Specific quality assurance responsibilities for the TMI-2 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:

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

11.1.3 Deputy Manager for Operations Support

The responsibility for developing the appropriate revisions to the contractor's contract with DOE-ID is delegated to the Assistant Manager for Administration 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 and the Assistant Manager for Operational 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:

- 1) Developing, reviewing, approving, issuing, and maintaining DOE-ID's implementing procedures
- 2) Verifying that the Quality Assurance Program is properly established and executed
- 3) Ensuring that quality is verified by an organization not responsible for the work and ensuring that the Quality Assurance Program is adequate and being effectively implemented

- 4) Ensuring Quality Assurance training and qualification programs are developed for DOE-ID and contractor personnel who perform quality affecting activities.
- 5) Develop, manage, update, and implement a Quality Assurance Audit Plan and schedule, and coordinate NRC participation in audit activities
- 6) Identifying quality problems; initiating, recommending, or providing solutions to quality problems; and verifying the implementation of solutions to quality problems
- 7) Determining the cause of significant conditions adverse to quality and ensuring that corrective action is initiated for all conditions adverse to quality
- 8) Accepting final resolution for all DOE-ID audit findings and proposed corrective actions
- 9) Initiating stop work orders within the license oversight program, when required
- 10) Receiving and compiling Quality Assurance information and forwarding Quality Assurance program status reports to management
- 11) Interfacing with NRC to coordinate and clarify NRC Quality Assurance requirements, the Quality Assurance Program, and to resolve Quality Assurance issues to NRC requirements
- 12) Interfacing with NRC to coordinate plans and schedules relevant to Quality Assurance for NRC overview of licensing activities
- 13) Being responsible for interpreting and approving Quality Assurance Program requirements as they apply to the contractor's scope of work.
- 14) Assignment of the Quality Assurance Specialist (QAS) staff.

11.1.4 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. All contractor personnel have the authority to stop work pending resolution of any quality problem. If a member of another area disagrees, that individual is instructed to take the matter to appropriate management. The disagreement may either be resolved at this level or at any level up to and including the DOE-ID Office of the Manager.

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

1.2 Requirements

Requires preparation of controlled documents describing internal and external interfaces.

1.2.1 Line Management

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

1.2.2 Quality Assurance Management

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

1.2.3 Responsibility For Quality

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

1.2.4 Delegation of Work

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

1.2.5 Resolution of Quality Disputes

Process for resolution of quality disputes.

1.3.3 Other OCRWM Affected Organizations

Section "A" and "C" only

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

11.2 Quality Assurance Program

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

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

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

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

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

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

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

Design verification methods include, but are not limited to design reviews, alternate calculations, and qualification testing or a combination thereof. When a test program is to be used to verify the adequacy of a design, a qualification test of a prototype unit under adverse design conditions shall be used. Independent design verification is completed before relying on the item to

- 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:

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

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

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

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

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

- 4.2.1 Procurement Document Preparation
 - Describes necessary provisions for issued procurement documents.
- 4.2.2 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 Section 5.0, Implementing Documents, that are implemented from the QARD are:

5.2 Requirements

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

5.2.1 Types of Implementing Documents

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

5.2.2 Content of Implementing Documents

Describes the information that implementing documents shall contain.

5.2.3 Review and Approval of Implementing Documents

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

5.2.4 Compliance With Implementing Documents

Requires individuals to comply with QARD requirements and describes what to do when work 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:

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

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

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

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

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

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

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

- 6.2.1 Types of Documents
 Requires that implementing documents and documents that specify technical and quality requirements be controlled per this section.
- 6.2.2 Preparing Documents
 Requires assignment for preparation and maintenance of documents to appropriate organizations.
- 6.2.3 Reviewing Documents
 Requires that documents shall be reviewed per QARD Section 2.2.10, Document Review.
- 6.2.4 Approving Documents
 Requires identification of the position which has approval authority for documents.
- 6.2.5 Distribution and Use of Documents
 Provides criteria for distribution and use of documents.
- 6.2.6 Changes To Documents
 Provides criteria governing changes to documents.
- 6.2.7 Expedited Changes
 Provides criteria for initiating changes at the work location by responsible management.
- 6.2.8 Editorial Corrections
 Describes the criteria for editorial changes to documents.

