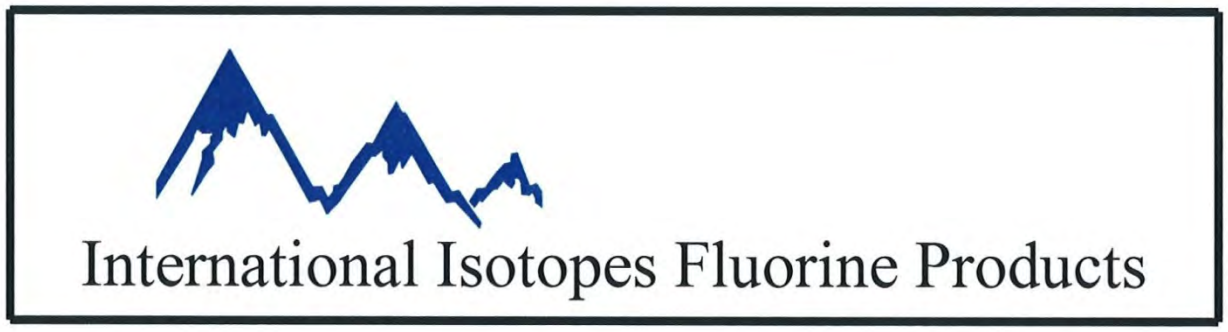

International Isotopes Fluorine Products, Inc. (IIFP)

A Wholly Owned Subsidiary of

International Isotopes, Inc. (INIS)

Fluorine Extraction Process & Depleted Uranium De-conversion (FEP/DUP) Plant

License Application

Chapter 11

Management Measures

Revision B

December 13, 2011

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

No List of Table Entries

11 MANAGEMENT MEASURES

This Chapter of the International Isotopes Fluorine Products, Inc. (IIFP), License Application (LA) describes the management measures that are applied to Items Relied on for Safety (IROFS) for the IIFP Facility to be built near Hobbs, New Mexico. IIFP is a wholly owned subsidiary of International Isotopes, Inc. (INIS). The IIFP Facility (also referred to as the FEP/DUP Plant) is being licensed under Title 10 Code of Federal Regulations (CFR) Part 40. Throughout this Chapter, where there is discussion on management measures applied to IROFS, it also includes application to those items that affect IROFS.

In the absence of the U.S. Nuclear Regulatory Commission (NRC) final rulemaking for depleted uranium de-conversion facility requirements, IIFP is anticipating that NRC will amend Part 40 to include Integrated Safety Analysis (ISA) completions and require de-conversion plant licensees to meet requirements similar to those in Subpart H of Title 10 CFR Part 70 (CFR, 2009g), or equivalent. Likewise, because the IIFP Facility is a Part 40 licensed facility and more related to a chemical plant operation, a graded approach is used to apply management measures based on the risk-based results of the Integrated Safety Analysis. This graded approach for management measures is implemented in accordance with the Quality Assurance (QA) Program as described in the IIFP QA Program Description (QAPD) in Appendix A Revision B of the IIFP LA. The QA graded levels are defined in Subsection 11.8.2.2 below. The relative importance of the IROFS is determined using both the severity of the consequence and unmitigated likelihood of an initiating event. Based on the assigned safety importance, the appropriate types and number of management measures are applied to assure the IROFS are functional when needed. The QA Program also provides measures for ensuring that design, construction, operation and decommissioning of IROFS are controlled commensurate with their importance to safety.

IIFP maintains full responsibility for assuring the IIFP Facility is designed, constructed, tested and operated in conformance with good engineering practices, applicable regulatory requirements and specified design requirements and in a manner to protect the health and safety of the public.

The President of IIFP is the highest level of management responsible for IIFP's corporate QA policies, goals and objectives. The IIFP project is currently in the development, conceptual design and licensing phase. A Design and Build (DB) Contractor will be selected to perform the detailed design and construction of the IIFP Facility. The QA programs of the selected DB Contractor will be evaluated to ensure the DB Contractor has mature QA programs and to ensure that the organization has the controls and methodologies in place for the design and change control processes. The design shall be developed and implemented in accordance with IIFP management measures to ensure that the critical components and the IROFS will be available and reliable to perform their function when needed. The provisions contained in the QAPD are applicable for design, construction and procurement activities taking place beginning on the date the DB Contactor assumes the detailed design and engineering role and establishes the design organization and controls. Once the DB Contractor begins the IIFP Facility detailed design (the design that will be verified and used for construction) , the IIFP Chief Operations Officer (COO) is responsible for assuring implementation of the management measures necessary in accordance with the graded QA Program (See Figure 11-1 "IIFP Project Design and Construction Organization").

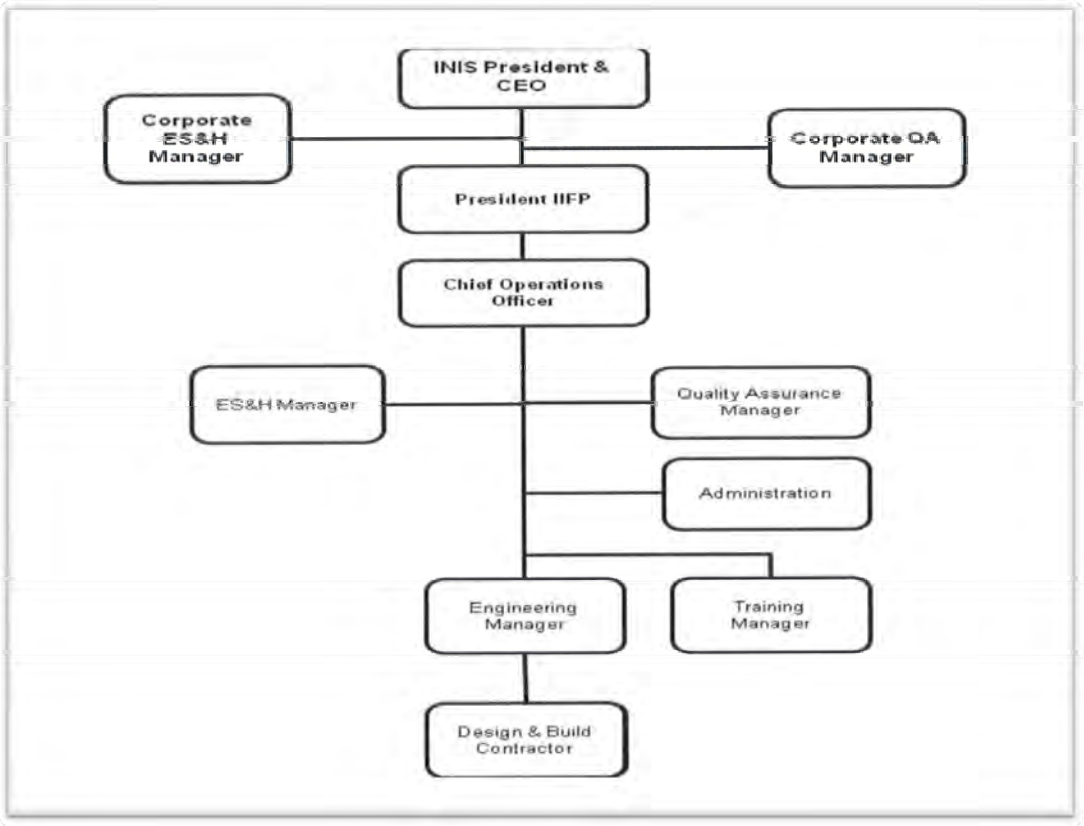

Figure 11- 1 IIFP Project Design and Construction Organization

Management measures not only apply during the design and construction of the IIFP Facility but throughout the operations and maintenance of the facility. Upon completion of construction, the Plant Operation Organization takes responsibility for startup and operation of the facility, led by the IIFP COO who reports to the IIFP President. The COO is responsible for implementing and maintaining the management measures for the operating facility. The IIFP Facility line managers are responsible for implementing and maintaining the management measures policies and procedures in accordance with the approved facility safety design basis, licenses and permits and the QA Program requirements. The IIFP Plant Operation Organization is shown in Figure 11-2. In the operating organization, the Plant Manager and the Engineering Manager have key roles in ensuring that safe design and operation of the facility is maintained.

Critical documents applicable to operations include procedures. All activities involving IROFS and Quality Level 1 (QL-1) and Quality Level 2 (QL-2) items are conducted in accordance with approved procedures. As noted throughout this document, procedures are used to control IROFS activities to ensure the activities are carried out in a safe manner and in accordance with regulatory requirements. Applicable safety limits and IROFS are clearly identified in the procedures. IIFP will incorporate a methodology for identifying, developing, approving, implementing and controlling operating procedures. Identifying needed procedures will include consideration of the ISA results.

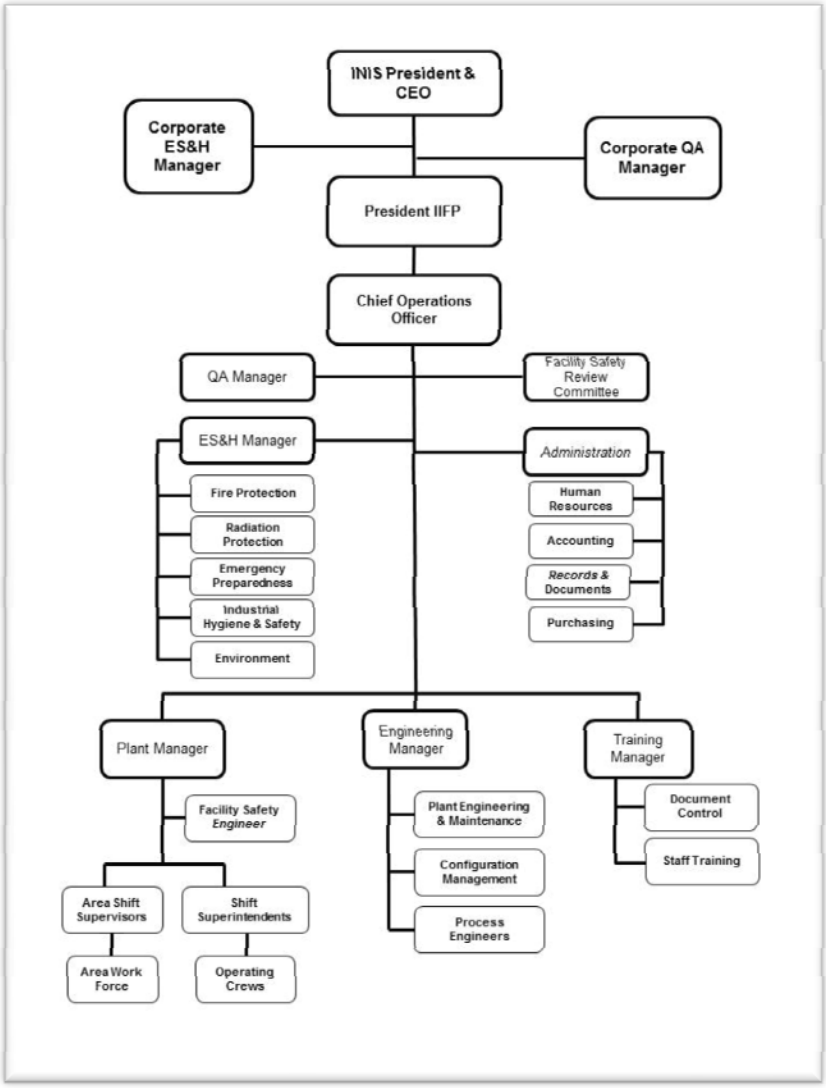

Figure 11-2 Plant Operation Organization

The IIFP QA Manager and Environmental, Safety and Health (ESH) Manager have key management measure responsibilities and authorities independent of the production, engineering and maintenance organizational functions. The QA Manager and the ESH Manager provide authorized oversight to ensure the QA Program and management measures are implemented such that production never takes priority over the safety of employees, the public and the environment with respect to the plant construction and operation. The QA Manager and the ESH Manager report directly to the COO.

More descriptive details of key management responsibilities and qualifications are provided in the IIFP LA, Chapter 2 Revision B "Organization and Administration" and in the LA, Appendix A. Revision B "Quality Assurance Program Description."

Management measures include the Configuration Management (CM) Program which is fully described in the LA, Section 11.1 through 11.1.6. The Configuration Management Policy is described in Section

11.1.1, the “Design Requirements” in Section 11.1.2, “Configuration Management Controls on the Design Requirements” in Section 11.1.3, “Document Control” in Section 11.1.4, “Change Control” in Section 11.1.5 and “Assessments” in Section 11.1.6.

IROFS and any items that affect the safe and reliable function of the IROFS are designated as Quality Level 1 or Quality Level 2 (see Subsection 11.8.2.2). In Section 6 of the IIFP ISA Summary Revision B, Table 6-1 provides a list of IROFS in the identified high and intermediate accident sequences. Table 6-1 identifies the control type, the initiating event failure frequency index, the IROFS failure probability index and the failure frequency/probability index basis. A small number of sole IROFS are identified in Table 8-1 and Table 8-2 of Section 8 of the ISA Summary. Each Table identifies the type of IROFS and the safety function of each sole IROFS.

11.1 CONFIGURATION MANAGEMENT

This section describes the Configuration Management Program for the IIFP Facility. Configuration management for the facility is implemented through requirements of the QA Program and associated procedures.

11.1.1 Configuration Management Policy

The IIFP Project is currently in the conceptual design and development stage. CM will be provided throughout facility design, construction, testing and operation and will start when the Project transitions to the detailed design and construction of the facility. A Design and Build contract is planned and the detailed design and engineering is expected to begin by late 2012. A selected qualified and experienced Configuration Management Manager (CMM) will be assigned to report to the DB Contractor Engineering Manager. During the project design and construction, the DB Contractor Engineering Manager with oversight and support of the CMM has responsibility for CM through the engineering established design control process. The DB Contractor Engineering Manager and the Contractor Construction Director will report to the DB Contractor Project Manager. The DB Contractor Project Manager will report to the IIFP Engineering Manager (or the IIFP COO until the IIFP Engineering Manager position is filled) as shown in Figure 11-1.

Upon start of the detailed design, selected documentation, including the ISA, is controlled under the CM system in accordance with procedures associated with design control, document control and records management. Design changes undergo formal review, including interdisciplinary reviews as appropriate, in accordance with these procedures and the graded-level requirements of the QA Program. This interdisciplinary review includes, as a minimum, the review for ISA impacts.

Configuration management provides the means to establish and maintain a technical baseline for the facility based on clearly defined requirements. During detailed design of the project, CM is based on the design control provisions and associated procedural control of the design documents to establish and maintain the technical baseline. Design documents are those that provide design input, design analysis or design results specifically for IROFS. Structures, systems and components (SSCs) of each IROFS receive a quality level classification that applies throughout the life of the facility or until new safety analysis provides a technical safety basis, justification, documentation and approval for changing the classification. These IROFS final detailed design documents undergo interdisciplinary review during the initial issue and during each subsequent revision.

During the construction, changes to drawings and specifications issued for construction, procurement or fabrication shall be systematically reviewed and verified, evaluated for impact, including impact to the

ISA and approved prior to implementation. Proper implementation is verified and reflected in the design basis documentation.

Configuration management provides the means to establish and maintain the essential features of the design basis of IROFS included in the ISA. As the project progresses from design and construction to operation, CM responsibilities are transferred to the IIFP Engineering organization as the overall focus of activities changes.

Upon startup and operation of the facility, measures continue to be implemented to ensure that the quality of IROFS is not compromised by planned changes (modifications). After the facility operations begin, the Engineering Manager is responsible for ensuring the design and control of modifications to facility IROFS. See Figure 11-2 "Plant Operation Organization." The design and implementation of modifications are performed in a manner so as to ensure quality is maintained in a manner commensurate with the remainder of the system that is being modified, or as dictated by applicable license requirements.

More detailed description of the configuration change control process, as it applies to the design, construction and operation stages, is provided below in Subsections 11.1.5.1, 11.1.5.2 and 11.1.5.3, respectively.

11.1.1.1 Scope of Structures, Systems and Components

The scope (boundary definition) of structures, systems and components (SSCs) under CM includes all IROFS identified by the ISA design basis and any items which may affect the safety and reliability function of the IROFS. Design documents subject to CM include calculations, safety analyses**,** design criteria, engineering drawings, system descriptions, technical documents and specifications that establish design requirements for IROFS. During the design stage, these design documents are maintained under CM when initially approved.

The scope of documents included in the CM Program expands throughout the design process. When drawings and specification sections related to IROFS (or items affecting the safety and reliability functions of IROFS) are prepared and issued, these documents are included in CM.

During construction, initial startup and operations, the scope of documents under CM similarly expands to include, as appropriate:

- Vendor data
- Test data
- Inspection data
- Initial startup, testing, operating and administrative procedures as applicable to IROFS

These documents include documentation related to IROFS that is generated through functional interface with QA (procedures, incident investigations, audits and assessments, etc.), maintenance, records management and document control and training and qualifications of personnel. Configuration management procedures will provide for evaluation, implementation and tracking of changes to IROFS, processes, equipment, computer programs and activities of personnel that impact IROFS.

11.1.1.2 Objectives of Configuration Management

The objectives of CM shall be to ensure design and operation within the design basis of IROFS by:

- Identifying and controlling preparation and review of documentation associated with IROFS
- Controlling changes to IROFS
- Maintaining the physical configuration of the facility consistent with the approved design

The ISA determines the IROFS and establishes the safety function(s) associated with each IROFS. Configuration control is accomplished during detailed design through the use of procedures for controlling design. The controlling procedures address preparation, review (including interdisciplinary review), verification of design, where appropriate, approvals and distribution for use. Engineering documents are assessed for quality level classification. Changes to the approved design are subject to a review to ensure consistency with the design basis of IROFS. Configuration verification is also accomplished through design verification, which ensures that design documents are consistent and that design requirements for IROFS are met. During construction and testing, this verification also extends to verification that as-built configurations are consistent with the design and that testing that is specified to demonstrate performance of IROFS is accomplished successfully. Periodic audits and assessments of the CM Program and of the design confirm that the system meets its goals and that design is consistent with the design basis. The corrective action process occurs in accordance with the QA Program and associated procedures in the event problems are identified. Prompt corrective actions are developed as a result of incident investigations or in response to audit or assessment results.

