



International Isotopes Fluorine Products

International Isotopes Fluorine Products, Inc. (IIFP)
A Wholly Owned Subsidiary of
International Isotopes, Inc. (INIS)

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

License Application

Appendix A.
Quality Assurance Program Description

Revision B
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ACRONYMS and ABBREVIATIONS

ALARA	As Low As Reasonably Achievable
ASL	Approved Suppliers List
ASTM	American Society for Testing and Materials
CFR	Code of Federal Regulations
CM	Configuration Management
CMM	Configuration Management Manager
COO	Chief Operations Officer
DB	Design and Build
ESH	Environmental, Safety and Health
FEP	Fluorine Extraction Process
FEP/DUP	Fluorine Extraction Process & Depleted Uranium De-Conversion Process
FSRC	Facility Safety Review Committee
HFE	Human Factors Engineering
HSI	Human System Interfaces
IIFP	International Fluorine Products, Inc.
INIS	International Isotopes, Inc.
IROFS	Items Relied on for Safety
ISA	Integrated Safety Analysis
ISO	International Organization for Standardization
LA	License Application
MT&E	Measuring and Test Equipment
NDE	Nondestructive Examination
NRC	Nuclear Regulatory Commission
PM	Plant Manager
QA	Quality Assurance
QAPD	Quality Assurance Program Description
QA/QC	Quality Assurance/Quality Control
OJT	On-the-job Training
QL-1	Quality Assurance Level 1
QL-2	Quality Assurance Level 2
QL-3	Quality Assurance Level 3
SSCs	Structures, Systems and Components

APPENDIX A. QUALITY ASSURANCE (QA) PROGRAM DESCRIPTION

International Isotope Fluorine Products, Inc. (IIFP), a wholly owned subsidiary of International Isotopes, Inc. (INIS), will build and operate a commercial plant to produce specialty fluoride gas products using its patented fluorine extraction process (FEP). IIFP also will include a new uranium processing plant as part of the facility, thereby offering toll services to the commercial uranium enrichment industry for converting depleted uranium hexafluoride (DUF_6) into depleted uranium oxides. Depleted uranium hexafluoride, referred to as “tails”, is the by-product of the uranium enrichment industry. This IIFP Facility is also referred to as the “Fluorine Extraction Process and Depleted Uranium De-conversion Plant (FEP/DUP).”

The proposed licensed action is the issuance of a U.S. Nuclear Regulatory Commission (NRC) license under Title 10 Code of Federal Regulations (CFR) Part 40, “Domestic Licensing of Source Material” (CFR, 2009) for the IIFP Facility. The facility is being licensed under Title 10 CFR Part 40 and does not possess a critical mass of special nuclear material. An Integrated Safety Analysis (ISA) Summary has been completed and submitted in anticipation that NRC rulemaking would amend Part 40 to require “de-conversion” facilities to meet requirements similar to those stipulated in Subpart H, “Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material” of Title 10 CFR, Part 70, “Domestic Licensing of Special Nuclear Material” (CFR, 2009a).

The IIFP Project is currently in its development, conceptual design and licensing phase. A Design and Build (DB) Contractor will be contracted to perform the detailed design and construction of the IIFP Facility. The provisions contained in this IIFP Quality Assurance Program Description (QAPD), Revision B are applicable during design and construction of the IIFP Facility for 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. The IIFP License Application (LA) Revision B and supporting documentation addresses construction and operation of the IIFP Facility in Lea County, New Mexico. The IIFP Facility (referred to initially as Phase 1 of the project) will utilize DUF_6 to produce high-purity inorganic fluorides, depleted uranium oxides and anhydrous hydrofluoric acid (AHF). In performing the de-conversion services, IIFP utilizes the fluoride extracted from the DUF_6 de-conversion to manufacture high-purity fluoride products. These products are valuable materials for applications in the solar, semiconductor, catalytic chemical and electronics industries. In addition, AHF is a by-product of the de-conversion process and is sold as a high demand chemical for various industrial applications. There is no known existing private commercial de-conversion capacity in the U.S. or in this hemisphere. IIFP plans to expand the facility de-conversion capacity by constructing an addition to the IIFP Phase 1 Facility, thus resulting in a Phase 2 Facility. The expansion is expected to begin approximately 3-4 years after startup of the Phase 1 Facility. The current IIFP License Application is for the Phase 1 Facility only. Amended licensing and revisions to the IIFP ISA Summary, Revision B will be developed and submitted in the future at an appropriate time for the planned expansion project. The expansion will provide additional de-conversion capability using a chemical process for direct de-conversion of DUF_6 to depleted uranium oxide. The Phase 2 Facility is not the increment of expansion but it is the result of the Phase 1 Facility plus the expansion.