11.7 Control of Purchased Items and Services

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

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

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

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

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

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

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

upon receipt. That verification documentation shall be available for the life of the NRC issued operating license for the operation of the ISFSI.

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

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

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

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

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

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

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

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

- | | | |
|-------|---------------------------------|---|
| 7.2.1 | Procurement Planning | Describes criteria for adequate procurement planning and documentation. |
| 7.2.2 | Source Evaluation and Selection | Provides criteria for determining supplier selection and supplier capability in providing items and services that affect quality. |
| 7.2.3 | Proposal/Bid Evaluation | |

- Provides criteria for the proposal/bid evaluation process and who shall participate in that evaluation.
- 7.2.4 Supplier Performance Evaluation
Provides criteria for interfacing with suppliers and verifying their performance.
- 7.2.5 Control of Supplier Generated Documents
Establishes criteria for controlling, processing and accepting procurement documents.
- 7.2.6 Acceptance of Items and Services
Provides criteria for objective evidence used in the acceptance of procured items and services.
- 7.2.7 Certificate of Conformance
Provides criteria for when a Certificate of Conformance is used for acceptance of an item or service.
- 7.2.8 Source Verification
Provides criteria where various methods of source verification may be used. Includes description of the process involved to control and personnel qualifications for source verification.
- 7.2.9 Receiving Inspection
Establishes the criteria for when receiving inspection is used to accept an item.
- 7.2.10 Post-installation Testing
Establishes that QARD Section 11, Test Control and that post-installation testing criteria are mutually established by purchaser and supplier.
- 7.2.11 Control of Supplier Nonconformances
Establishes requirements for both purchaser and supplier to document the process for disposition of items that do not meet procurement document requirements.
- 7.2.12 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 Section 8.0, Identification and Control of Items, that are implemented from the QARD are:

- 8.2.1 Identification
 - Establishes the requirements for maintenance of identification of items.
- 8.2.2 Physical Markings
 - Establishes physical marking requirements for item identification.
- 8.2.3 Traceability
 - Provides requirements for the established and maintenance of traceability criteria to items.
- 8.2.4 Conditional Requirements
 - Establishes controls for item identification to be specified in specifications.

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

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

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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:

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

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

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

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.

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11.11 Test Control

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

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

Written test procedures incorporate and reference:

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

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

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

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

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

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

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

- 11.2.1 Test Planning
 Establishes criteria for effective test planning.
- 11.2.2 Performing Tests
 Establishes criteria that implementing documents shall address for tests.
- 11.2.3 Use of Other Testing Documents
 Establishes criteria for incorporation of test information directly from testing documents into the testing implementation documents.
- 11.2.4 Test Results
 Establishes criteria for documentation and evaluation of test results.
- 11.2.5 Test Documentation
 Establishes criteria for contents of test documentation.
- 11.2.6 Qualification of Test Personnel
 Establishes criteria that test personnel shall be qualified per QARD Section 10, Inspection.

11.12 Control of Measuring and Test Equipment

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

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

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

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

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

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

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

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

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

12.2.1 Calibration

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

- 12.2.2 Documenting the Use of Measuring and Test Equipment
 - Requires that use of M&TE be documented.
- 12.2.3 Out-of-Calibration Measuring and Test Equipment
 - Provides criteria for when MT&E shall be considered as out-of-calibration.
- 12.2.4 Lost Measuring and Test Equipment
 - Provides criteria for lost M&TE.
- 12.2.5 Handling and Storage
 - M&TE shall be properly handled and stored to maintain accuracy.
- 12.2.6 Commercial Devices
 - Provides criteria for rulers, tape measures, levels, and other commercial equipment.
- 12.2.7 Measuring and Test Equipment Documentation
 - Provide criteria for M&TE documentation information.