11.1.1.3 Description of Configuration Management Activities

Configuration management includes those activities conducted under design control provisions for ensuring that design and construction documentation is prepared, reviewed and approved in accordance with a systematic process. This process includes interdisciplinary reviews appropriate to ensure consistency between the design and the design basis of IROFS. During construction, it also includes those activities that ensure that construction is consistent with design documents. Finally, it includes activities that provide for operation of the IROFS in accordance with the limits and constraints established in the ISA and that provide for control of changes to the facility in accordance with 10 CFR 70.72 (CFR, 2009e). Configuration management also includes records to demonstrate that personnel conducting activities that are relied on for safety (or that are associated with IROFS) are appropriately qualified and trained to conduct that work.

Implementing documents are controlled within the document control system. These documents support CM by ensuring that only reviewed and approved procedures, specifications and drawings are used for procurement, construction, installation, testing, operation and maintenance of IROFS, as appropriate.

11.1.1.4 Organizational Structure and Staffing Interfaces

The CM Program is administered by the DB Engineering Manager during the IIFP Project detailed design, engineering and construction. After completion of the project, the IIFP Engineering Manager administers the CM Program for startup and ongoing operation and maintenance of the IIFP Facility. Design engineering includes the engineering disciplines. The discipline engineers have primary technical responsibility for the work performed. The CMM is responsible for ensuring the conduct of interdisciplinary reviews as discussed previously in this section. Reviews are also conducted, as appropriate, by construction management and QA and procurement personnel. The design control process also interfaces with the document control and records management process via procedures.

The various IIFP departments and contractors of IIFP ensure implementation of management measures. The primary IIFP contractors are responsible for development of their respective QA programs and CM elements to be consistent with the requirements for activities determined to be within the scope of the

IIFP QA Program. The interfaces between contractors and IIFP or among the contractors are documented. IIFP and contractor personnel have the responsibility to identify quality problems. If a member of another functional 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 IIFP President.

CM is implemented through or otherwise related to other management measures. Key interfaces and relationships to other management measures are described below.

Quality Assurance

The QA Program establishes the framework for CM and other management measures for IROFS and items that affect the function of the IROFS.

Records Management

Records associated with IROFS and items affecting IROFS are generated and processed in accordance with the applicable requirements of the QA Program and provide evidence of the conduct of activities associated with the CM of those IROFS.

Maintenance

The maintenance requirements are established as part of the design basis which is controlled under CM. Maintenance records for IROFS and items affecting IROFS shall provide evidence of compliance with preventive and corrective maintenance schedules.

Training and Qualifications

Training and qualifications are controlled in accordance with the applicable provisions of the QA Program. Personnel qualifications and/or training to specific processes and procedures are elements of management measures that support the safe operation, maintenance or testing of IROFS. Also, work activities that are themselves IROFS, (i.e., administrative controls) are included in procedures and personnel shall be trained and qualified to these procedures. Training and qualification requirements and documentation of training may be considered part of the design basis controlled under CM.

Incident Investigation/Audits and Assessments

Audits, assessments and incident investigations are described in Sections 11.5 “Audits and Assessments” and 11.6 “Incident Investigations and Corrective Action Process.” Corrective actions identified as a result of these management measures may result in changes to design features, administrative controls or other management measures (e.g., operating procedures).The Corrective Action Program is described in Section 11.6. Changes are evaluated under the provisions of CM through the QA Program and procedures. Periodic assessments of the CM Program are also conducted in accordance with the audit and assessment program described in Section 11.5.

Procedures

Operating, administrative, maintenance and emergency procedures are used to conduct various operations associated with IROFS, and items affecting IROFS, and are reviewed for potential impacts to the design

basis. Also, work activities that are themselves IROFS, (i.e., administrative controls) are contained in procedures.

A description of the QA elements is provided in the Appendix A, Revision B of the LA, "Quality Assurance Program Description." The location of each QA element described in the QAPD is shown below.

Quality Assurance Elements

Organization	Section A.1
Quality Assurance Program	Section A.2
Design Control	Section A.3
Procurement Document Control	Section A.4
Instructions, Procedures and Drawings	Section A.5
Document Control	Section A.6
Control of Purchased Items and Services	Section A.7
Identification and Control of Materials, Parts and Components	Section A.8
Control of Special Processes	Section A.9
Inspection	Section A.10
Test Control	Section A.11
Control of Measuring and Test Equipment	Section A.12
Handling, Storage and Shipping	Section A.13
Inspection, Test and Operating Status	Section A.14
Control of Nonconforming Items	Section A.15
Corrective Action	Section A.16
Quality Assurance Records	Section A.17
Audits	Section A.18

11.1.2 Design Requirements

Design requirements and associated design basis are established and maintained by the design engineering functional organization (designated by the Configuration Management Manager and approved by the COO) during the design/construction stage and designated/approved by the Engineering Manager after operations begin. The CM controls on design requirements and the ISA of the design basis are described previously in this section.

Design requirements are documented in design requirement documents i.e. calculations, safety analysis, design criteria, engineering drawings, system descriptions, technical documents and specifications. The design requirements and basis of detailed design documents are controlled under the design control provisions of the CM Program as described above and are subject to the same change control as analysis, specifications and drawings.

IROFS and any items that affect the function of the IROFS are designated as QL-1 or QL 2. The design documents associated with IROFS are subject to interdisciplinary reviews and design verification. Changes to the design are evaluated to ensure consistency with the design basis. Computer codes used in the design of IROFS are also subject to these design control measures, with additional requirements as appropriate for software control, verification and validation.

IROFS are listed in the ISA Summary, Revision B. This list is augmented and maintained current as appropriate during detailed design of the facility.

A qualified individual who specifies and includes the appropriate codes, standards and licensing commitments within the design documents prepares each design document, such as a calculation, specification, procedure or drawing. This individual also notes any deviations or changes from such standards within the design documentation package. Each final draft design document is then checked by another individual qualified in the same discipline and is reviewed for concept and conformity with the design inputs. These design inputs are in sufficient detail to permit verification of the document. The manager having overall responsibility for the design function approves the final document. The CMM ensures that the designated engineering organization documents the entire review process in accordance with approved procedures. These procedures include provisions to assure that appropriate quality standards are specified in design documents, including quantitative or qualitative acceptance criteria. The QA Manager conducts audits on the design control process using independent technically qualified individuals to augment the QA audit team.

During the check and review process described above, emphasis is placed on assuring conformance with applicable codes, standards and LA design commitments. The individuals in engineering assigned to perform the check and review of design requirements documents (calculations, design criteria, engineering drawings, system description, technical specifications, etc.) have full and independent authority to withhold approval until questions concerning the work have been resolved. Design reviews, alternative calculations or qualification testing accomplishes verification of design. The basis for a design, such as analytical models, examples, tables, codes and computer programs must be referenced in the design document and their application verified during check and review. Model tests, when required to prove the adequacy of a concept or a design, are reviewed and approved by the responsible qualified individual. Testing used for design verification shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. The tests used for design verification must meet all the design requirements.

Qualified individuals other than those who performed the design may be from the same organization. Verification may be performed by the supervisor of the individual performing the design, provided that: 1) the need is documented, 2) it is approved in advance by the supervisor's management, 3) the supervisor did not specify a singular design approach or rule out certain design considerations, 4) the supervisor did not establish the design inputs used in the design or 5) the supervisor is the only individual in the organization competent to perform the verification.

Independent design verification shall be accomplished before the design document (or information contained therein) is used by other organizations for design work or to support other activities such as procurement, construction or installation. When this is not practical due to time constraints, the unverified portion of the document is identified and controlled. In all cases, the design verification shall be completed before relying on the item to perform its function or installation becomes irreversible. Any changes to the design and procurement documents, including field changes, must be reviewed, checked and approved commensurate with the original approval requirements.

After design documents have been properly prepared, checked, reviewed and approved by the appropriate parties, the responsible engineer sends the design documents to document control for distribution. When required, each recipient of a design document verifies receipt of such document to the document control center. The document control center, after verification of distribution to a recipient, maintains the required documentation in its files.

When deficiencies are identified which affect the design of IROFS, such deficiencies are documented and resolved in accordance with approved Corrective Action Program procedures. In accordance with these procedures, the nonconformance report (NCR) is forwarded for appropriate review to the responsible

manager, who coordinates further review of the problem and revises all design documents affected by the deficiency as necessary. Where required, the responsible manager forwards the report to the engineers in other areas, who coordinate necessary revisions to their affected documents.

Design interfaces are maintained by communication among the principals. Methods by which this is accomplished include the following:

- Design documents are reviewed by the responsible engineer or authorized representative. As appropriate, subsequent review or waiver of review by the other area engineers is documented.

- Project review meetings are scheduled and held to coordinate design, procurement, construction and pre-operational testing of the facility. These meetings provide a primary working interface among the principal organizations.

- Reports of nonconformance are transmitted and controlled by procedures. As required by the nonconformance procedure, the QA Manager approves resolution of reports of nonconformance.

During the operational phase, measures are provided to ensure responsible facility personnel are made aware of design changes and modifications that may affect the performance of their duties.

11.1.3 Configuration Management Controls on the Design Requirements

Configuration management control is accomplished during design through the use of procedures for controlling design, including preparation, review, design verification, approval and release and distribution for use. Engineering documents are assessed based on the QA level classification of the item being reviewed. Changes to the approved design also are subject to a review to ensure consistency with the design basis of IROFS.

Configuration verification is also accomplished through design verification, which ensures that design documents are consistent and that design requirements for IROFS are met. During construction and testing, this verification also extends to verification that as-built configurations are consistent with the design and that testing that is specified to demonstrate performance of IROFS is accomplished successfully.

The QA Program requires procedures that specify that work performed is accomplished in accordance with the requirements and guidelines imposed by applicable specifications, drawings, codes, standards, regulations, quality assurance criteria and site characteristics.

Acceptance criteria established by the designer shall be incorporated in the instructions, procedures and drawings used to perform the work. Documentation is maintained, including test results and inspection records, demonstrating that the work has been properly performed. Procedures also provide for review, audit, approval and documentation of activities affecting the quality of items to ensure that applicable criteria have been met.

Maintenance, modification and inspection procedures are reviewed by qualified personnel knowledgeable in the quality assurance disciplines to determine:

- The need for inspection, identification of inspection personnel and documentation of inspection result

- Necessary inspection requirements, methods and acceptance criteria have been identified

Facility procedures are reviewed by an individual knowledgeable in the area affected by the procedure on a frequency determined by the age and use of the procedure to determine if changes are necessary or desirable. Procedures are also reviewed to ensure procedures are maintained up-to-date with facility configuration. These reviews are intended to ensure that any modifications to IROFS are reflected in current maintenance, production and other facility procedures.

11.1.4 Document Control

Procedures are established which control the preparation and issuance of documents such as manuals, instructions, drawings, procedures, specifications, design documents, procurement documents and supplier-supplied documents, including any changes. Procedures are established to control the life-cycle of documents that pertain to the CM function. Measures are established to ensure documents, including revisions, are adequately reviewed, approved and released for use by authorized personnel.

Document Control Program procedures require documents to be transmitted and received in a timely manner at appropriate locations including the location where the prescribed activity is to be performed. Controlled copies of these documents and their revisions are distributed to and used by the persons performing the activity.

Superseded documents are destroyed or are retained only when they have been properly labeled. Indexes of current documents are maintained and controlled.

Document control is implemented in accordance with procedures. A document management system is used both to file project records and to make available the latest revision (i.e., the controlled copy) of design documents. The system provides a record copy of the current controlled document and personnel are trained to use this system to retrieve controlled documents. The system is capable of generating indices of controlled documents, which are uniquely numbered (including revision number). Controlled documents are maintained until cancelled or superseded. Cancelled or superseded documents are maintained as a record, currently for the life of the project or termination of the license, whichever occurs later. Hardcopy distribution of controlled documents is provided when needed in accordance with applicable procedures (e.g., when an electronic document management system is being used but is not available).

The Document Control Program encompasses those documents that are relied on for safety, e.g. the ISA, all procedures that pertain to IROFS, procedures involving training, QA, maintenance, audits and assessments, emergency operating procedures, emergency response plans, system modification documents, assessment reports and others that the applicant deems part of CM. See Subsection 11.1.1.1 “Scope of Structures, Systems and Components,” for a general accounting of the documents subject to configuration management during design, construction and operations of the IIFP Facility. A more detailed listing of documents under configuration control during design is provided in Section 11.1.2 “Design Requirement” and Section 11.1.3 “Configuration Management Controls on the Design Requirements.” Documentation under CM during construction is delineated in Subsection 11.1.5.2 below. Similarly, Subsection 11.1.5.3 provides a discussion of documentation under CM during the operations stage.

11.1.5 Change Control

Procedures control changes to the technical baseline includes an appropriate level of technical, management and safety review and approval prior to implementation. During the detailed design stage of the project, the method of controlling changes is the design control process described in the IIFP QA procedures. This process includes the conduct of interdisciplinary reviews that constitute a primary mechanism for ensuring consistency of the design with the design basis. During construction and operation, appropriate reviews are conducted to ensure consistency with the design basis of IROFS and the ISA. Similarly these reviews ensure that the design is constructed and operated/modified within the limits of the design basis. Additional details are provided below.

The administrative instructions for modifications are contained in a procedure that is approved (including revisions) by the ESH Manager, or Designee. The modification procedure contains the following items necessary to ensure quality in the modification program:

- The technical and quality requirements which are met to implement a modification
- The requirements for initiating, approving, monitoring, designing, verifying and documenting modifications

The facility modification procedure is written to ensure that policies are formulated and maintained to satisfy the requirements specified in the IIFP QA Program, as applicable.

Each change to the facility shall have an evaluation performed with a review of the ISA, in accordance with the requirements of 10 CFR 70.72(2009e), as applicable. Each modification shall also be evaluated for any required changes or additions to the facility's procedures, personnel training, testing program or regulatory documents.

Human Factors Engineering (HFE) will be included in the facility modification procedure as a review/evaluation activity for any modifications that may impact Human System Interface (HSI). Human Factors Engineering and its implementation are described in detail in the IIFP License Application, Chapter 3 “Integrated Safety Analysis” Revision B Section 3.1.4. Modifications affecting HSI and human factors may be implemented for the following reasons:

- Address obsolescence
- Lack of spare parts
- Lack of vendor support
- New functionality requirements
- Improve process performance
- Enhance operator performance
- Others

If the assessment reveals that the modification affects HSI, the HFE process will be applied. Guidelines will be provided that will address the modification for efficient design characteristics, licensing issues and operation and maintenance considerations, as a minimum. One efficient way to address these issues is by imposing a checklist that addresses such ergonomic areas as: 1) information display, 2) user interfaces controls (hard/soft), 3) alarms, 4) procedures, 5) communications, 6) workstations, 7) maintenance and 8) configuration management, among others.

This approach to assessing modifications will be included in the HFE Implementation Plan.

Detailed design and engineering have not begun for the IIFP Facility and a level of detail is not available for including specific actions, design or style guides, inventory lists, Control Room displays and other details of task analysis, operating experience reviews and specifics of the verification and validation (V&V) process.

11.1.5.1 Design Stage

Changes to the design include a systematic review of the design basis for consistency. In the event of changes, the ISA and other documents affected by design basis of IROFS are properly modified, reviewed and approved prior to implementation. Approved changes are made available to personnel through the document control function discussed previously in this section.

During detailed design, the method of ensuring consistency between documents, including consistency between design changes and the safety assessment, is the interdisciplinary review process.

The interdisciplinary reviews ensure design changes either:

- Do not impact the ISA
- Are accounted for in subsequent changes to the ISA
- Are not approved or implemented

11.1.5.2 Construction Stage

When the project enters the construction stage, changes to documents issued for construction, fabrication and procurement are documented, reviewed, approved and posted against each affected design document. Vendor drawings and data will also undergo an interdisciplinary review to ensure compliance with procurement specifications and drawings and to incorporate interface requirements into facility documents. Design changes are expected as detailed design progresses and construction begins. During construction, design changes will continue to be evaluated against the approved design basis.

Changes to the approved design (certified for construction) also are subject to a review using a systematic change process to ensure consistency with the design basis of IROFS and the ISA. The configuration change process will fully implement the provisions of 10 CFR 70.72(CFR, 2009e), including those changes made without prior NRC approval in accordance with 10 CFR 70.72(d). Any change that requires NRC approval will be submitted as a license amendment request as required by 10 CFR 70.72(d)(1) and the change will not be implemented without prior NRC approval.

11.1.5.3 Operations Stage

Changes to the approved design will also be documented, reviewed and approved prior to implementation. IIFP will implement a change control process that implements the provisions of 10 CFR 70.72 as described in the paragraph above. Measures are provided to ensure responsible facility personnel are made aware of design changes and modifications that may affect the performance of their duties.

To provide for the continued safe and reliable operation of the IROFS, measures are implemented to ensure that the quality of these IROFS is not compromised by planned changes (modifications). Upon acceptance by the Plant Manager's organization, the Engineering organization is responsible for the

design of and modifications to facility IROFS. The design and implementation of modifications are performed in a manner so as to assure quality is maintained in the remainder of the system that is being modified, or as dictated by applicable regulations.