IIFP is committed in ensuring safety for employees and the public relative to its facility operation and in providing the quality products and services to its customers. This commitment and the QAPD are applicable to the detailed design, construction, operation and decommissioning of the IIFP Facility.

A.1 ORGANIZATION

All IIFP employees including senior managers, line and staff managers and team leaders have responsibility for ensuring safe facility design and operation and that IIFP products and services meet all

necessary requirements. To achieve this, effective and efficient management controls are established to guide project and operational performance and are applied appropriately.

The IIFP President is the senior executive responsible for quality assurance and is the highest level of responsibility for QA policies and quality-related goals and objectives.

One of the first positions that will be filled in the IIFP organization will be the Chief Operations Officer (COO) who will take direct responsibility and will be delegated the commensurate authority by the IIFP President for all aspects of the project including selecting additional IIFP management staff. As the project moves into construction, startup, and finally operations, the COO will add appropriate management positions in order that they gain knowledge of the plant at the appropriate stages and to put additional staff and programs in place to support the safe operation of the facility.

A.1.1 Quality Assurance Responsibilities during Project Design and Construction

A Quality Assurance program provided by the DB Contractor and equivalent to the IIFP QAPD may be used during the design and construction stage upon review and evaluation by the IIFP Quality Assurance staff and approval of the IIFP COO or the IIFP President.

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 must be developed and implemented in accordance with IIFP management measures to ensure that the critical components and the Items Relied on for Safety (IROFS) will be available and reliable to perform their function when needed. When the DB Contractor begins the IIFP Facility detailed design (the design that will be verified and used for construction), the IIFP Chief Operations Officer is responsible for assuring implementation of the management measures necessary for safe design and construction in accordance with the QA program.

The Project design and construction organization is shown in Figure A-1. Responsibilities for key management positions during this stage of the project are described in the IIFP LA, Chapter 2 Revision B “Organization and Administration.” The IIFP COO has responsibility and authority for ensuring that appropriate QA policies and organizations are in place to effectively implement the QA program during detailed design and construction. Upon startup of the facility operations, the provisions of the IIFP Quality Assurance Program (as described in the QAPD), or its approved revisions, remain in effect. The IIFP COO is responsible for ensuring implementation of the IIFP QA Program and its provisions for facility operations.