11.13 Handling, Storage, and Shipping

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

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

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

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

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

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

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

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

11.14 Inspection, Test, and Operating Status

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

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

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

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

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

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

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

14.2.1 Identifying Items

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

14.2.2 Indicating Status

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

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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:

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

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

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

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

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

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

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

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

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

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

- 15.2.1 Documenting and Evaluating Nonconforming Items
Provides criteria for nonconformance identification and describing nonconforming characteristics of an item. Corrective action criteria used for evaluation use the requirements of QARD Section 16.0, Corrective Action.
- 15.2.2 Identifying Nonconforming Items
Provides criteria for identification of nonconforming items through marking, tagging or other means.
- 15.2.3 Segregating Nonconforming Items
Provides criteria for segregation of nonconforming items to prevent inadvertent use.
- 15.2.4 Disposition of Nonconforming Items
Provides criteria of the use of "use-as-is", "reject", "repair", or "rework" dispositions for nonconforming items.
- 15.2.5 Quality Trending
Requires that nonconforming documentation shall be periodically analyzed to identify quality trends per QARD Section 16.0, Corrective Action.

11.16 Corrective Action

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

Procedures have been established and implemented for the identification and correction of conditions adverse to quality including the causes of significant conditions adverse to quality identified through internal DOE-ID surveillance and assessments or external surveillance and assessments performed on the program. Procedural instructions and policy guidance provide criteria for determining the existence of significant conditions adverse to quality. The ISFSI 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 the 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 Section 16.0, Corrective Action, that are implemented from the QARD are:

- 16.2.1 Identifying Conditions Adverse To Quality
 - Provides criteria for identification of conditions adverse to quality.
- 16.2.2 Classification of Conditions Adverse To Quality
 - Provides classification criteria for conditions adverse to quality
- 16.2.3 Conditions Adverse To Quality
 - Provides criteria for documenting and reporting to appropriate levels of management conditions adverse to quality.
- 16.2.4 Significant Conditions Adverse To Quality
 - Provides criteria for determining, evaluating, investigating, and concurring of proposed remedial actions for significant conditions adverse to quality.
- 16.2.5 Follow-up and Closure Action
 - Requires Quality Assurance verify implementation of corrective actions and closed related corrective action documentation when complete.
- 16.2.6 Quality Trending
 - Provides criteria for determining adverse quality trends and the manner in which trend evaluation shall be conducted.

11.17 Quality Assurance Records

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

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

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

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

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

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

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

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

17.2.1 Classifying Quality Assurance Records

Provides criteria for classification of quality assurance records17.2.2
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 facilities17.2.7
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. All audits of the contractor related to NRC regulated activities will be lead by and Audit Team Leader who is not an employee of the contractor or parent organizations. Subjects for Quality Assurance audits and surveillances shall include, but not be limited to:

- Compliance, implementation, and effectiveness of the DOE-ID and contractor's Quality Assurance programs,
- Compliance with the 10 CFR Part 21 reporting requirements,
- Personnel training, and
- The managerial and administrative controls used to ensure safe operation of the TMI-2 ISFSI.

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

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

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

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

18.2.1 Scheduling Internal Audits

Provides criteria for scheduling internal quality audits.

18.2.2 Scheduling External Audits

Provides criteria for scheduling external quality assurance audits.

- 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 assure implementation and adequacy.

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

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

- 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
 Stipulated 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 TMI ISFSI. Scientific samples taken, handled, or recorded for any purpose in order for the TMI 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 TMI 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 TMI ISFSI. The facility construction location is pre-established and identified in existing documents. The L TMI ISFSI does not need the surveying controls as outlined for a mined geological repository in the QARD.

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

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

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

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

DOE-ID's contractor is assigned implementation authority for QARD Supplemental V, Control of the Electronic Management of Data, for design, construction, fabrication, and assembly and/or operation functions which support program activities. The contractor is required to 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 Supplement V, Control of the Electronic Management of Data, that are implemented from the QARD are:

V.2.1 Control of the Electronic Management of Data

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

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

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

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11.20 References

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

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