Each modification is also evaluated and documented for radiation exposure to minimize worker exposures in keeping with the facility as low as reasonably achievable (ALARA) Program, worker safety requirements and/or restrictions. Other areas of consideration in evaluating modifications include, but are not limited to the review of:

- Quality Assurance requirements
- Lessons learned from similar completed modifications
- Potential operability or maintainability concerns
- Constructability concerns
- Post-modification testing requirements
- Environmental considerations
- Human factors
- Modification costs

After completion of a modification to an IROFS structure, system or component, the Plant Manager, or Designee, shall ensure that all applicable testing has been completed to ensure correct operation of the system(s) affected by the modification and documentation regarding the modification is complete. To ensure operators are able to operate a modified system safely, when a modification is complete, all documents necessary, (e.g., the revised process description, checklists for operation and flow sheets) are made available to production and maintenance departments prior to the startup of the modified system. Appropriate training on the modification is completed before a system is placed in operation. A formal notice of a modification being completed is distributed to all appropriate managers. As-built drawings incorporating the modification are completed promptly in accordance with the design control procedures. These records are retained in accordance with the records management procedures.

11.1.6 Assessments

Initial and periodic assessments of the CM Program are conducted to determine the system's effectiveness and to correct deficiencies. These assessments include review of the adequacy of documentation and system walk downs of the as-built facility. Such audits and assessments are conducted, documented and scheduled in accordance with procedures. Planned internal and independent assessments of the CM Program and of the design confirm that the system meets its goals and that the design is consistent with the design basis. Incident investigations are conducted in accordance with the QA Program and associated corrective action procedures if problems are encountered. Prompt corrective actions are developed as a result of incident investigations or in response to adverse audit/assessment results, in accordance with these procedures.

More detailed discussion is provided below in Section 11.5 titled “Audits and Assessments.”

11.2 MAINTENANCE

This section outlines the maintenance and functional testing programs to be implemented for the operations stage of the facility. Preventive maintenance activities, surveillance and performance trending provide reasonable and continuing assurance that IROFS will be available and reliable to perform their safety functions.

The purpose of planned and scheduled maintenance for IROFS is to ensure that the equipment and controls are maintained in a condition of readiness to perform the planned and designed functions when required. Appropriate plant management is responsible for ensuring the operational readiness of IROFS under this control. For this reason, the maintenance function is administratively closely coupled to the engineering function.

11.2.1 Maintenance Program

A comprehensive Process Hazard Analysis (PHA) was conducted as part of the ISA. Four types of IROFS controls were used to maintain an acceptable risk level. These included Passive Engineered Controls, Active Engineered Controls, Enhanced Administrative Controls and Administrative Controls. The ISA identified management measures for IROFS, where applicable. See the IIFP ISA Summary, Revision B Section 4 for additional details.

To provide for the continued safe and reliable operation of the facility IROFS, the management measures for change control are implemented to ensure that the quality of the IROFS is not compromised by planned changes (modifications) or maintenance activities. Change control for modifications is described in Section 11.1.5 above. In maintenance of the facility, IIFP utilizes a systems-based program for planning, scheduling, tracking and maintaining records for maintenance activities affecting IROFS. Use of approved maintenance procedures for IROFS-related maintenance is a vital part of that program. The details of maintenance procedure acceptance criteria, reviews and approval are provided in Section 11.4 “Procedures Development and Implementation.”

As applicable, contractors that work on or near IROFS identified in the ISA Summary will be required by IIFP to follow the same maintenance procedures described for the corrective, preventive, functional testing or surveillance/monitoring activities listed below for the maintenance function.

Maintenance supervisors or planners provide the planning function in accordance with the work control process. Maintenance supervisors or planners are responsible for the planning of maintenance work activities and for maintaining a record of work accomplished. Listed below are methods or practices that will be incorporated into the work control process for the corrective, preventative and functional-test maintenance elements. IIFP will prepare written procedures for performance of these methods and practices. These methods and practices include, as applicable:

- Authorized work instructions with detailed steps and a reminder of the importance of the IROFS identified in the ISA Summary
- Parts lists
- As-built drawings
- A notification step to the Plant Manager’s organization before conducting repairs and removing an IROFS from service
- Radiation Work Permits, if required
- Replacement with like-kind parts and the control of new or replacement parts to ensure compliance with 10 CFR 21 (CFR, 2009a1) for applicable IROFS
- Compensatory measures while performing work on IROFS
- Procedural control of removal of components from service for maintenance and for return to service
- Ensuring safe operations during the removal of equipment and components from service
- Notification to the Plant Manager’s organization personnel that repairs have been completed

The work control process includes provisions for:

- Planning tasks to ready-to-work status
- Ensuring that safety, safeguards, quality and configuration management are properly and effectively implemented in performance of maintenance
- Assuring that work package instructions and procedures identify multiple IROFS involved in the same accident sequences and that scheduling and maintenance activities do not adversely affect surrounding, peripheral and interactive IROFS
- Closing out, including final validation of work performed and review of the acceptance tests

Written procedures for maintenance involving IROFS commit to the management measures listed below for corrective and preventive maintenance, post-maintenance testing and surveillance/monitoring maintenance activities:

- Pre-maintenance activities require reviews of the work to be performed, including procedure reviews for accuracy and completeness.
- Notification of all affected parties (Plant Manager's organization and other appropriate functional organizations) is required before performing work and on completion of maintenance work. The discussion includes potential degradation of IROFS during the planned maintenance.
- Control of work described above is accomplished by maintenance personnel following comprehensive procedures
- Radiation Protection, Industrial Safety/Industrial Hygiene, Environmental, Safety and Health representatives provide personnel safety and radiological control requirements needed to perform work safely.
- Procedures address the qualifications of personnel authorized to perform the maintenance or surveillance.
- Procedures also address controls on and specifications of any replacement components or materials to be used as well as post-maintenance testing to verify operability of the equipment.
- Procedures address tracking and records management of maintenance activities.
- Quality Assurance performs inspections that are specified in work packages and procurement documents.
- Written procedures are used for maintenance and scheduling that ensure IROFS in the same accident sequence are not affected by maintenance, testing or calibrations of related or multiple IROFS.

The details of maintenance procedure acceptance criteria, reviews and approval are provided in Subsection 11.4.1.3 "Procedures Development and Implementation."

11.2.2 Types of Maintenance

Maintenance activities generally fall into the following categories:

- Surveillance/monitoring
- Corrective maintenance
- Preventive maintenance
- Functional testing

These maintenance categories are discussed in the following sections.

11.2.2.1 Surveillance/Monitoring

Surveillance/monitoring activities are utilized to detect degradation and adverse trends of IROFS so that action may be taken prior to component failure. The monitored parameters are selected based upon their ability to detect predominate failure modes of the critical components. Data sources include the following:

- Surveillance
- Periodic and diagnostic test results
- Plant computer information
- Operator rounds
- Walk downs
- As-found conditions
- Failure trending
- Predictive maintenance

IIFP utilizes active engineered controls that are integrated into routine operations to the degree practical. The IROFS are monitored as a routine part of the operating process. IROFS associated with passive engineered systems are typically fixed physical design features to maintain safe process conditions. Availability and reliability of IROFS are maintained through pre-operational audits and periodic verifications as prescribed by written procedures and includes consideration of the importance of the IROFS as well as available quality and reliability information.

Surveillance/monitoring and reporting are required for IROFS and any administrative controls that could impact the functions of an IROFS. During surveillance/monitoring, maintenance utilizes the management measures delineated in the paragraphs below.

Plant performance criteria are established to monitor plant performance and to monitor IROFS functions and component parameters. These criteria are established by industry experience, operating data, surveillance data and plant equipment operating experience. These criteria ensure the reliability and availability of IROFS. The performance criteria are also used to demonstrate that the performance or condition of an IROFS is being effectively controlled through appropriate predictive and repetitive maintenance strategies so that IROFS remain capable of performing their intended function.

Surveillances are included in the work control process to permit timely planning, scheduling, establishing of system or facility conditions, executing work and creating documentation that identifies the results of the surveillance. The established frequencies are based on the IROFS degree of safety importance. Surveillance of IROFS is performed at specified intervals. The purpose of the surveillance program is to measure the degree to which IROFS meet performance specifications. The results of surveillances are trended and when the trend indicates potential IROFS performance degradation, preventive maintenance frequencies are adjusted or other appropriate corrective action is taken.

Incident investigations may identify root causes of failures that are related to the type or frequency of maintenance. The investigation is to determine their specific or generic root cause(s) and generic implications, to recommend corrective actions and to report to the NRC as required by 10 CFR 70.74 (CFR, 2009f) or to other regulatory agencies, accordingly. The record of IROFS failures required by 10 CFR 70.62(a) (3) (CFR, 2009c) for IROFS is reviewed as part of the investigation. See Section 11.6 “Incident Investigations and Corrective Action Program,” for further details. The lessons learned from

such investigations are factored into the surveillance/monitoring and preventive maintenance programs as appropriate.

Maintenance procedures prescribe compensatory measures, if appropriate, for surveillance tests of IROFS that can be performed only while equipment is out of service.

Records showing the current surveillance schedule, performance criteria and test results for all IROFS will be maintained in accordance with the Record Management system.

Results of surveillance/monitoring activities related to IROFS via the CM Program are evaluated by the appropriate safety and engineering disciplines to determine any impact on the ISA and any updates needed.

11.2.2.2 Corrective Maintenance

Corrective maintenance involves repair or replacement of equipment that has unexpectedly degraded or failed. Corrective maintenance of IROFS restores the equipment to acceptable performance through a planned, systematic, controlled and documented approach for the repair and replacement activities.

Following any corrective maintenance on IROFS and before returning an IROFS to operational status, functional testing (as described in Subsection 11.2.2.4) of the IROFS, if applicable, is performed to ensure the IROFS performs its intended safety function. If the performance of a repaired or replaced component could be different from that of the original component, the change to the safety control is specifically reviewed and approved under the CM Program and pre-operationally tested to ensure it will perform its desired function when needed.

Results of corrective maintenance activities related to IROFS via requirements of the CM Program will be evaluated by the facility safety function, including appropriate interdisciplinary reviews, to determine any impact on the ISA and any updates needed.

11.2.2.3 Preventive Maintenance

Preventive maintenance includes preplanned and scheduled periodic refurbishment, partial or complete overhaul or replacement of IROFS, as necessary, to ensure their continued safety function. Planning for preventive maintenance includes consideration of results of surveillance and monitoring, including failure history. This includes the review of the record of IROFS failures as required by 10 CFR 70.62(a) (3) (CFR, 2009c). Preventive maintenance also includes instrument calibration and testing.

The basis for the preventive maintenance tasks is developed through a review of available industry standards, manufacturer recommendations and historical operating information, where available. Formal documentation of the basis and tasks for preventive maintenance are developed, evaluated and approved by the Plant Engineering and Maintenance functional organization and includes input from the operating organization and various disciplines within the Engineering organization. New preventive maintenance tasks may be added, or tasks may be changed or deleted upon review, evaluation and approval by the Plant Engineering and Maintenance organization. Changes to preventive maintenance tasks that may affect IROFS require review and evaluation by the facility safety engineering function and the ESH Manager, or Designee, including appropriate interdisciplinary reviews.

In determining the frequency of preventive maintenance, consideration is given to appropriately balancing the objective of preventing failures through maintenance against the objective of minimizing

unavailability of IROFS because of preventive maintenance. Specifically, preventive measures to alleviate premature failures may be added to the preventive maintenance schedule or the frequency of a particular preventive maintenance activity may be reduced due to as-found conditions indicating that the preventive maintenance is occurring more often than needed. In addition, feedback from preventive maintenance and corrective maintenance and the results of incident investigations and identified root causes are used, as appropriate, to modify the frequency or scope of preventive maintenance.

The Preventive Maintenance Program procedures and calibration standards (traceable to the national standards system or to nationally accepted calibration techniques, as appropriate) enable the facility personnel to calibrate equipment and monitoring devices important to plant safety and safeguards. Testing performed on IROFS that are not redundant will provide for compensatory measures to be put into place to ensure that the IROFS function is performed until it is put back into service.

After conducting preventive maintenance on IROFS and before returning an IROFS to operational status, functional testing of the IROFS, if necessary, is performed to ensure the IROFS performs its intended safety function.

All records that pertain to preventive maintenance of IROFS and items affecting IROFS are maintained in accordance with the Records Management system (described in Section 11.7).

Results of preventive maintenance activities related to IROFS via the CM Program are evaluated by the facility safety function, including appropriate interdisciplinary reviews, to determine any impact on the ISA and any updates needed.

11.2.2.4 Functional Testing

Functional testing is performed as appropriate on engineered IROFS SSCs as part of periodic surveillance testing and after corrective maintenance, preventive maintenance or calibration to ensure that the item is capable of performing the designed safety function when required. IIFP commits to perform functional tests in accordance with approved written procedures that define the method for the test and the required acceptable results. The results of the tests are recorded and maintained as quality records.

Administrative controls that are identified as IROFS are documented in approved written procedures. Administrative controls are assured to be available and reliable prior to and during operations by applying the applicable management measures described above, including the use of procedures and the employee training programs. See Section 11.3 “Training and Qualifications” and Section 11.4 “Procedures Development and Implementation” for additional information on how these management measures are applied to administrative controls.

Pre-Operational Testing

Pre-operational testing at the IIFP Facility consists of testing conducted to initially determine various facility parameters and to initially verify the capability of SSCs to meet performance requirements. The major objective of pre-operational testing is to verify that IROFS essential to the safe operation of the facility are capable of performing their intended function. Initial startup testing is performed beginning with the autoclave depleted uranium hexafluoride (DUF_6) feed system and de-conversion process and followed by startup of depleted uranium tetrafluoride (DUF_4) and the FEP operations. The purpose of initial startup testing is to ensure safe and orderly operation of the process systems and to verify parameters and controls assumed in the ISA. Records of the pre-operational and startup tests required prior to operation are maintained. These records include testing schedules and results for IROFS.

Operational Testing

Operational functional testing includes surveillance/monitoring (periodic testing), testing after corrective or preventive maintenance (post-maintenance testing) or special testing.

The periodic testing program at the facility consists of testing conducted on a periodic basis to verify the continuing capability of IROFS to meet performance requirements. The facility periodic testing program begins during the pre-operational testing stage and continues throughout the facility life. A schedule is established to ensure that all required testing is performed and properly evaluated on a timely basis. The schedule is revised periodically, as necessary, to reflect changes in periodic testing requirements and experience gained during plant operations. An integral part of the operational testing program is post-maintenance testing.

Post-maintenance testing is established to provide assurance that IROFS will perform their intended function following maintenance activities. Post-maintenance testing confirms that the maintenance performed was satisfactory, the identified deficiency has been corrected and the maintenance activity did not adversely affect the reliability of the item. Post-maintenance testing is performed until acceptable results are obtained, prior to returning the equipment to service. If acceptable results are not obtained, corrective action is taken and documented via the NCR process. Engineering will dictate the path forward in the NCR process. See Subsections 11.2.2.2 and 11.2.2.3 for additional information on actions taken prior returning the IROFS to service.

Special testing is testing conducted at the IIFP Facility that is not a facility pre-operational test, periodic test or post-maintenance test. Special testing is of a non-recurring nature and is conducted to determine facility parameters and/or to verify the capability of IROFS to meet performance requirements. The determination that a certain plant activity is a special test is intended to exclude those plant activities which are routine surveillances, normal operational evolutions and activities for which there is previous experience in the conduct and performance of the activity.

Operational testing requirements of IROFS are developed and included in work packages during the work planning process. The Plant Manager organization may provide support to the Plant Engineering and Maintenance organization in identifying operational testing requirements. Operational testing meets applicable codes and technical requirements and is conducted with specified acceptance criteria. The results of operational testing are documented and retained in the work package with other documentation generated during the maintenance evolution.

11.3 TRAINING AND QUALIFICATIONS

This section describes the Training Program for operations of the facility, including pre-operational functional testing and initial startup testing. Training is provided to each individual commensurate with the roles and responsibilities. Training Program requirements shall be applicable to but are not limited to those plant personnel who perform activities that affect IROFS, or items that may affect the function of IROFS.

The QA Program provides training and qualification requirements, during the design, construction and operations stages: 1) for QA training of personnel performing QL-1 and QL-2 (See Subsection 11.8.2.2) work activities, 2) for nondestructive examination, inspection and test personnel and 3) for QA auditors.

The principle objective of the IIFP Training Program system is to ensure job proficiency of facility personnel through effective training and qualification. The Training Program system is designed to

accommodate future growth and meet commitments to comply with applicable established regulations and standards. Employees are provided with training to establish the knowledge foundation and on-the-job training (OJT) to develop work performance skills. Continuing training will be provided, as required, to maintain proficiency in these knowledge and skill components and to provide further employee development.

Qualification is indicated by successful completion of prescribed training, demonstration of the ability to perform assigned tasks and the maintenance of requirements established by regulation. Exceptions from training requirements may be granted when justified and documented in accordance with approved written procedures and approved by the appropriate level of management as identified in the written procedure. A graded approach to systematic training will be used that applies the level of detail needed relative to safety. This graded approach incorporates methods to accomplish the analysis, design, development, implementation and evaluation of training.

11.3.1 Organization and Management of the Training Function

Training programs for personnel who perform activities relied on for safety are provided through shared responsibility between the Environmental, Safety and Health disciplines and line management. Line managers have responsibility and commensurate authority to develop and effectively conduct training for their personnel. Training responsibilities for line managers are included in position descriptions and line managers are given the authority to implement training for assigned personnel. The training functional organization provides support to line managers by facilitating the planning, directing, analyzing, developing, conducting, evaluating and controlling the performance-based training process.

Facility procedures establish the requirements for the training of personnel performing activities related to IROFS. Additionally these procedures ensure the training program is conducted in a reliable and consistent manner. Procedures also allow for exceptions from training when justified and properly documented and approved by appropriate management.