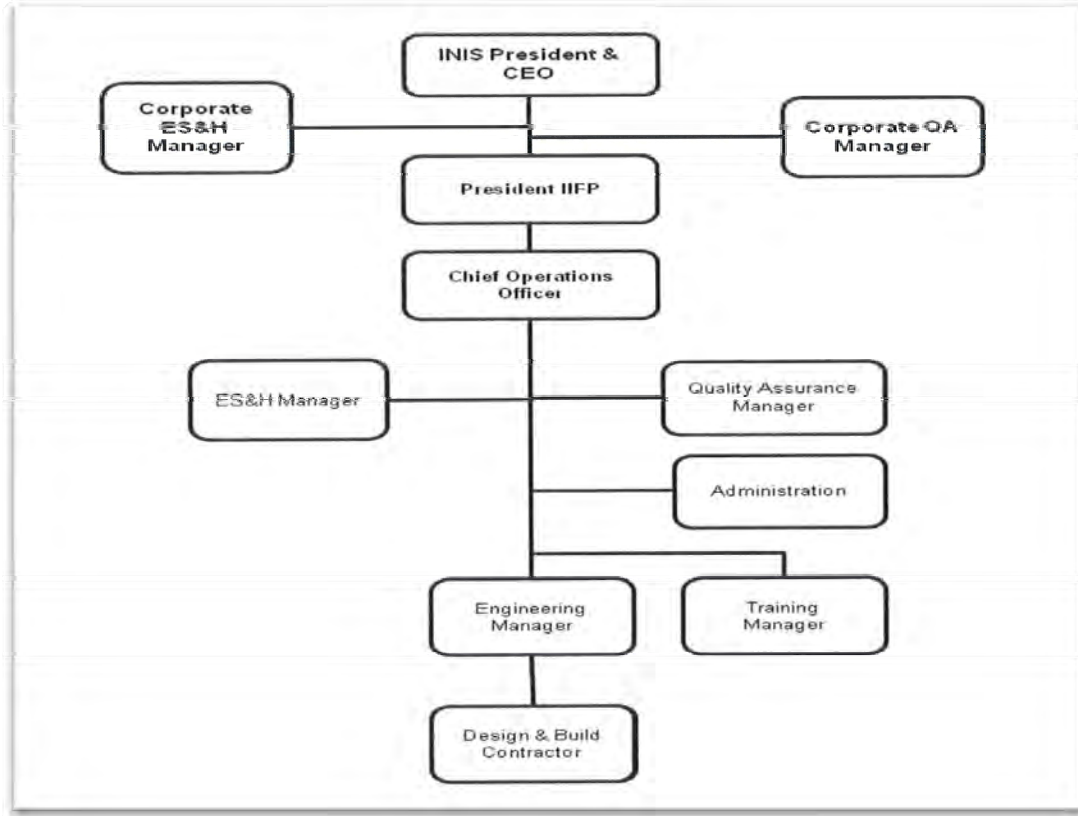


Figure A.-1 IIFP Project Design and Construction Organization

During the Project design and construction, the DB Contractor will assign a DB Project Manager to lead the IIFP Project. The DB Contractor Project Manager will report to the IIFP Engineering Manager (or to the IIFP COO until the IIFP Engineering Manager position vacancy is filled). The IIFP Engineering Manager reports to the COO. The DB Contractor coordinates work on the project and controls subcontractors, inspections and startup functions to ensure a safe design, construction, acceptance testing and final turnover to the IIFP Plant Operation Organization. The DB Contractor will also ensure, as part of the written contract, that design meets all the applicable federal, state and local codes and standards.

As shown in Figure A-1, the IIFP President reports to the INIS President/Chief Executive Officer and the COO reports to the IIFP President. The COO is responsible for managing the design, engineering, administration, construction, quality assurance, environmental, safety and health and training. The IIFP Engineering Manager will have direct oversight of the DB Contractor. The INIS parent organization will provide QA and Environmental, Safety and Health (ESH) management who will be responsible for the respective programs and provide support to the IIFP COO during the early stages of the project until the IIFP QA Manager and the IIFP ESH Managers are hired. Prior to start of construction activities, IIFP will establish a full time Quality Assurance Manager and an ESH Manager. The IIFP QA Manager reports to and supports the COO.

The IIFP QA Manager is responsible for ensuring compliance of the IIFP QAPD and procedures. The QA Manager is responsible for verifying compliance to the QA Program during design and construction of the IIFP Facility. The QA Manager reviews the DB Contractor qualified QA programs in accordance with the IIFP QAPD. Approval of vendor, DB Contractor and sub-contractor QA programs, where required, shall

be obtained prior to commencing with the design, procurement and construction work activities. Contractors and their sub-contractors may work under the IIFP QA Program or their respective QA programs per approved written procurement procedures or contracts.

Procurement for the commercial IIFP Facility is generally performed by the DB Contractor, but in some cases may be performed by IIFP staff or subcontractors. The IIFP QA organization function ensures that evaluation and pre-approval of vendor qualification is performed or applicable inspection requirements are implemented where the procurement involves IROFS as identified in the IIFP ISA Summary. This review and pre-approval is to ensure the vendor quality assurance programs are in accordance with the requirements of the IIFP QAPD Revision B. Likewise, the IIFP QA function ensures reviews of vendor performance in accordance with the QAPD, where the procurement systems, structures and components (SSCs) involve IROFS as identified by the IIFP QA procedures.

A.1.2 Transition from Design and Construction to Startup and Plant Operation

Prior to the end of construction, the focus of the organization will shift from design and construction to initial startup and operation. At an appropriate time during construction, IIFP will supplement and expand the initial organization structure to include a Plant Manager (PM) and other management positions and disciplines necessary to ensure readiness of the facility for safely starting and effectively transitioning from construction activities to operating activities. These additional positions will be hired in advance of the scheduled startup of operations and may serve in interim organizational roles during the construction stage of the Project.

As shown in Figure A-2, the COO is responsible, with delegated commensurate authority from the IIFP President, for managing the administration, ESH, QA, Engineering and Training for the IIFP Facility. The ESH and QA Managers have the responsibility and authority to elevate and report any ESH or QA unresolved concern to the IIFP President. The IIFP President is ultimately responsible for ESH, QA and other safety-related issues. All reported ESH and QA concerns will be followed through to resolution and documented.

The reporting authority of the IIFP ESH and QA Managers is intentionally structured to provide significant continued focus on the ESH goals and stop-work authority during design, construction and transition periods when the operating organization is not yet fully implemented.