Lesson plans or other approved process controlling documents are used for classroom and on-the-job training to provide consistent presentation of subject matter. When design changes or facility modifications are implemented, updates of applicable lesson plans, where IROFS are affected, are included in the change control process of the CM Program.

Training programs and training records at the facility are the responsibility of the Training organization. Training attendance records, examinations, employee qualification records and program needs are maintained in an accurate, auditable manner to document each employee’s training. Training records are maintained to support management information needs associated with programmatic and individual training, job performance and qualifications. Records are maintained on each employee's qualifications, experience and training. The employee training file shall include records of all general initial site training, safety training, technical training and employee development training conducted at the facility. The employee training file shall also contain records of special company sponsored training conducted by others. The training records for each individual are maintained so that they are accurate and retrievable. Training records are retained in accordance with the records management procedures.

11.3.2 Analysis and Identification of Functional Areas Requiring Training

A needs/job task analysis is performed and tasks are identified to ensure that appropriate training is provided to personnel working on tasks related to IROFS. Identification of job hazards are referred to as

precautions and limitations in the procedure related to that task. These limits and precautions will be part of the needs/job task analysis performed for that task.

The Training lead consults with management personnel to develop a list of tasks for which personnel training for specific jobs is required. The list of tasks selected for training are reviewed and compared to the training materials as part of the evaluation of training effectiveness. The task list will also be updated periodically as necessitated by changes in procedures, processes, plant systems, equipment or job scope.

11.3.3 Position Training Requirements

Minimum training requirements are developed for those positions whose activities are related to IROFS. Entry-level criteria (e.g., education, technical background and/or experience) for these positions are contained in position descriptions.

The Training Program will be designed to prepare initial and replacement personnel for safe, reliable and efficient operation of the facility. Appropriate training for personnel of various abilities and experience backgrounds will be provided. The level at which an employee initially enters the Training Program is determined by an evaluation of the employee's past experience, level of ability and qualifications.

Training is made available to facility personnel to initially develop and maintain minimum qualifications. The objective of the training shall be to ensure safe and efficient operation of the facility and compliance with applicable established regulations and requirements. Training requirements are applicable to, but not necessarily restricted to, those personnel within the plant organization who have a direct relationship to the operation, maintenance, testing or other technical aspect of the facility IROFS. Training courses are updated prior to use to reflect plant modifications and changes to procedures when applicable.

Continuing training courses shall be established when applicable to ensure that personnel remain proficient. The training may consist of periodic exercises, instruction and review of subjects as appropriate to maintain proficiency of personnel assigned to the facility.

11.3.4 Training Basis and Objectives

The Training Program is designed to prepare initial and replacement personnel for safe, reliable and efficient operation of the IIFP Facility. Emphasis is placed on safety requirements where human actions are important to safety.

Learning objectives are established to identify the training content and to define satisfactory trainee performance for the task, or a group of tasks, selected for training from the job analysis. Learning objectives state the requisite knowledge, skills and abilities the trainee must demonstrate. The conditions under which the required actions take place and the standards of performance required of the trainee are also determined in development of the learning objectives. Learning objectives are sequenced within training materials based on the relationship to one another. Learning objectives are documented in lesson plans and training guides and revised as necessary based on changes in procedures, facility SSCs or job scope.

11.3.5 Organization of Instruction Using Lesson Plans and Other Training Guides

Lesson plans or other approved process controlling documents are developed from the learning objectives that are based on job performance requirements. These documents and other training guides are developed under the guidance of the training functional organization. The documents are reviewed by the

training function and generally by the organization cognizant of the subject matter. These documents are approved prior to issue or use. The documents are used for classroom training and on-the-job training as required and include standards for evaluating acceptable trainee performance.

Learning objectives identify the training content, as established by needs/job task analyses and position-specific requirements. The task list from the needs/job task analysis is used to develop action statements that describe the desired post-training performance.

11.3.6 Evaluation of Trainee Learning

Trainee understanding and command of learning objectives is evaluated through observation and demonstration; and oral or written tests, as appropriate. Such evaluations measure the trainee's skills and knowledge of job performance requirements. Evaluations are performed by individuals qualified in the training subject matter. Operator training and qualification requirements are met prior to process safety related tasks being independently performed or prior to startup following significant changes to safety controls.

11.3.7 Categories of Required Training

The following sections describe the categories of required training.

11.3.7.1 General Employee Training

General Employee Training (GET) encompasses the quality assurance, radiation protection, environmental, safety and health, emergency response/security and administrative policies and general procedures established by IIFP Facility management and applicable regulations. The industrial safety/industrial hygiene training for IIFP complies with the applicable sections of the U.S. Occupational Safety and Health Administration (OSHA) regulations such as 29 CFR 1910 "Occupational Safety and Health Standards" (CFR, 2009j), 10 CFR 19 "Notices, Instructions and Reports to Workers: Inspection and Investigations" (CFR, 2009h), 1910.1200 "Hazard Communication" (CFR, 2009k) and with NRC regulations. Continuing training in these areas is conducted as necessary to maintain employee proficiency. All persons under the supervision of facility management (including contractors) must participate in GET; however, certain facility support personnel, depending on their normal work assignment, may not participate in all topics of this training. Temporary maintenance and service personnel receive GET to the extent necessary to assure safe execution of their duties. Personnel access procedures ensure the completion of the appropriate level of GET training prior to permitting unescorted access into the Controlled Area (CA).

GET topics are listed below:

- General administrative controls and procedure use
- Quality assurance policies and procedures
- General radiological (includes the use of dosimeters, protective clothing and equipment)
- Industrial safety/industrial hygiene and general first aid
- Emergency Management Plan (EMP) and implementation procedures associated with alarm response and evacuation
- Facility Security awareness and general requirements
- Chemical Process Safety (hazard communication)
- New employee orientation

- General environmental and waste management controls
- Fire protection and fire extinguisher use

11.3.7.2 Radiation Protection Training

Training programs are established for the various types of job functions (e.g., production, maintenance, radiation protection technician and contractor personnel) commensurate with radiation protection responsibilities associated with each such position.

Radiation protection training includes information about radiation and radioactive materials, risks involved in receiving low-level radiation exposure in accordance with 10 CFR 19.12, "Instructions to Workers" (CFR, 2009i) and the basic criteria and practices for radiation protection. Further description of the IIFP Facility Radiation Protection Training Program is provided in the IIFP LA, Revision B Chapter 4 Section 4.5 "Training Commitments."

Training sessions covering radiation protection are conducted on a regular basis to accommodate new employees or those attending continuing training. Topics covered in these sessions depend upon the job responsibilities and include the following, when applicable to the job responsibility:

- Notices, reports and instructions to workers
- Practices designed to keep radiation exposures ALARA
- Methods of controlling radiation exposures
- Contamination control methods (including decontamination)
- Use of monitoring equipment
- Emergency procedures and actions
- Nature and sources of radiation
- Biological effects of radiation
- Use of personnel monitoring devices
- Risk to pregnant females
- Radiation protection practices
- Protective clothing
- Respiratory protection
- Personnel surveys

Individuals attending these sessions must pass an initial examination covering the training contents to assure the understanding and effectiveness of the training. The effectiveness of the Training Program is also evaluated by audits and assessments of production and maintenance personnel responsible for following the requirements related to the topics listed above.

Since contractor employees perform diverse tasks in the CA, training for these employees is designed to address the type of work they perform. In addition to applicable radiation safety topics, training contents may include radiation work permits (RWP), special bioassay sampling and special precautions for welding, cutting and grinding in the Restricted Areas (RA).

These training programs are conducted by instructors assigned by the Training Manager as having the necessary knowledge to address chemical safety and radiation protection. Records of the training programs are maintained.

Individuals requiring unescorted access to the CA and the RA(s) receive annual continuing training.

Production personnel are further instructed in the specific safety requirements of their work assignments by qualified personnel during on-the-job training. Employees must demonstrate understanding of work assignment requirements based on observations by qualified personnel before working without direct supervision. Changes to work procedures including safety requirements are reviewed with production personnel by their immediate supervisor or delegate.

11.3.7.3 Industrial Safety/Industrial Hygiene

General industrial safety/industrial hygiene training topics are included in the GET. More specific training in various aspects of industrial and chemical safety protection is conducted to train new employees in specific job duties and to provide refresher training topics to workers depending on employee job responsibilities. The industrial safety/industrial hygiene training is an important part of establishing a strong safety culture and ensuring workers are aware of safety procedures, requirements and hazards involved in assigned duties.

The Industrial Safety/Industrial Hygiene Program includes a training matrix that identifies employees that require initial training in a particular safety element and in what program element the employee is required to have the specific training. For example, individuals whose job duties involve operating a mobile fork truck would be identified as requiring the approved OSHA forklift training module in accordance with written procedures. The industrial safety/industrial hygiene training matrix also includes a required frequency by job duty for refresher training in each applicable element. The Industrial Safety/Industrial Hygiene Program elements include, but are not limited to, the following:

- Mobile equipment and vehicle safety
- Forklift operation and licensing
- Crane safety
- Fall protection
- Hoisting and rigging
- Confined space permits and entry
- Personnel protective equipment
- Respirator usage, fitting and cleanliness
- Job hazard analysis
- Electrical safety, permits and lockout procedures
- Hot work permits (welding and burning)
- Eye and head protection
- Hand and foot protection
- Back awareness and protection

11.3.7.4 Emergency Preparedness/Security and Fire Brigade

Emergency preparedness/Security personnel and the Emergency Response Organization (ERO) develop, maintain and implement the IIFP Emergency Management Plan and its Emergency Management Plan Implementation procedures (EPIPs). Initial training and refresher training is conducted, at the appropriate frequencies, in accordance with the IIFP EMP and EPIPs and is based on the specific responsibilities of the ERO and emergency response personnel. Further description of training, including drills and exercises, related to emergency response personnel is provided in Sections 10.2 and 10.3 of the IIFP Emergency Management Plan.

The IIFP Fire Brigade is organized, operated, trained and equipped in accordance with NFPA 600. The Fire Brigade is comprised of facility employees that have their normal job responsibilities and serve in a dual role on the Fire Brigade. The Fire Brigade is considered an incipient fire brigade as classified under NFPA 600 and its members are not required to wear thermal protective clothing nor self-contained breathing apparatus (SCBA) during firefighting. The intent of the IIFP Facility Fire Brigade is to be able to handle all minor fires and to be a first response effort to supplement the local fire department for major fires at the facility. The Fire Brigade members are trained and equipped to respond to fire emergencies and contain fire damage until offsite help from a neighboring fire department arrives. The IIFP Facility Fire Brigade response includes the use of hand held portable and wheeled fire extinguishers as well as hoses to fight interior/exterior incipient fires and to fight larger exterior fires in a defensive mode (e.g., vehicle fires).

The Fire Brigade Training Program provides for initial training of all new fire brigade members, classroom refresher training and drills, annual practical training and leadership training for fire brigade and incident commanders. Incident command, first-responder and firefighting training all are conducted by qualified instructors in accordance with procedures that prescribe the instructor qualifications and that are approved by the IIFP ESH Manager, or Designee.

11.3.7.5 Technical Training

Technical training is designed, developed and implemented to assist facility employees in gaining an understanding of applicable fundamentals, procedures and practices related to IROFS. Also, technical training is used to develop skills necessary to perform assigned work related to IROFS. Technical training consists of four segments:

- Initial training
- OJT and qualifications
- Continuing (and refresher) training
- Special training

Initial Training

Initial job training is designed to provide an understanding of the fundamentals, basic principles and procedures involved in work related to IROFS that an employee is assigned. This training may consist of, but is not limited to, live lectures, taped and filmed lectures, self-guided and interactive study, demonstrations, laboratories and workshops and on-the-job training.

Certain new employees or employees transferred from other sections within the facility may be partially or wholly qualified by reason of previous applicable training or experience. The extent of further training for these employees is determined by applicable regulations, performance in review sessions, comprehensive examinations or other techniques designed to identify the employee's current level of ability.

Initial job training and qualification programs are developed for production, maintenance and technical classifications. Training for each program is grouped into logical blocks or modules and presented in such a manner that specific behavioral objectives are accomplished. Trainee progress is evaluated using written examinations, oral or practical tests. Depending upon the regulatory requirements or individual's needs and plant operating conditions, allowances are made to suit specific situations.

On-the-Job Training and Qualifications

On-the-job training is a systematic method of providing the required job-related skills and knowledge for a position. This training is conducted in an environment as close to the work environment as feasible. Applicable tasks and related procedures make up the OJT qualifications program for each technical area. Training is designed to supplement and complement training received through classroom and laboratory.

OJT is an element of the Technical Training Program. OJT is used in combination with classroom training for activities involving IROFS. Designated personnel competent in the program standards and conducting training shall conduct OJT using current performance-based training materials. Completion of OJT is demonstrated by actual task performance or performance of a simulation of the task with the trainee explaining task actions using the conditions encountered during the performance of the task, including references, tools and equipment reflecting the actual task to the extent practical.

Continuing Training

Continuing (or refresher) training is any training not provided as initial qualification or basic training that maintains and improves job-related knowledge and skills such as the following:

- Facility systems and component changes
- Policy and procedure changes
- Lessons learned from operating experience program documents review to include industry and in-house operating experiences
- Continuing training required by regulation (e.g., emergency plan training)
- General employee, special, administrative, vendor and/or advanced training topics supporting tasks that are elective in nature
- Training identified to resolve deficiencies (task-based) or to reinforce seldom used knowledge skills
- Refresher training on initial training topics
- Structured pre-job instruction, mock-up training and walk through
- Quality awareness
- Requalification training
- Training designed to maintain proficiency

Continuing training may consist of classroom and components performed on a frequency needed to maintain proficiency on the job. Once the objectives for continuing training have been established, the methods for conducting the training may vary. The method selected must provide clear evidence of objective accomplishment and consistency in delivery.

Special Training

Special training involves those subjects of a unique nature required for a particular area of work.

11.3.8 Evaluation of Training Effectiveness

Periodically the Training Program is systematically evaluated to measure the Program's effectiveness in producing competent employees. The trainees are encouraged to provide feedback after completion of classroom training sessions to provide data for this evaluation for program improvements. These evaluations identify program strengths and weaknesses, determine whether the Program content matches

current job needs and determine if corrective actions are needed to improve the Program's effectiveness. The Training functional organization is responsible for leading the Training Program evaluations and for implementing any corrective actions.

Evaluation objectives follow that are applicable to the Training Program or topical area being reviewed:

- Management and administration of training and qualification programs
- Development and qualification of the training staff
- Position training requirements
- Determination of training program content, including its facility change control interface with the CM system
- Design and development of training programs feedback, including lesson plans
- Conduct of training
- Trainee examinations and evaluations
- Training program assessments and evaluations

Evaluation results are documented, with program strengths and weaknesses being highlighted. Identified weaknesses are reviewed, improvements are recommended, changes are made to procedures and practices or training materials as necessary.

Periodically, training and qualifications activities are monitored by designated facility and/or contracted training personnel. The QA Manager audits the facility training and qualification system. In addition, trainees and vendors may provide input concerning training program effectiveness. Methods utilized to obtain this information may include surveys, questionnaires, performance appraisals, staff evaluations and overall Training Program effectiveness evaluation techniques. Courses that are conducted frequently are not evaluated each time. However, those are routinely evaluated at a frequency sufficient to determine program effectiveness. Evaluation information may be collected through:

- Verification of program objectives as related to job duties for which intended
- Periodic working group program evaluations
- Testing to determine trainee accomplishment of objectives
- Trainee evaluation of the instruction
- Supervisor's evaluation of the trainee's performance after training on-the-job
- Supervisor's evaluation of the instruction

Unacceptable individual performance is transmitted to the appropriate line manager.

11.3.9 Personnel Qualification

The qualification requirements for key management positions are established. (See the IIFP LA, Revision B Chapter 2. Training and qualification requirements associated with QA personnel are provided. In addition, qualification and training requirements for operations personnel are established and implemented in plant procedures.

11.3.10 Provisions for Continuing Assurance

Continuing or periodic retraining shall be established, when applicable, to ensure personnel remain proficient. Periodic training is generally conducted to ensure retention of knowledge and skills important to Operations. The training may consist of periodic retraining exercises, instructions or review of subjects

as appropriate to maintain the proficiency of personnel assigned to the facility. The results of the retraining are documented.

Personnel performing activities related to IROFS are evaluated periodically to determine whether they are capable of continuing their activities that are related to IROFS. The evaluation may be by written test, oral test or on-the-job performance observation by the supervisor. The results of the evaluation are documented. Unacceptable individual performance is transmitted to the appropriate line manager for investigation and corrective action where appropriate. When the results of the evaluation dictate, retraining or other appropriate actions are provided. Continuing training is also required due to plant modifications, procedure changes and QA Program changes that result in new or revised information.

11.4 PROCEDURES DEVELOPMENT AND IMPLEMENTATION

The IIFP Facility utilizes a hierarchy of policies, plans and procedures to document management expectations and commitments, as well as to provide instructions and guidance to IIFP personnel. Policies and plans are upper tier documents that define and describe senior management expectations and guidelines for safe operation of the IIFP Facility and compliance with state and federal regulations, permits and licenses. Procedures are used to ensure implementation of the requirements set forth in policies and plans.

All activities involving IROFS and QL-1 and QL-2 items are conducted in accordance with approved procedures. As noted throughout this document, procedures are used to control IROFS activities to ensure the activities are carried out in a safe manner and in accordance with regulatory requirements.

11.4.1 Type of Procedures

Procedures are categorized as management control procedures or operating procedures/instructions. Management control procedures describe administrative and general practices approved and issued by management at a level appropriate to the scope of the practice. These procedures direct and control activities across the various organizational functions and assign functional responsibilities and requirements for these activities. Operating procedures provide specific direction for task-based work and are used to directly control process operations at the work place.

Compliance with IIFP Facility procedures is mandatory. If any aspect of a procedure is unclear or incorrect as written, personnel shall safely stop the operation and/or activity and contact management. The operation and/or activity shall not restart until corrective action has been taken. If a situation is not defined in the procedure content or an unexpected response is obtained, management notification is also required.

Generally, four types of plant procedures are used to control QL-1 and QL- 2 activities: operating procedures, management control (administrative) procedures, maintenance procedures and emergency procedures. Procedures may also be used to control other plant and administrative activities.

11.4.1.1 Operating Procedures

Operating procedures/instructions include direction for normal operations, off-normal operations, alarm response and emergency operations caused by failure of an IROFS or human error. These procedures provide reasonable assurance for radiation protection, industrial safety/industrial hygiene, emergency preparedness/security and environmental protection. Operating procedures are used to directly control production. Operating procedures include, as applicable:

- Purpose of the activity
- Regulations, polices and guidelines governing the procedure
- Type of procedure
- Steps for each operating process stage include:
  - Initial startup
  - Normal production
  - Temporary operations
  - Emergency shutdown
  - Emergency operations
  - Normal shutdown
  - Startup following an emergency or extended downtime
  - Hazards and safety considerations
  - Production limits
- Measures to be taken if hazard contact or exposure occurs
- IROFS associated with the process and their functions
- The timeframe for which the procedure is valid

Applicable safety limits and IROFS are clearly identified in the procedures. IIFP will incorporate methodology for identifying, developing, approving, implementing and controlling operating procedures. Identifying needed procedures will include consideration of ISA results. The method will ensure that, as a minimum:

- Operating limits and IROFS are specified in the procedure.
- Procedures include required actions for off-normal conditions of production, as well as normal production.
- Needed safety checkpoints are identified at appropriate steps in the procedure.
- Procedures are validated through field tests.
- Procedures are approved by functional managers responsible and accountable for the operation.
- A mechanism is specified for revising and reissuing procedures in a controlled manner.
- The QA elements and CM Program at the facility provide reasonable assurance that current procedures are available and used at all work locations.

11.4.1.2 Management Control (Administrative) Procedures

Management control procedures deal with policy or programs and administrative systems, provide programmatic requirements and do not normally involve manipulation of equipment. Management control procedures are used to perform activities that support production and control processes with IROFS and/or hazardous chemicals incident to the processing of licensed material. Site-wide safe work practices (such as lockout/tagout, confined space entry, exclusion area requirements, radiation or hot work permits, industrial safety/industrial hygiene and environmental issues) apply to workers, visitors, contractors and vendors.

These management control procedures include management measures such as the following:

- Configuration management
- Industrial safety/industrial hygiene, radiation safety, chemical safety and fire safety
- Quality Assurance
- Design control
- Facility personnel training and qualification

- Audits and assessments
- Incident investigations
- Record keeping and document control
- Reporting
- Procurement

Procedures for construction will be an integral part of the procedures of the DB Contractor chosen by IIFP. The DB Contractor will use those procedures during the construction phases of the IIFP Facility.

Additionally, criticality safety procedures will not be applicable for the IIFP Facility since the facility will only process depleted uranium.

11.4.1.3 Maintenance Procedures

Maintenance, including testing and calibration of facility IROFS, is performed in accordance with approved written procedures, documented instructions, checklists or drawings that conform to applicable codes, standards, specifications and other appropriate criteria. Key maintenance requirements for safety controls, such as calibration, functional testing and replacement of specified components are derived from the analyses described in the ISA Summary, Revision B. Procedures are developed that are commensurate with the need as determined by the ISA review (for example, skills normally possessed by qualified maintenance personnel may not require detailed step-by-step delineation in a written procedure).

Functional testing is on a periodic basis to determine various facility parameters and to verify the continuing capability of IROFS to meet performance requirements. The functional testing is conducted in accordance with approved, written procedures. Periodic test procedures are utilized to perform such testing and are sufficiently detailed that qualified personnel can perform the required functions without direct supervision.

The selection and qualification of Maintenance personnel for IROFS work activities are documented and implemented through written procedures. Contractors working or performing activities that could affect IROFS are required to follow the same procedures as IIFP Maintenance personnel.

Maintenance procedures address:

- Preventive and corrective maintenance of IROFS
- Surveillance (includes calibration, inspection and other surveillance testing)
- Functional testing of IROFS (includes operational, pre-operational, periodic, post-maintenance and special testing)
- Requirements for pre-maintenance activity involving reviews of the work to be performed and reviews of procedures for accuracy and completeness

The procedures describe, as a minimum, the following:

- Pre-maintenance activities involving reviews of the work to be performed including procedure reviews for accuracy and completeness
- Steps that require notification of all affected parties (operators and appropriate supervisors) before performing work on completion of maintenance work (The discussion includes potential degradation of IROFS during the planned maintenance.)

- Controls on and specification of any replacement components or materials to be used to ensure like-kind replacement
- Post-maintenance testing to verify operability of the equipment
- Tracking and records management of maintenance activities
- Safe work practices (e. g., lockout/tag-out, confined space entry, control of exclusion area, radiation or hot work permits and fire, chemical and environmental requirements)

The administrative control of maintenance is maintained as follows:

- A comprehensive maintenance program for the facility's IROFS is established to assure safe, reliable and efficient operation.
- Personnel performing maintenance activities are qualified in accordance with applicable codes and standards and procedures.
- Maintenance is performed with approved written procedures that conform to applicable codes, standards, specifications and other appropriate criteria.
- Maintenance is scheduled so as not to jeopardize facility operation or the safety of facility personnel.
- Maintenance histories are maintained on facility IROFS.
- The administrative control of facility modifications is maintained as in Section 11.1.5 “Change Control.”

Before approval, new Maintenance procedures are reviewed by the various safety disciplines, including fire, radiation and industrial safety/industrial hygiene and chemical process safety.

See Section 11.2.1 for additional information on requirements for maintenance procedures.

11.4.1.4 Emergency Procedures

IIFP develops and maintains a documented controlled set of IIFP Emergency Management Plan Implementation Procedures applicable to the IIFP Facility. Emergency instructions pertinent to specific accident scenarios and other categorized non-routine operational events are developed and included in the EPIPs. These procedures clearly state the duties, responsibilities, action levels and actions to be taken by responders. Administrative procedures are established to ensure that individuals and groups assigned responsibilities in an emergency have easy access to a current copy of each procedure that pertains to their functions. Responsibilities are provided for each emergency position.

In accordance with established IIFP procedural guidelines, departmental administrative procedures are established which assign responsibility for the development, review, approval and update of the IIFP Emergency Management Plan and supporting EPIPs. The IIFP EMP is reviewed periodically by the ESH functional organization for accuracy and updated as needed. A decrease in effectiveness review is completed for all proposed changes to the EMP. Changes to the Plan that decrease the effectiveness are not implemented without prior NRC approval. Changes that do not decrease the effectiveness of the EMP may be implemented without NRC prior approval provided the changes are submitted to the NRC within three (3) months of making the changes. Additionally, any proposed changes that affect an off-site organization are provided to that organization for review and comment at least sixty (60) days prior to the change being implemented, unless mutually agreed otherwise. Any material revision to the EMP is distributed to affected parties before the effective date and is submitted to the NRC within three (3) months of the revision.

11.4.2 Procedures Process

Procedures are developed or modified through a formal process incorporating the change controls described in Section 11.1.5 “Change Control.” The procedures process utilizes nine basic elements to accomplish procedure development, review, approval and control. These elements are Identification, Development, Verification, Review and Comment Resolution, Approval, Validation, Issuance, Change Control and Periodic Review. The elements are discussed in detail in the following paragraphs.

11.4.2.1 Identification

Site managers have the responsibility for identifying which tasks are included in procedures within their areas of control. Procedures are required where actions are taken necessary to prevent or mitigate the consequences of accidents described in the ISA. As a minimum, a procedure is required for any task or activity that affects QL-1 and QL-2 SSCs.

A procedure is normally not needed if it does not involve IROFS and if the work is not complex or only involves a few actions (unless failure to properly conduct those actions could result in significant consequences), if the task requires those skills normally possessed by a qualified person (otherwise known as "skill-of-the-craft"), or if the consequences of error are minimal.

Maintenance activities, not involving QL-1 or QL-2 SSCs, may be addressed by written procedures, documented work instructions, skill-of-the-craft or drawings appropriate to the circumstances.

New or revised NRC certification requirements are evaluated to determine impact on existing implementing procedures or to identify the need for new implementing procedures.

11.4.2.2 Development

The procedure use category is determined. This determination documents the designation of a procedure as In Hand (Continuous Use), General Intent (Reference Use) or Information Use. The designation is based on the administrative or non-administrative use of the procedure and the safety or financial consequences of failing to adhere to procedural requirements.

Procedure development, preparation and quality are the user organization's responsibility. Input and review is required by affected parties. Other selected reviews are obtained, such as Safety and Quality, to ensure that safety and quality assurance requirements are identified and included where QL-1 or QL-2 SSCs are involved.

Interviews with procedure users and process walk-downs are utilized to ensure procedures are usable, reflect as-built conditions, production operations and maintain management controls for safety and quality. During development, regulatory commitments, ISA and QA Program requirements are identified and incorporated in the procedure.

As the procedure is drafted, attributes that enhance procedural use are included, such as standard style organization and format. Additionally, essential elements are included that are generic to all procedures including chemical process and fire safety, warning notes, reminders or pertinent information regarding specific hazards or concerns, Materials Safety Data Sheet availability, special precautions, radiation and explosive hazards and special personal protective equipment.

11.4.2.3 Verification

Verification is a process that ensures the technical accuracy of the procedure and that it can be performed as written. Non-administrative procedures are verified by the procedure owner/user during the procedure development/change process. There are two basic attributes of the verification process. The first attribute relates to the technical accuracy of the procedure. It ensures that all technical information including formulas, set points and acceptance criteria are correctly identified in the procedure. The second attribute is administrative, in that it verifies the procedure format and style and that it is consistent with the procedure-on-procedures. Verification consists of a walk-down of the procedure in the field or a table-top walk through.

11.4.2.4 Review and Comment Resolution

Draft new procedures and procedure changes are distributed for technical reviews and cross-discipline reviews, as needed. Functional area and cross-discipline reviews are performed by individuals not having direct responsibility for processing the new procedure or procedure change. Comments/questions generated during the review process are resolved with the originating organizations. If comments are so extensive that resolution of the comments changes the intent of the original draft, the revised draft procedure is verified a second time and the validation checked. Reviews by facility personnel ensure that the production limits and controls involving IROFS as well as quality assurance, programmatic and regulatory requirements are specified in procedures.

The QA function reviews QA implementing procedures for compliance and consistency with the QA Program and ensures that the provisions of the QA Program are effectively incorporated into QA implementing procedures.

11.4.2.5 Approval

Following the resolution of review comments, procedures are approved. Approval authority rests with the responsible manager. Managers ensure that necessary training or required reading is completed prior to procedure implementation.

11.4.2.6 Validation

The purpose of procedure validation is to ensure that technical errors or human factor issues were not inadvertently introduced during the procedure review process. Validation is performed by qualified personnel and may be accomplished by detailed evaluation of the procedure as part of a walk through exercise or as part of a walk through drill (particularly for emergency or off-normal procedures). If the particular system or process is not available for a walk through validation, talk through may be performed in the particular shop or training environment. Performance of procedure validation is documented.

11.4.2.7 Issuance and Distribution

Procedures are issued and controlled in accordance with the Records Management and Document Control Program practices. Line managers, or designees, shall be responsible for ensuring personnel doing work that requires the use of procedures have access to controlled copies of the required procedures.

11.4.2.8 Procedures Process Change Control

Changes to procedures are processed as described below:

- The preparer documents the change as well as the reason for the change.
- An evaluation shall be performed to determine if the change may affect safety or involves IROFS, as appropriate. If the evaluation reveals that a change to the license is needed to implement the proposed changes, the change will not be implemented until prior approval is received from the NRC.
- The procedure with proposed changes shall be reviewed by a designated reviewer.
- The functional manager shall be responsible for approving procedure changes and for determining whether a cross-disciplinary review is necessary and by which department(s).

The need for following cross-disciplinary reviews shall be considered as a minimum for: 1) proposed changes having a potential impact on chemical or radiation safety; a review shall be performed for chemical and radiation hazards, 2) proposed changes having a potential impact on IROFS by facility safety engineering personnel and the QA Manager, or Designee and 3) proposed changes that have potential impact on environmental controls are reviewed by the ESH functional organization. Records of completed cross-functional reviews are maintained for all changes to procedures involving IROFS.

Temporary changes to procedures are issued for production activities that are of a nonrecurring nature. Temporary changes to procedures are used when revision of a production or other permanent procedure is not practical. Temporary changes to procedures shall not involve a change to IROFS and shall not alter the intent of the original procedure. Examples of uses of temporary changes to procedures are:

- To direct production activities during special testing, maintenance and modification
- To provide guidance in unusual situations not within the scope of normal procedures
- To ensure orderly and uniform production for short periods of time when the facility, a system or a component is performing in a manner not addressed by existing procedures or has been modified in such a manner that portions of existing procedures do not apply

The temporary changes to procedures are approved by two members of the facility management staff, at least one of whom is a shift superintendent, or designee. Temporary changes to procedures have a designated expiration date and may be made permanent once the change is reviewed and approved through the normal procedure change and approval process.

11.4.2.9 Periodic Review

Periodic reviews are performed on procedures to assure their continued accuracy and usefulness. Specifically, reviews of operating procedures are conducted every three (3) years and EPIPs are reviewed annually. In addition, applicable procedures are reviewed after unusual incidents (such as an accident, unexpected transient, a significant error by production personnel, equipment malfunction or after any modification to a system) to determine if changes are appropriate based on the cause and corrective action determination for the particular incident. Procedures are revised as needed. When conducting the periodic review, the procedure owner or subject matter expert performs a complete administrative and technical review ensuring information is complete and accurate and that the procedure is usable as written.

11.4.3 Use and Control of Procedures

In-Hand (continuous use) procedures are performed step-by-step without deviation unless deviation is allowed by the procedure. General Intent (Reference Use) procedures are followed as written, unless deviation is allowed by the procedure. Information Use procedures are followed to implement programmatic requirements.

Controlled copies of procedures are marked "Controlled Copy." Working copies are verified as the latest version. This may be managed by limited access to the most current revision of the document. Information Only copies of In-Hand (Continuous Use) or General Intent (Reference Use) procedures are marked "Information Only" to indicate they are not used to perform work.

If a step of a procedure involving QL-1 and QL- 2 SSCs cannot be performed as written, work is stopped, the system is immediately placed in a safe condition and corrective actions initiated in accordance with site procedures.

11.4.4 Topics to be Covered in Procedures

Activities defined in Section 11.4.1 “Types of Procedures,” are the minimum activities to be covered by controlled documents. Maintenance activities listed below may be covered by approved written procedures, documented work instructions or drawings, whichever is appropriate to the circumstance. The list below is not intended to be all-inclusive, as many other activities carried out during operations may be covered by procedures not included in the list. Similarly, this listing is not intended to imply that procedures need to be developed with the same titles as those in the list. This listing provides guidance on topics to be covered rather than specific procedures.

Management Control Procedures (Administrative)

1. Configuration Management

2. Maintenance, with the Following Additional Procedures
   - Maintenance Modifications
   - Work Control Procedures
   - Control of Measuring and Test Equipment

3. Training and Qualifications Procedures

4. Procedures Development and Implementation

5. Audits and Assessments Procedures, Including
   - Audits
   - Certification of Audit Personnel
   - Management Assessments

6. Incident Investigations and Corrective Actions Management

7. Records Management and Document Control

8. Other Quality Assurance Elements
   - Organization

- Quality Assurance Program
- Design Control
- Procurement Document Control
- Supplier Qualification
- Instructions, Procedures and Drawings
- Document Review
- Continuous Improvement
- Control of Purchased Items and Services
- Identification and Control of Items
- Inspection
- Test Control
- Control of Special Processes
- Control of Nonconforming Items, Materials and Components
- Inspection, Test and Operating Status
- Quality Assurance Records

9. Environmental, Safety and Health Procedures
    - Hazard Communication Program (HAZCOM)
    - Fire Prevention Plan
    - Energy Control (Lock/out/Tag/out)
    - Respirator Program
    - Confined Space Entry
    - Exposure Control Plan (Bloodborne Pathogens Program)
    - Fall Protection
    - Chemical Hygiene Plan (Laboratory Safety Program)
    - Hazardous Waste Operations and Emergency Response (HAZWOPER)
    - Process Safety Management
    - Radiation Protection
    - Environmental Protection
    - Spill Control Response

10. Fire Protection Procedures

11. Non-radiological/Radioactive Waste Management Procedures

12. Laboratory Analytical Procedures

13. Security Procedures

Operating Procedures (Non-Administrative)

1. System Procedures That Address Startup, Operation, Shutdown, Control of Process Operations and Recovery After a Process Upset Including the Following:
    - DUF_4 Process Operations
    - Autoclave Area Operations, Feeds, Controls, Scales
    - Hydrogen Fluoride (HF) Containment/Loading/Packaging
    - BF_3 Feed and Reaction Controls
    - BF_3 Product Collection/Packaging
    - SiF_4 Feed and Reaction Controls

- SiF_4 Product Collection/Packaging
- Scrubbing Systems
- Potassium Hydroxide (KOH) Regeneration
- Environmental Protection Process Operations
- Fire Protection Systems
- Utility Plant Operations
  - Sanitary Plant Operations
  - Operation of the Drinking Water Purification System
  - Operation of the Monitoring Wells
  - Switchgear
  - Boiler Operations
  - Plant Utilities
  - Hydrogen Supply System
  - Nitrogen Supply System
  - Chillers
  - Closed Loop Air Coolers
- Decontamination Area Operations
- DUF_6 Cylinder Hauler Operations
- FEP Area Emergency Scrubber
- FEP Product Cylinder Evacuation/Storage
- Shift Turnover

2. Abnormal Operations/Alarm Response, Including Procedures for:
   - Loss of Cooling Water
   - Loss of Instrument Air
   - Loss of Electrical Power
   - Operational Loss of Alarms Systems
   - Chemical Process Releases

Maintenance Activities Or Procedures

1. Surveillance/Monitoring Including IROFS

2. Corrective Maintenance Including IROFS and Repairs/Replacement of Equipment Unexpectedly Degraded/Failed IROFS

3. Preventive Maintenance, Including the Following:
   - Functional Testing of IROFS
   - Measuring and Test Equipment (M&TE) Calibration Procedures
   - Calibration of IROFS
   - Scheduled Refurbishment/Overhaul/Replacement of Equipment, Including IROFS
   - Preventive Repairs of IROFS

4. Functional Testing, Including the Following:
   - Testing Following Calibration of Equipment
   - Testing of Failed/Degraded Equipment, Including IROFS

Emergency Procedures

Emergency Management Plan Implementation Procedures:

- Identification and Reporting of Emergency Conditions
- Emergency Classification and Notifications
- Field Incident Commander and Field Incident Commander Staff Activities
- Emergency Response Organization Activation and Deactivation
- Emergency Response Team Activities
- Employee Evacuation and Accountability
- Personnel and Equipment Decontamination under Emergency Conditions
- Maintaining Emergency Preparedness/Security

11.4.5 Temporary Procedures

Temporary procedures may be issued only when permanent procedures do not exist, 1) to direct operations during testing, maintenance and modifications, 2) to provide guidance in unusual situations not within the scope of permanent procedures and 3) to ensure orderly and uniform production for short periods when the plant, a system or component of a system is performing in a manner not covered by existing permanent procedures, or has been modified or extended in such a manner that portions of existing procedures do not apply. These temporary procedures may be used for a period of time which should not exceed ninety (90) days, or a period for which the temporary condition must exist, whichever is greater. Temporary procedures that need to exceed the ninety (90) days are assessed to ensure it is appropriate to extend the use of the temporary procedure.