When construction of the facility and process systems is complete, the equipment and systems undergo acceptance testing in accordance with the QA program and approved written procedures. Following successful completion of integrated equipment and systems testing and acceptance, the responsibilities for managing the facility operating equipment and systems are transferred from the Design and Construction Organization to the Plant Operation Organization as shown in Figure A-2 by means of a transition plan. The COO and the Plant Manager ensure the development of a transition plan and an orderly, safe and thorough turnover. The turnover includes the physical systems, corresponding design information, records of the facility and as-built drawings. Following turnover, the COO is responsible for facility safe operations, maintenance, configuration management (CM) and facility safety reviews of modifications affecting the as-built plant.

The Plant Manager reports directly to the COO. The PM is responsible for implementing safe practices, procedures and activities related to the operation of the production processes, utilities, environmental protection and waste treatment systems, fire system, laboratory and warehouses. The Plant Manager is responsible for the safe conduct and control of operations and protection of employees.

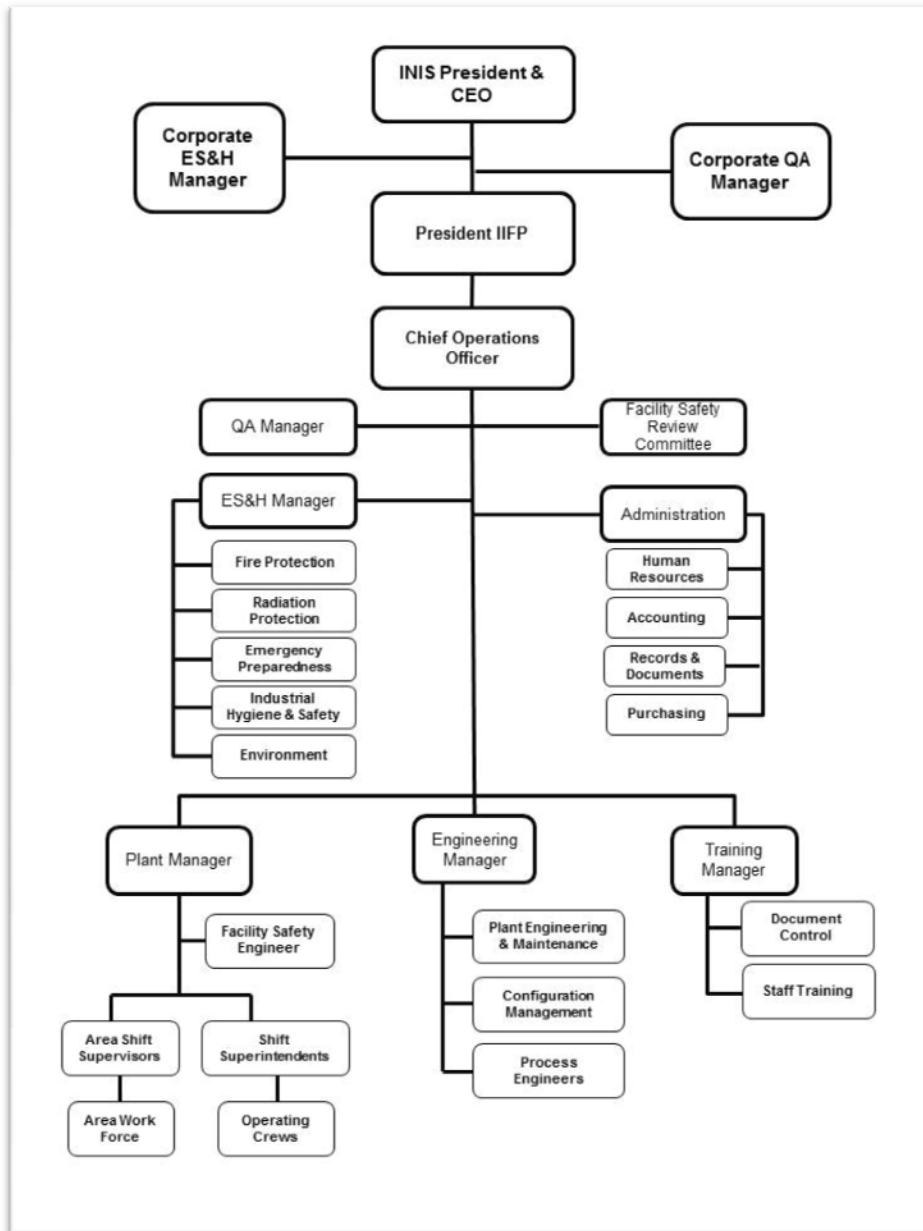


Figure A.-2 Plant Operation Organization

The Plant Manager also has responsibility for day-to-day regulatory and procedural compliance associated with the facility operations. The PM is responsible for hiring and training of qualified staff and operating personnel in the Plant Management organization.