11.4.6 Records

Records generated during procedure use are identified in the governing procedure and controlled according to the plant Records Management and Document Control Program practices. Further description of the Records Management Program is presented below in Section 11.7.

11.5 AUDITS AND ASSESSMENTS

The IIFP Facility has a tiered approach to verifying compliance to procedures and performance to regulatory requirements. Audits are focused on verifying compliance with regulatory and procedural requirements and licensing commitments. Assessments are focused on effectiveness of activities and ensuring that IROFS and any items that affect the function of IROFS are reliable and are available to perform their intended safety functions. This approach includes performing assessments and audits on critical work activities associated with facility safety, environmental protection and other areas as identified via trends.

11.5.1 Audits

Audits of the QL-1 and QL-2 work activities associated with IROFS and any items that affect the function of the IROFS are conducted in accordance with the QA Program.

These audits and their associated frequencies are conducted in accordance with written plans and checklists. Audits are performed under the direction of a lead auditor. Lead auditors and staff auditors are functionally and organizationally independent of the programs and activities examined. Where appropriate, audit teams are supplemented with on-site and/or off-site technical specialists.

Audit results are documented and reported as specified in plant procedures. Provisions are made for immediate reporting and corrective action where warranted. A plant Corrective Action Program is administered to ensure proper control of corrective actions (See Section 11.6).

11.5.2 Assessments

Assessments are performed by management responsible for implementing the respective portions of the QA Program to assess the adequacy of that part of the QA Program and to assure its effective implementation. Personnel from the area being assessed may perform the assessment, provided that they do not have direct responsibility for the specific area being assessed. Results of assessments are documented. Any observations from the program assessments are resolved by the responsible organization manager.

11.5.2.1 Management Assessments

Management assessments may be conducted by the line organizations responsible for the work activity. Site managers follow a management assessment process within their organization to assess the adequacy of and effectiveness of the implementation of the programs under their cognizance. The Quality functional organization will monitor the management assessment process.

Managers evaluate findings from audits and assessments from plant facilities in the areas of occupational safety and health, radiation protection, environmental compliance, fire safety, emergency preparedness/security, safety requirements, conduct of operations and conduct of maintenance. Issues relating to training, QA, maintenance, CM, etc. are also assessed during these management assessments.

11.5.2.2 Independent Assessments

Independent audits/assessments, where required by procedure, are conducted by individuals not involved in the area being assessed. These assessments are performed routinely by qualified staff personnel that are not directly responsible for production activities. Deficiencies identified during the assessment requiring corrective action are forwarded to the responsible manager of the applicable area or function for action in accordance with the Corrective Action Program. Future assessments shall include a review to evaluate if corrective actions have been effective.

11.5.3 Conduct of Audits and Assessments

Audits and assessments are performed to assure that facility activities are conducted in accordance with the written procedures and that the processes reviewed are effective and in compliance with established processes or work instructions.

Audits are conducted by the IIFP ESH, quality and technical organizations (independent of production operations) in accordance with procedures and checklists by qualified auditors. Audits verify the effectiveness of occupational safety and health and environmental programs and their implementation and determine the effectiveness of the assessment process.

Audits are performed in accordance with a written plan that identifies and schedules audits to be performed. Audit team members shall not have direct responsibility for the function and area being audited. Team members shall have technical expertise or experience in the area being audited and are indoctrinated in audit techniques. The frequency of audits is based upon the status and safety importance

of the activities being performed and upon work history. Major activities as described in Section 11.5.4 are audited or assessed on a periodic basis.

The results of the audits and assessments are provided in a written report in a timely manner to the COO and the managers responsible for the activities audited or assessed. Any deficiencies noted in the audits and assessments are responded to promptly by the responsible managers or designees, entered into the Corrective Action Program and tracked to completion and re-examined during future audits and assessments to ensure corrective action has been completed.

Records of the instructions and procedures, persons conducting the audits or assessments and identified violations of license conditions and corrective actions taken are maintained.

11.5.4 Activities Subject to Audits and Assessments

Audits and assessments may be conducted to include:

- Radiation protection
- Chemical safety
- Industrial safety/industrial hygiene including fire protection
- Environmental protection
- Emergency management
- Quality Assurance
- Configuration management
- Maintenance
- Training and qualification
- Procedures
- Corrective Actions/Incident investigations
- Records management

11.5.5 Scheduling of Audits and Assessments

A schedule is established that identifies audits and assessments to be performed and the responsible organization assigned to conduct the activity. The frequency of audits and assessments is based upon the status and safety importance of the activities being performed and upon work history. All major activities are audited or assessed on a periodic basis. The audit and assessment schedule is reviewed periodically and revised as necessary to ensure coverage commensurate with current and planned activities.

11.5.6 Procedures for Audits and Assessments

Internal and external audits and assessments are conducted using approved procedures that meet the QA Program requirements. These procedures provide requirements for the following audit and assessment activities:

- Scheduling and planning of the audit and assessment
- Training requirements of audit personnel
- Development of audit plans and audit/assessment checklists as applicable
- Performance of the audit and assessment
- Reporting and tracking of findings to closure
- Closure of the audit and assessment

The applicable procedures emphasize reporting and correction of findings to prevent recurrence.

Audits and assessments are conducted by:

- Using the approved audit and assessment checklists as applicable
- Interviewing responsible personnel
- Performing plant area walk-downs
- Reviewing controlling plans and procedures
- Observing work in progress
- Reviewing completed QA documentation

Audit and assessment findings are tracked in the Corrective Action Program. The data is periodically analyzed for potential trends and needed program improvements to prevent recurrence and/or for continuous program improvements. The resulting trend is evaluated and reported to applicable management. This report documents the effectiveness of management measures in controlling activities as well as deficiencies. Deficiencies identified in the trend report require corrective action. The QA organization also performs follow up reviews on identified deficiencies and verifies completion of corrective actions reported as a result of the trend analysis.

The audit and/or assessment team leader is required to develop the audit and/or assessment report documenting the findings, observations and recommendations for program improvement. These reports provide management with documented verification of performance against established performance criteria for IROFS. These reports are developed, reviewed, approved and issued following established formats and protocols detailed in the Corrective Actions procedure. Responsible managers are required to review the reports and provide any required responses due to reported findings.

Corrective actions following issuance of the audit and/or assessment report require compliance with the corrective action procedure(s). The QA organization will verify the corrective actions taken were effective and were completed in a timely manner. In addition, future assessments will include a review to evaluate if corrective actions have been effective.

11.5.7 Qualifications and Responsibilities for Audits and Assessments

The QA Manager coordinates the audits. The responsible lead auditor and QA Manager determine the scope of each audit. The QA Manager may initiate special audits or expand the scope of audits. The lead auditor directs the audit team in developing checklists, instructions or plans and performing the audit. The audit shall be conducted in accordance with the checklists, but the scope may be expanded by the audit team during the audit. The audit team consists of one or more auditors.

Auditors and lead auditors are responsible for performing audits in accordance with the applicable QA procedures. The audit team consists of appropriately trained and experienced individuals. Before being assigned to audits, auditors must complete training on the following topics:

- IIFP QA Program
- Audit fundamentals, including audit scheduling, planning, performance, reporting and follow-up action involved in conducting audits
- Objectives and techniques of performing audits

Qualifications of auditors and lead auditors are based on the QA Manager's evaluation of education, experience, professional qualifications, leadership, sound judgment, maturity, analytical ability, tenacity

and past performance and completion of QA training courses and audits. Personnel performing assessments are required to complete QA orientation training, as well as training on the assessment process. Personnel performing these assessments do not report to the production organization and have no direct responsibility for the function or area being assessed.

11.6 INCIDENT INVESTIGATIONS AND CORRECTIVE ACTION PROGRAM

The following sections describe the incident investigations and corrective action process.

11.6.1 Incident Investigations

Incident investigations are performed to assure that the upset condition(s) is understood and appropriate corrective actions are identified and implemented to prevent recurrence. The incident investigation process is a simple mechanism available for reporting deficiencies, abnormal events and potentially unsafe conditions or activities. Each event is considered in terms of its requirements for reporting in accordance with regulations and is evaluated to determine the level of investigation required. The process of incident identification, investigation, root-cause(s) analysis, recording, reporting and follow-up are addressed in and performed by written incident investigations and corrective action procedures. Radiological, hazardous chemicals and industrial safety/industrial hygiene requirements are addressed. Guidance for classifying occurrences shall be contained in the incident investigation procedures, including examples of threshold off-normal occurrences. The depth of the investigation will depend upon the severity of the classified incident in terms of the levels of uranium or chemicals released and/or the degree of potential for exposure of workers, the public or the environment.

The Quality Assurance Manager shall ensure that a record is maintained of corrective actions to be implemented as a result of off-normal occurrence investigations in accordance with the corrective action procedures. These corrective actions shall include documenting lessons learned and implementing worker training where indicated and are tracked to completion by the QA Manager, or Designee.

11.6.1.1 Incident Identification, Categorization and Notification

The IIFP Facility commits to maintain a system to identify, track, investigate and implement corrective actions for abnormal events (unusual incidents). Through this system, the facility will investigate abnormal events that may occur during operation of the facility, determine the specific or generic root cause(s) and generic implications, recommend corrective actions and report to the NRC as required by 10 CFR 70.50, “Reporting Requirements” (CFR, 2009 a2) and 10 CFR 70.74, “Additional Reporting Requirements” (CFR, 2009f). Specifics of the Incident Investigation process are as follows:

- IIFP will establish a process to investigate abnormal events that may occur during operation of the facility and that involve QL-1 and QL-2 SSCs or activities, abnormal excursions to the environment that have potential to exceed regulatory limits or abnormal industrial safety/industrial hygiene events that would require reporting under OSHA regulations.

- The investigation process includes a prompt risk-based evaluation and depending on the complexity and severity of the event, the investigation may be conducted by one subject-matter-expert. The investigator(s) is independent from the line function(s) involved with the incident under investigation.

- Investigations begin within 48 hours of the abnormal event, or sooner, depending on safety significance of the event. The record of IROFS failures required by 10 CFR 70.62(a) (3) (CFR,

2009c) for IROFS is reviewed as part of the investigation. Record revisions necessitated by post-failure investigation conclusions are made accordingly.

- Where determined necessary by the ESH Manager, the COO, or Designee, appoints qualified internal or external investigators to serve on investigating teams when required. The team includes at least one process expert and at least one team member trained in root cause analysis.

11.6.1.2 Conduct of Incident Investigation

Incident investigations are implemented according to approved written procedures. The investigation process follows the steps listed in the 11.6.1.1 section above and includes a prompt risk-based evaluation. Record revisions necessitated by post-failure investigation conclusions shall be made within five (5) working days of the completion of the investigation. Additional specifics of the Incident Investigation process are as follows:

- IIFP will derive an understanding of the issues and drivers and determine the cause(s).

- IIFP will develop appropriate corrective and preventive actions.

- IIFP will monitor and document corrective actions through completion.

- IIFP will maintain auditable records and documentation related to abnormal events, investigations and root cause analyses so that lessons learned may be applied to future production of the facility.

- For each abnormal event, the incident report includes a description, contributing factors, a root cause analysis, findings and recommendations. Relevant findings are reviewed with affected personnel.

- Details of the event sequence are compared with accident sequences already considered in the ISA and the ISA Summary, Revision B is modified to include evaluation of the risk associated with accidents of the type actually experienced.

IIFP will develop procedures for conducting an incident investigation and the procedures will contain the following elements:

- A documented plan for investigating an abnormal event

- A description of the functions, qualifications and/or responsibilities of the manager who would lead the investigative team and those of the other team members, the scope of the team's authority and responsibilities and assurance of cooperation of management

- Assurance of the team's authority to obtain all the information considered necessary and its independence from responsibility for or to the functional area involved in the incident under investigation

- Guidance for personnel conducting the investigation on how to apply a reasonable, systematic, structured approach to determine the specific or generic root cause(s) and generic implications of the problem

- Requirements to make available original investigation reports to the NRC on request

- A system for monitoring the completion of appropriate corrective actions

11.6.2 Corrective Action Program

The QA Program identifies the responsibilities and provides authority for those individuals involved in quality activities to identify any condition adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective materials and equipment and non-conformances. These individuals identify and document conditions adverse to quality, analyze and determine how the conditions can be corrected or resolved and take such steps as necessary to implement corrective actions in accordance with documented procedures. The Corrective Action Program is specifically described in the IIFP LA, Appendix A Revision B "Quality Assurance Program Description" (QAPD) Section A.16.

The QA Program requires regularly scheduled audits and assessments to ensure that needed corrective actions are identified. Employees have the authority and responsibility to initiate the corrective action process by reporting issues or concerns to their line management or to the ESH or QA organization. The QA Program contains procedures for identifying, reporting, resolving, documenting and analyzing conditions adverse to quality. Reports of conditions adverse to quality are analyzed to identify trends in quality performance. Significant conditions adverse to quality and significant trends are reported to senior management in accordance with corrective action procedures.

Significant conditions adverse to quality, the cause of the conditions and the corrective action taken to preclude repetition are documented and reported to management for review and assessment in accordance with corrective action procedures. The QA Manager verifies proper and timely implementation of corrective actions.

11.7 RECORDS MANAGEMENT AND DOCUMENT CONTROL

Records Management and Document Control Programs are established to ensure records and documents required by the QA Program are appropriately managed and controlled. These programs provide administrative controls that establish standard methods and requirements for collecting, maintaining and disposing of records. These programs also ensure that documents are controlled and distributed in accordance with identified written requirements and authorizations. The administrative controls for the generation and revision of records and documents are contained in site implementing procedures. The principal elements with the brief description are listed and described in Subsections 11.7.1.1 through 11.7.1.14 and the types of records are identified in Subsection 11.7.1.12. The principal elements for Document Control are described in Subsections11.7.2.1 through 11.7.2.13.

11.7.1 Records Management Program

The following elements and requirements of the Records Management Program shall be applied to QL-1and QL- 2 SSCs and activities or to ESH, financial, quality assurance, emergency response or investigation related records as required by regulations or approved procedures. These elements may be also applied to commercial quality and other plant activities where determined by facility management or required by procedure. The Records Management Program provides direction for the handling, transmittal, storage and retrieval of records. Records media may include microfilm, electronic (magnetic or optical) or hard copy. Records are categorized and handled in accordance with their relative importance to safety and storage needs. The Record functional organization is responsible for the administration of

the records management program. The managers and functional organizations that generate the records are responsible for ensuring compliance with the Records Management Program.

The IIFP QAPD requires procedures for reviewing, approving, handling, identifying, retention, retrieval and maintenance of quality assurance records. These records include the results of tests and inspections required by applicable codes and standards, construction, procurement and receiving records, personnel certification records, design calculations, purchase orders, specifications and amendments, procedures, incident investigation results and approvals or corrective action taken, various certification forms, source surveillance and audit reports, component data packages and any other QA documentation required by specification and procedures. Implementing procedures assign responsibilities for records management, specify the authority needed for records retention or disposal, specify which records must have controlled access and provide the controls needed, provide for the protection of records from loss, damage, tampering and theft or during an emergency and specify procedures for ensuring that the records management system remains effective. Implementing procedures will include:

- Assign responsibilities for records management
- Specify the authority needed for records retention or disposal
- Specify which records must have controlled access and provide the controls needed
- Provide for the protection of records from loss, damage, tampering and theft or during an emergency
- Specify procedures for ensuring that the Records Management System remains effective

Records management is implemented through procedures that provide guidance for the following program elements.

11.7.1.1 Legibility, Accuracy and Completeness

Documents designated to become records are legible, accurate, completed and contain an appropriate level of detail commensurate with the work being performed and the information required for that type of record.

11.7.1.2 Identification of Items and Activities

Records clearly and specifically identify the items or activities to which they apply.

11.7.1.3 Authentication

Records are authenticated or validated by the manager of the organization which originates the record, or his or her Designee, as specified in the procedure which controls the generation and revision of these records.

11.7.1.4 Indexing and Filing

Methods are specified for indexing, filing and locating records within the record system to ensure the records can be retrieved in a timely manner.

11.7.1.5 Retention and Disposition

Records retention times are specified in a retention schedule. The process for disposition of records that have reached the end of their retention lifetime is specified by procedures and conforms to applicable requirements.

11.7.1.6 Corrections

Corrections to records are approved by the organization which created the record unless other organizations are specifically designated. Changes are made by clearly indicating the correction, the date of the correction and the identification of the individual making the correction.

11.7.1.7 Protection of Records

Controls are established for protection of records from deterioration, loss, damage, theft, tampering and/or unauthorized access for the life of the record. Requirements include instructions on protection of records by the record originator until they are transferred to the Records Management function. Instructions for the protection of special record media such as radiographs, photographs, negatives, microform and magnetic media are provided to prevent damage from excessive light, stacking, electromagnetic fields, temperature, humidity or any other condition adverse to the preservation of those records. Records which cannot be duplicated are stored in a manner that minimizes deterioration.

11.7.1.8 Storage Requirements

Records are stored in authorized facilities or containers providing protection from fire hazards, natural disasters, adverse environment, insect infestation, mold or rodents. Storage facilities are maintained to ensure continuous protection of the records. Requirements are for permanent and temporary storage of records.

11.7.1.9 Receipt of Records

A record transmittal process is used to formally transmit records to Records Management. The process includes a receipt acknowledgment that notifies the sending organization that the records have been received and accepted.

11.7.1.10 Access to Records and Accountability for Removed Records

Requirements for controlling access to records and maintaining accountability for records are provided to ensure that only authorized personnel have access to records and to prevent loss, damage or inadvertent destruction of records.

11.7.1.11 Records Requirements for Procured Goods or Services

Records management requirements for goods or services procured from outside suppliers are specified in the applicable procurement documents. These requirements cover:

- Supplier methods for collection, storage and maintenance of records
- Identification of required records and applicable retention periods
- Records submittal plans or indexes

- Availability, accessibility and if applicable, disposition criteria for records retained by the supplier
- Accessibility of the supplier's records prior to the final transfer to the purchaser

11.7.1.12 Types of Records

Records series which are included in the Records Management Program, where applicable as described in Section 11.7.1, include, but are not limited to:

- Transportation and shipping records for nuclear materials
- Radiation protection records, including ALARA findings and occupational radiation exposure records
- Training, qualification and requalification records
- Procurement documents/records
- Design documents and changes involving design modifications made to safety systems and equipment
- Certification documents
- Reportable event records
- Gaseous and liquid radioactive and hazardous waste records
- ISA reviews and evaluations
- Plant radiation surveys and environmental survey records;
- QA activity records required by the QA Program
- Regulatory agency reports and responses
- Emergency Management assessments
- Fire Safety evaluations
- Audits and assessments records where identified by procedures

Records of IROFS failures will be maintained and updated in accordance with 10 CFR 70.62(a) (3). See Section 11.6.1 on incident investigations for additional records requirements.

Specific records are retained for a period of time specified by applicable NRC, federal or state regulations.

11.7.1.13 Usage and Control of Computer Codes and Data

Computer programs used in the Records Management Program are controlled and maintained in accordance with procedures. These requirements and practices provide for virus protection as well as access control to the Records Management Program database and ensure continuing usability of the codes as hardware and software technology change. Routine backups of the records management database are performed by application administrators. Precautions are taken to ensure that computer data that constitute a record are stored in a format that is readily retrievable even as hardware and software technology evolve. The storage format of computer data is reviewed as required to determine threats to future retrieval and if necessary, the data are translated to an updated format and verified acceptable.

11.7.1.14 Assessment

The overall effectiveness of the Records Management Program is evaluated through the audit program described in the QA Program. Deficiencies identified are corrected in a timely manner in accordance with the QA Program and implementing procedures which provide such guidance.

11.7.2 Document Control Program

The following elements and requirements of the document control program shall be applied to QL-1 and QL- 2 SSCs and activities or to ESH, financial, quality, emergency response or investigation related documents as required by regulations or procedures. These elements may also be applied to commercial quality and other plant activities where determined by plant management or approved procedures. The Document Control Program provides direction for the handling, distribution and transmittal of documents important to safety and quality that specify requirements or prescribe activities affecting quality, such as procedures, drawings and calculations. This program is implemented through procedures that provide guidance on the following program elements. The Document Control Program is further discussed in the IIFP LA, Appendix A Revision B QAPD Section A.6.

11.7.2.1 Unique Identifier

A unique identification number is assigned or obtained by the generator for each document requiring controlled distribution. Document Control concurs with the numbering scheme for each document type.

11.7.2.2 Approval and Release of Documents

For documents and changes to documents required by the QA Program are established for approval and release of those documents for distribution.

Controlled documents are approved by the organization authorized to approve them as identified in the procedures which control their generation and revision. Changes to controlled documents are approved and released by the organization that performed the document's initial approval unless other organizations are specifically designated. After approval, the documents are forwarded to Document Control for control and distribution to the locations on the approved distribution list.

11.7.2.3 Master Copy

A master copy of all approved controlled documents is maintained by Document Control to ensure the document is available for controlled copy issuance.

11.7.2.4 Controlled Document Index and Distribution Lists

Creation and maintenance of a controlled document index and controlled distribution list(s) for each document or document type shall be required. The controlled document index is used to maintain a list of controlled documents and to track the current (latest) approved revision levels of those documents. The index is available to users to verify current document revision levels. The controlled document index and the distribution lists are maintained and updated by Document Control.

11.7.2.5 Copies of Controlled Documents

Each controlled copy is stamped, marked or otherwise identified. A method is established in procedures for duplicating and marking controlled documents so that duplicates are distinguishable from the controlled version. Copies of controlled documents that are not marked or otherwise identified in accordance with procedural requirements are considered information only.

11.7.2.6 Distribution

Controlled documents are distributed in accordance with controlled distribution lists to ensure that controlled documents are available in a timely manner at locations where work is being performed. Specific time requirements are established for controlled document distribution. Document Control uses a distribution acknowledgement as part of the document change form to manage distribution of controlled documents control points.

11.7.2.7 Voided, Canceled or Superseded Documents

When notified by the generator of a controlled document that the document has been voided, canceled or superseded, Document Control removes the document from distribution and notifies copyholders of the changed status. The document generator must use a document change request form to formalize the cancellation or obsolescence of a document.

11.7.2.8 Change Documents

Change documents are documents which are used to modify controlled documents. Controls are also applied to the change documents to provide revision approval and distribution controls equivalent to the original document until completion of installation, at which time the original document is revised. Documents showing the current configuration are not changed until the modifications are completed.

11.7.2.9 Revision Identification

The controlled document revision level is clearly identified on the document.

11.7.2.10 Document User Responsibilities

Responsibilities of the end user and copyholders are defined. Responsibilities include requirements for the use of controlled documents and working copies.

11.7.2.11 Usage and Control of Computer Codes and Data

Computer programs used in the Document Control Program are controlled and maintained in accordance with procedures. These requirements provide for virus protection as well as access control to the Document Control Program database and ensure continuing usability of the codes as hardware and software technology change. Routine backups of the document control database are performed by application administrators.

11.7.2.12 Assessment

The overall effectiveness of the Document Control Program is evaluated through the Audit Program described in the QA Program. Deficiencies identified are corrected in a timely manner in accordance with the program description.

11.7.2.13 Archiving Documents

The record copy of all revisions of controlled documents is transmitted to Records Management and Document Control personnel in accordance with the requirements of the Records Management Program.

11.8 QUALITY ASSURANCE PROGRAM ELEMENTS

IIFP has developed a QA Program that applies to the design, construction, operations and decommissioning of the IIFP Facility. The QA Program is described and documented in the IIFP LA, Appendix A Revision B "Quality Assurance Program Description." Application of the QA Program is mandatory for items (SSCs, equipment and activities) identified as IROFS in accordance with 10 CFR 70.4 (CFR, 2009a), 10 CFR 70.61 CFR, 2009b), 10 CFR 70.64 (CFR, 2009d) and 10 CFR 21 "Reporting of Defects and Noncompliance," (CFR, 2009a1). The QA Program, in conjunction with the other management measures, ensures IROFS will be available and reliable to perform the required safety functions when needed. A brief description of the QA Program elements follows. The program elements are discussed in detail in the IIFP QAPD.

11.8.1 Organization

Line Managers/Leads have primary responsibility for ensuring safety of the employees and public and that IIFP products and services meet all necessary requirements. The QA Manager is responsible for implementing and overseeing the QA Program and assuring it is in compliance with applicable regulations, codes and standards of the LA. Personnel who are responsible for ensuring that appropriate QA has been established have the authority, access to work areas and organizational independence to carry out their responsibilities. See Figure 11-1 "IIFP Project Design and Construction Organization" and Figure 11-2 "Plant Operation Organization." Additionally, see Chapter 2 Revision B of the License Application and the LA, Appendix A Revision B Section A.1 "Organization" of the QAPD.

11.8.2 Quality Assurance Program Basis

The IIFP Facility is committed to ensuring a safe facility operation and to providing the best quality products possible. It is IIFP policy that its activities will comply fully with all applicable regulations, codes and standards to which the work is subject.

The QA Program specifies mandatory requirements for performing activities affecting quality and is set forth in procedures which are distributed on a controlled basis to organizations and individuals responsible for quality. When work cannot be accomplished as specified in implementing QA procedures, or accomplishment of such work would result in an unsafe condition, work is stopped until proper corrective action is taken. If procedures cannot be used as written, then work is stopped until the procedures are modified. Revisions to these procedures are also distributed on a controlled basis. Applicable portions of the QA Program are documented, approved and implemented prior to undertaking an activity.

11.8.2.1 Applicability

The IIFP QA Program applies to IIFP workers at all levels of the organization, including contractor personnel, who perform quality-affecting activities associated with safety-related aspects of the IIFP Facility. The QA Program is risk-based and utilizes only those elements and principles appropriate for assuring the quality-related aspects (management measures) of the facility.

IIFP contractors may work under the IIFP QA Program or their respective QA programs per approved written procurement procedures. Contractor QA programs shall be consistent with the requirements of the IIFP QA Program for quality-affecting activities. The interfaces between contractors and IIFP shall be documented. IIFP and contracted personnel have the responsibility to identify quality problems.

The QA Program is a management system established to ensure that IIFP products are safe and reliable and that those products and IIFP services meet or exceed customers' requirements, needs and expectations.

The QA Program applies to all products and services using a graded approach. The establishment of the QA Program shall include consideration of the technical aspects of the activities affecting quality. The QA Program sets forth the minimum requirements for those items, activities and services and is established, maintained and executed as described in the QAPD.

The QA Program for design, construction and pre-operational testing continues simultaneously with the QA Program for the operational phase when construction activities are in progress during plant operation.

11.8.2.2 Graded Application

This section is a summary of the graded application of the IIFP QA Program.

Risk is the fundamental consideration in determining to what extent the requirements of the QA Program apply. Certain activities, items or processes may require extensive control measures while others may require only a limited degree of control. The application and degree to which these control measures are employed for an activity, item or process is established through the risk assessment decision process.

The QA Program shall conform to the criteria established in 10 CFR 70, Subpart H. Facility components and processes are assigned a QA level, if they are determined to be IROFS, based on their safety significance. Each IROFS component will receive a classification of Quality Level 1 or Quality Level 2 that applies throughout the life of the facility unless otherwise changed by the safety basis ISA and change approval process. The classification is based on the following definitions:

Quality Level 1 Requirements: The QL-1 Program shall be applied to a sole Item Relied on for Safety (sole IROFS) preventing or mitigating a high consequence event. All QA Program requirements and management measure attributes are applied to QL-1 IROFS.

Quality Level 2 Requirements: The QL-2 Program is applied where two or more IROFS are credited to prevent or mitigate a high consequence event or any single IROFS (sole IROFS) preventing or mitigating an intermediate consequence event.

Management measures are applied to QL-2 IROFS consistent with the QL-2 graded requirements to assure that the IROFS remains reliable at its credited failure frequency when called upon to be available. QA Program requirements are applied to QL-2 IROFS in a manner necessary to achieve this goal.

Quality Level 3 (QL-3) Requirements: The QL-3 Program is defined as standard commercial practice. A documented QL-3 Program is not required. QL-3 components or processes do not require a QL-3 designation on any documentation or system requirements. QL- 3 governs all activities that are not designated as QL-1or QL-2.

Extent of QA Program Elements and Management Measures Graded Application

The extent of management measure attributes and QA Program elements that are applied to QL-1 and QL-2 IROFS will be determined by evaluating the factors that contribute to risk importance, function and reliability of each IROFS. The following QA elements are applied to QL-1 and QL-2 IROFS: 1) design

control, 2) procurement document control, 3) control of purchased items and services,4) identification and control of materials, parts and components, 5) control of measuring and test equipment, 6) control of nonconforming items, 7) corrective actions and 8) quality assurance records. For the QA elements listed above, the management measures that are applied from these elements will be the same regardless of whether the IROFS is QL-1 or QL-2.

For the remaining QA elements, the management measure(s) applied to those aspects of the activity that influence reliability of the IROFS will be determined by evaluating the design, function and task analyses associated with operating and maintaining the IROFS and by assigning the characteristic to the attribute taking into consideration the following:

- Risk significance
- Relative importance to safety, safeguards and security
- Consequences of failure
- Probability of failure
- Applicable regulations, industry codes and standards
- Complexity or uniqueness of an item/activity and the environment in which it has to function
- Quality history of the item in service or activity
- Degree to which functional compliance can be demonstrated or assessed by test, inspection or maintenance methods
- Anticipated life span
- Degree of standardization
- Importance of data generated
- Reproducibility of results

11.8.2.3 QA Program Implementation

The QA Program, along with associated policies, procedures and contractual documents, provides the means of communicating and documenting the program goals, objectives, requirements and elements to all organizational levels.

The QA Program is implemented through policies, procedures, instructions, specifications, drawings, procurement documents, contractual documents and other documents. Procedures are established to ensure that these documents are consistent with the requirements in the QAPD, the ISA and regulatory requirements. These documents also provide measures which ensure that activities within the scope of the QA Program are planned and accomplished under suitably controlled conditions as necessary to accomplish the goals and objectives of the Program.

Management measures shall be controlled and conducted using documented procedures (including instructions, drawings, process diagrams or other appropriate documents).These procedures may be procedures within the QA Program, QA implementing procedures, other administrative procedures, or other procedures developed by IIFP.

The procedures used shall provide for accomplishment of management measures under suitably controlled conditions. Examples of conditions to address include: 1) use of appropriate equipment, 2) any environmental restriction and 3) verification that prerequisites for the process activities have been met.

The QA Program and supporting procedures are reviewed periodically to ensure they are in compliance with applicable regulations, codes and standards. New or revised regulations, codes and standards as well

as lessons learned and revised activities are reviewed for incorporation into the QA Program, supporting QA implementing procedures and administrative/technical procedures as necessary.

Personnel performing activities covered by the QA Program shall perform work in accordance with approved procedures and must demonstrate suitable proficiency in their assigned tasks. Training programs are established for quality assurance policies, requirements, procedures and methods. Ongoing training is provided to ensure continuing proficiency as procedural requirements change. New employees are required to participate in a QA indoctrination or OJT process describing authority, organization authority, policies, the QA Program, QA implementing procedures and other procedures necessary to conduct their assigned tasks.

Additional training is conducted based on NRC specific regulations and guidance, procedures, auditing and applicable codes and standards. Supplemental training is performed as required. OJT is performed by the employee's supervisor in area-specific procedures and requirements. Training records are maintained for each person performing job functions.

IIFP will participate in the planning and scheduling for system turnover as construction is completed. Prior to system turnover, written procedures will be developed for control of the transfer of systems, structures and components and associated documentation. The procedures include checklists, marked drawings, documentation lists, system status and receipt control.

Major work activities contracted by IIFP are identified and controlled. The performance of contracted activities shall be formally evaluated by IIFP commensurate with the importance of the activities to safety.

11.8.2.4 Quality Improvement

It is a basic concept of quality improvement that all work activities can be planned, performed, measured and improved. Managers at all levels are responsible for creating an atmosphere where improvement is continuous and an integral part of the work activities. Managers should encourage the development and exploration of new ideas. Managers are expected to increase staff awareness of the importance of quality and emphasize enhanced product and process safety and reliability, including the identification of nonconforming items and potential areas for improvement.

Processes have been established to detect and prevent quality problems and to ensure quality improvement.

Products, services and processes that do not meet established requirements shall be identified, controlled in accordance with Section A.15 of the QAPD, “Control of Nonconforming Items” and corrected through the Corrective Action Program documented in Section A.16 of the QAPD. The process of correction includes identifying the root cause of problems and preventing recurrence.

The QA Manager shall establish procedures to periodically perform a trend analysis of nonconformances and corrective actions.

Line management of the organizations implementing the QA Program, or portions thereof, regularly assesses the adequacy of the program for which they are responsible through an appropriate combination of reviews, self-assessments or audit processes, thereby assuring its effective implementation. Responsible line managers regularly assess the adequacy and effective implementation of the QA Program through methods such as review meetings and reviewing audit reports and corrective action

plans. The combination of internal IIFP audits and management reviews serve as tools for identifying opportunities for improvement.

Work process performance should be measured and evaluated to identify improvement opportunities.

11.8.2.5 Qualifications and Certification of Personnel

The principle objective of the IIFP Training Program is to ensure job proficiency of facility personnel through effective training and qualification. The Training Program is designed to meet commitments to comply with applicable established regulations and standards. Employees are provided with training to establish the knowledge foundation and on-the-job training to develop work performance skills. Continuing training is provided, as required, to maintain proficiency in these knowledge and skill components and to provide further employee development.

Qualification is indicated by successful completion of prescribed training, demonstration of the ability to perform assigned tasks and the maintenance of requirements established by regulation. A graded approach to systematic training is used that applies the level of detail needed relative to safety. This graded approach incorporates methods to accomplish the analysis, design, development, implementation and evaluation of training. See Section 11.3 “Training and Qualifications” and LA, Appendix A Revision B Sections A.2.2 “Qualification and Certification of Personnel.”

11.8.2.6 Work Control

The QA Program Description establishes requirements and defines the procedure for controlling project work activities to ensure that they comply with the requirements of both the applicable contract and the QA Program.

IIFP products are planned, authorized, accomplished and verified through a controlled process utilizing written instructions, procedures or other appropriate means. The degree of complexity and detail in instructions and procedures is commensurate with the risk associated with the work being performed and specific customer requirements. See Section 11.4 “Procedures Development and Implementation” and LA, Appendix A Revision B Section A.2.3 “Work Control.”

11.8.3 Design Control

These requirements and controls ensure that new design and design change activities are carried out in a planned, controlled and orderly manner and that design requirements such as design basis, regulatory requirements and appropriate quality standards are correctly translated into design output, procurement and procedural documents. These controls also establish provisions for verifying or checking the technical adequacy of design documents including computer codes. They also provide for the control of design changes. The design control provisions contained in the QAPD are applicable to design activities taking place beginning on the date the DB Contractor assumes the detailed design and engineering role and establishes the design organization and controls. Reconstitution of any prior conceptual design is not required; however if a deviation to the design is discovered, engineering shall resolve the deviation and as-built drawings if necessary. See Sections 11.1.2 “Design Requirements,” Section 11.1.3, “Configuration Management Controls on the Design Requirements” and Section 11.1.5 “Change Control.” Also see LA, Appendix A Revision B Section A.3 “Design Control.”

11.8.4 Procurement Document Control

The Procurement Document Control System ensures that applicable regulatory requirements, technical requirements and QA Program requirements are included or referenced in procurement documents for the procurement of items and services. This system also establishes provisions for the preparation, review, approval and control of procurement documents, including changes. See LA, Appendix A Revision B Section A.4 “Procurement Document Control.”

11.8.5 Instructions, Procedures and Drawings

Activities affecting the availability or reliability of IROFS are prescribed by and accomplished in accordance with documented specifications, requirements, procedures, instructions and drawings of a type appropriate to the circumstances. These documents include or reference appropriate acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. Standard guidelines for the format, content, review and approval processes for documents are established. See Section 11.4 “Procedures Development and Implementation” and LA, Appendix A Revision B Section A.5 “Instructions, Procedures and Drawings.”

Adherence to policies and procedures is mandatory. In the case of conflict or error involving a procedure, the activity in question shall be placed in a safe condition and the procedure shall be corrected or changed before proceeding to implement the procedure.

11.8.6 Document Control

A Document Control System is established for IROFS and related activities and services within the scope of the QA Program. This system ensures that documents defining the performance of management measures are controlled so only current and correct information is available at the location where the activity is performed prior to commencing the work. See LA, Section 11.7 “Records Management and Document Control” and LA, Appendix A Revision B Section A.6 “Document Control.”

11.8.7 Control of Purchased Items

A system for the control of purchased items and services is established for IROFS and services within the scope of the QA Program. Repair parts, components and material requirements for IROFS are listed on the engineering approved specifications. The engineering approved specifications and associated inspection plans provide the design criteria and inspection requirements needed when procuring such parts, components and materials for IROFS.

QL-1 and QL-2 items may be procured as commercially available items provided they are subjected to a dedication process. Items and services that are not relied on for safety may be designated as QL-2 or QL-3 and may be procured as commercially available items.

In accordance with 10 CFR 21 (CFR, 2009a1), the procurement process procedures include requirements that IIFP confirm each supplier/vendor approved to provide basic components has an approved process in place that implements the requirements of 10 CFR 21. In cases where commercial-grade items are to be procured and then dedicated for use as IROFS or parts thereof, the procurement process procedures include requirements that IIFP define to the supplier those elements of the supplier's process controls that are mandatory and any other requirements necessary to assure critical characteristics will be met.

Procurement activities are planned and documented to assure a systematic approach to the procurement process. The Procurement function is responsible for procurement planning and bid evaluation. The QA function provides procurement QA support such as verification, surveillance or qualification of the supplier's QA Program; receipt inspections and review of procurement documents during receipt inspections. The Engineering function assists the QA and Procurement functions by performing evaluations of supplier's technical capabilities. The Engineering function is also responsible for determining specific methods of acceptance to be applied to procured items and reviewing the specific method of acceptance to be applied to services. The Engineering function is also responsible for the approval of dispositions and technical evaluation of supplier non-conformances for items and services that are determined as "repair" or "use-as-is."

Supplier selection is based, in part, on an evaluation of the supplier's capability to provide items or services in accordance with the requirements of procurement documents. Supplier evaluations may include audits or assessments of the supplier program or system for ensuring quality or an evaluation of the supplier's history of providing an identical or similar product that performs satisfactorily in actual use. Measures are established to interface with the supplier and to verify supplier's performance, as necessary. See LA, Appendix A Revision B Section A.7 "Control of Purchased Items and Services."

11.8.8 Identification and Control of Materials, Parts and Components

A system is established for the identification and control of IROFS items within the scope of the QA Program. This system establishes the requirements for the identification and control of such items and associated materials, parts, spare parts, components and sub-assemblies. Traceability of repair parts, components and materials shall be maintained when they are received and placed in storage for use. Configuration management provides for parts traceability after they are installed in the plant.

Items are identified and controlled, as necessary, from initial receipt and fabrication of the items, up to and including installation and use, to ensure that only correct and accepted items are used or installed. Physical identification is used to the maximum extent possible. When physical identification is either impractical or insufficient to control the item, physical separation, procedural controls or other means are employed. When markings are used, measures are established to ensure the markings are clear, legible or machine readable and do not have a detrimental effect on the function or service life of the item. Markings are transferred to each part of an identified item and are not to be obliterated by surface treatments or coatings unless other means of identification are provided. See LA, Appendix A Revision B Section A.8 "Identification and Control of Materials, Parts and Components."

11.8.9 Control of Special Processes

Special processes affecting quality of items and services are controlled. Procedures, instructions, drawings, checklists, travelers, work orders or other appropriate means are used to control special processes. These means assure that special process parameters are controlled and that specified environmental conditions are maintained.

Special processes that control or verify quality (such as, those used in welding, heat treating and nondestructive examination) are performed by qualified personnel using approved written procedures in accordance with specified requirements, codes or standards. Special process procedures prescribe the necessary equipment, process parameters, calibrations and acceptance criteria. Records are maintained of currently qualified personnel, processes and equipment for special processes. See LA, Appendix A Revision B Section A.9 "Control of Special Processes."

11.8.10 Inspection

Planned inspections are performed, as required, to verify conformance of items or activities to specified requirements. Inspection requirements are specified in approved written procedures, with provisions for documenting and evaluating the inspection results. Personnel performing inspections are qualified based on experience, education, or certification, as appropriate. Personnel other than those who perform or directly supervise the work being inspected, perform inspection for acceptance. Inspection planning may utilize hold points, where applicable, to ensure work does not bypass required inspections. The hold points are established in documents that control the work.

The planning of inspection activities, methods and attributes is based on the importance of the item or activity to be inspected; mandatory inspections required by codes, standards, regulatory requirements and commitments; the complexity of the item or activity and the quality history of the process. Inspection planning includes characteristics to be inspected: 1) responsibility, 2) method, 3) measuring and test equipment, 4) acceptance criteria and 5) referenced instructions and design documents. A system is established for inspection of IROFS. This system provides measures to ensure that maintenance, repair or modification work is completed satisfactorily. Purchasing obtains the latest engineering approved specifications and inspection requirements and reviews for changes. Commercial-grade items are procured according to catalog specifications from the manufacturer or factory authorized dealer or distributor. Upon receipt, the item is placed in a segregated area for inspection and acceptance. See LA, Appendix A Revision B Section A.10 “Inspection.”

Requirements for the certification of personnel who perform inspection, examination, surveillance and testing are identified in the LA, Appendix A Revision B Section A.2.2.

11.8.11 Test Control

Tests required for conformance verification of an item or computer program to specified requirements and to demonstrate satisfactory performance for service are planned and executed. Characteristics to be tested and test methods to be employed are specified. Test results are documented and their conformance with acceptance criteria is evaluated.

Tests include design verification tests, acceptance tests, pre-operational and operational tests. Planning for tests may include mandatory hold points, as required. Test procedures contain the following information, as appropriate:

- Test purpose or objectives, responsibilities, characteristics to be tested, hold points and test methods to be employed
- References and related documents
- Provisions for ensuring that prerequisites for a given test have been met, to include, as applicable: calibrated instrumentation, appropriate equipment, trained personnel, condition of test equipment and the item to be tested and provisions for data acquisition
- Adequate instrumentation is available and suitable environmental conditions are maintained
- Provisions for documenting and evaluating the test results for conformance with acceptance criteria
- Qualifications for test personnel

Test records contain the following information: item tested, test date, tester or data recorder, type of observation, test procedure or reference, results and acceptability, actions taken in connection with any

deviations noted and person evaluating the results. See LA, Appendix A Revision B Section A.11"Test Control."

11.8.12 Control of Measuring and Test Equipment

A system is established for the control of measuring and test equipment (M&TE) used for measurement, test and calibration of IROFS items within the scope of the QA Program. This system establishes measures that ensure that tools, gauges, instruments, reference and transfer standards, nondestructive test equipment and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated and adjusted at specified intervals to maintain equipment performance within required limits. A list of devices and standards is established to identify those items within the calibration control system. This identification listing includes, as a minimum, the due date of the next calibration and any use limitations (when it is calibrated for limited use). M&TE is calibrated at specified intervals or prior to use against equipment having a known valid relationship to nationally recognized standards. If no nationally recognized standard exists, the basis for calibration is documented. M&TE is properly handled and stored to maintain accuracy.

The following M&TE items are addressed by IIFP procedures:

- A unique identifier
- Calibration intervals defined and entered into a recall system
- A label to indicate calibration status
- An inventory listing of controlled M&TE
- Evaluation of calibrations using M&TE that is subsequently found out of tolerance
- Preparation and maintenance of calibration records
- Measures for the storage and control of M&TE

This system also establishes measures to ensure that devices and standards used for measurement, tests and calibration activities are of the proper type, range, accuracy and tolerance to accomplish the function of determining conformance to specified requirements. When M&TE is found to be out of calibration, as-found data are recorded and an evaluation is made and documented as to the validity of previous inspection and test results and of the acceptability of items previously inspected or tested. Out-of-calibration devices are tagged or segregated and are not used until re-calibrated. When M&TE is found to be out of calibration, it is repaired or replaced or if the item/model is inadequate for the conditions, it will be substituted with a more suitable item. Records are maintained and equipment is suitably marked or otherwise identified to indicate its calibration status. See LA, Appendix A Revision B Section A.12 "Control of Measuring and Test Equipment."

11.8.13 Handling, Storage and Shipping

Handling, storage and shipping of IROFS items are conducted in accordance with established work and inspection implementing procedures, shipping instructions or other specified documents. For critical, sensitive, or high-value items or for IROFS, specific written procedures for handling, storage and shipping are prepared and used when essential to maintain acceptable quality. Special handling equipment involving IROFS is inspected and tested at specified time intervals in accordance with procedures implementing the requirements of Section 11.8.8, "Identification and Control of Materials, Parts and Components" and Section 11.8.10, "Inspections." Operators of special handling and lifting equipment shall be experienced or trained in the use of the equipment. See LA, Appendix A Revision B Section A.13 "Handling, Storage and Shipping."

11.8.14 Inspection, Test and Operating Status

Requirements are established for IIFP to identify the status of inspection and test activities. Status indicators are also provided for indicating the operating status of IROFS systems and components to prevent inadvertent operation. Policies, plans and procedures are established to ensure that the status of inspection and test activities are either marked or labeled on the item or in documents traceable to the item.

Status indicators (for example, physical location and tags, markings, work controlling documents, stamps, inspection records or other suitable means) are utilized when required. This includes indicating the operating status of systems and components to prevent inadvertent operation. Authority for the application and removal of tags, markings, labels and stamps is specified. See LA, Appendix A Revision B Section A.14 “Inspections, Test and Operating Status.”

11.8.15 Control of Nonconforming Items

A system is established for the control of nonconforming material and process for IROFS and related activities and services within the scope of the QA Program. The system establishes the requirements for identification, segregation, disposition, prevention of inadvertent installation or use, documentation and notification to affected organizations for items which do not conform to specified requirements.

Nonconforming items are reviewed and determined as "reject," "rework," "repair" or "use-as-is." Further processing, delivery, installation or use of the nonconforming item is controlled pending an evaluation and approved disposition by personnel as authorized in approved written procedures and documented notification to affected organizations is provided.

The responsibility and authority for the evaluation and disposition of nonconforming items is defined. The personnel performing evaluations to determine the dispositions have demonstrated competence in the specific area being evaluated, have an adequate understanding of the requirements and have access to pertinent background information. The disposition of nonconforming items is identified and documented as required to carry out the disposition. Technical justification for the acceptability of nonconforming items determined as "repair" or "use-as-is" is documented and subject to design control measures. Non-conformance documentation identifies the nonconforming item, describes the nonconformance, contains the disposition and any re-inspection requirements and contains the appropriate signatures approving the disposition. See LA, Appendix A Revision B Section A.15 “Control of Nonconforming Items.”

11.8.16 Corrective Action

A Corrective Action Program system is established for IROFS and related activities and services within the scope of the QA Program. This system establishes measures which ensure that conditions adverse to quality are identified and corrected as soon as practical. See Section 11.6.1 and the LA, Appendix A Revision B Section A.16.

11.8.17 Quality Assurance Records

A Records Management Program system is established for IROFS and related activities and services within the scope of the QA Program. This system provides measures to control quality assurance records. QA records shall be legible, identifiable and retrievable and shall be protected against damage, deterioration and loss for the specified record retention duration. Specific requirements and responsibilities for generation, classification, retention, receiving, storage and preserving of QA records

are established in approved written procedures. See LA, Appendix A Revision B Section A.17 “Quality Assurance Records.”

11.8.18 Audits

A management assessment of the QA Program will be performed at least six (6) months prior to scheduled receipt of licensed material on the site. Items identified as needing completion or modifications are entered into the Corrective Action Program and corrective action completed before scheduled receipt of licensed material. IIFP management monitors the QA Program prior to this initial management assessment through project review meetings and other assessments. This management assessment along with integrated schedules and program review meetings ensure that the QA Program is in place and effective prior to receiving licensed material.

An audit system is established for IROFS and activities and services within the scope of the QA Program. This system establishes planned and periodic audits to verify the compliance and the effectiveness of the QA Program in meeting quality requirements. Audit personnel have sufficient authority and organizational freedom to make the audit process meaningful and effective. Audits are executed in accordance with established procedures and are performed by personnel having no direct responsibilities in the areas being audited.

Organizations being audited provide access and assistance to the audit personnel. Objective evidence is examined to determine if the QA Program elements are being implemented effectively. Conditions requiring prompt corrective action are reported immediately to the management of the audited organization. Audit results are documented and reported to and reviewed by responsible management. Management of the audited organization or activity investigates adverse audit findings, schedules corrective action, including measures to prevent recurrence (if appropriate) and notifies the QA organization of the action taken. Adequacy of audit responses is evaluated by the QA organization and verification of corrective action is documented. Follow-up action is taken to verify the implementation and effectiveness of the corrective action and to determine if repetitive problems require further corrective action. Audit records include audit plans, audit reports, written responses to the audit findings and the record of completion of corrective action.

Internal audits of selected aspects of operational activities are performed with a frequency commensurate with their importance to safety and in such a manner as to assure that audits of activities within the scope of the QA Program are completed within specified time periods. See Section 11.5 and LA, Appendix A Revision B Section A.18 “Audits.”

REFERENCES

CFR, 2009a Title 10, Code of Federal Regulations, Section 70.4, “Definitions,” 2009.

CFR, 2009a1 Title 10, Code of Federal Regulations, Part 21, “Reporting of Defects and Noncompliance,” 2009.

CFR, 2009a2 Title 10, Code of Federal Regulations, Section 70.50, “Reporting Requirements,” 2009.

CFR, 2009b Title 10, Code of Federal Regulations, Section 70.61, “Performance Requirements,” 2009.

CFR, 2009c Title 10, Code of Federal Regulations, Section70.62, “Safety Program and Integrated Safety Analysis,” 2009.

CFR, 2009d Title 10, Code of Federal Regulations, Section 70.64, “Requirements for New Facilities or New Processes at Existing Facilities,” 2009.

CFR, 2009e Title 10, Code of Federal Regulations, Section 70.72, “Facility Changes and Change Process,” 2009.

CFR, 2009f Title 10, Code of Federal Regulations, Section 70.74, “Additional Reporting Requirements,” 2009.

CFR, 2009g Title 10, Code of Federal Regulations, Part 70, Subpart H, “Domestic Licensing of Special Nuclear Material,” 2009.

CFR, 2009h Title 10, Code of Federal Regulations, Part 19, “Notices, Instructions and Reports to Workers: Inspections and Investigations,” 2009.

CFR, 2009i Title 10, Code of Federal Regulations, Section 19.12 “Instructions to Workers,” 2009.

CFR, 2009j Title 29, Code of Federal Regulations, Section 1910, “Occupational Safety and Health Standards,” 2009.

CFR, 2009k Title 10, Code of Federal Regulations, Section 1910.1200, “Hazard Communication,” 2009.