The Plant Manager is responsible for coordinating with the Training Manager the development of safe and effective operating procedures and training program plans. The Plant Manager is responsible for ensuring operational readiness and implementation and acceptance testing plans, schedules and documentation for the IIFP Facility startup.

The Plant Manager will be responsible for application of the radiation protection, industrial safety and chemical process safety programs to facility operations and shall have the authority to enforce the shutdown of any process or building. The PM will also delegate facility shutdown authority to appropriate organizations and line managers. The PM must approve restart of an operation that was shut down due to safety and/or regulatory concerns.

The QA Manager has plant shutdown authority in matters relative to QA and ensures through the Plant Manager and COO that such shutdowns are implemented in a safe and orderly manner. The QA Manager, or Designee, must approve the restart of any operation shutdown by reasons of QA matters or by the QA function.

The design basis for the facility is maintained during the transition from construction to operations through the CM Program described in LA, Revision B Chapter 11 “Management Measures.”

A.1.3 Operation Organization QA Responsibilities

The IIFP President is ultimately responsible for approval of company policies that could impact the quality system. The IIFP President may delegate approval authority to the IIFP COO. The responsibility for performing specific activities is assigned within the individual procedures or work instructions.

Once the Plant Operation Organization is established and the project enters into the operational readiness and operations startup mode, the IIFP COO has the overall responsibility for implementation of the QA policies and programs. The COO is responsible with delegated authority from the IIFP President for the overall operation, maintenance, administration and regulatory compliance of the IIFP Facility. The COO is the individual with the overall responsibility for implementing safety and operational activities of the IIFP Facility. The responsibilities of the COO are defined by IIFP policies, procedures and instructions. The COO is responsible for the safe conduct and control of operations and protection of employees. The COO also has responsibility for regulatory compliance with the IIFP Facility NRC license and other federal, state and local permits or licenses. The COO ensures proper selection of staff for the key positions including positions for the Facility Safety Review Committee (FSRC) and the As Low as Reasonably Achievable (ALARA) Committee. In the discharge of these responsibilities, the COO leads the activities of the plant, including the following functions:

- Quality Assurance
- Plant Management (Operations/Technical)
- Engineering and Maintenance
- Administration
- Training
- Environmental, Safety and Health
- FSRC/ALARA Committee

The IIFP QA Manager reports to the COO directly. See Figure A-2, “Plant Operation Organization.”

The IIFP QA Manager is responsible for ensuring the IIFP Facility is complying with the QA Program. The QA Manager ensures compliance with the program elements identified in Chapter 11, Revision B of the IIFP NRC License Application and this QAPD and its implementing procedures. Those elements include:

- QA Program qualification and certification of personnel

- Work control
- Design control
- Procurement document control
- Instructions, procedures and drawings
- Document control
- Control of purchased items and services
- Identification and control of materials, parts and components
- Control of special processes
- Test control
- Inspection
- Control of measuring and test equipment
- Handling, storage and shipping
- Inspection, test and operating status
- Control of nonconforming items
- Corrective actions
- QA records
- Audits/assessments

QA policies are established and communicated to ensure that employees and contractors are informed of their responsibilities for reporting and resolving quality and safety related concerns, including but not limited to the following: 1) all plant personnel have the responsibility and commensurate authority to identify quality problems and to initiate, recommend, or provide solutions, 2) all line and functional managers are required to address identified quality problems and 3) should a manager's response not adequately address the identified quality concerns, the personnel involved are to submit their concerns to the next levels of management, including elevating any concerns to the IIFP President, where necessary.

The QA Manager is responsible for ensuring that identified project deficiencies are addressed by the appropriate management personnel and that containment actions including interim corrective actions are implemented until permanent corrective action are completed and verified. While providing oversight for the corrective action, the QA Manager will not be involved directly (avoids conflict of interest) in the affected project or production performance assignments.

Achieving quality in products and services is the responsibility of the individual staff and project team members. Validation that process quality measures are achieved will be independently verified.

The QA Manager is responsible for ensuring that periodic audits are conducted to ensure compliance with this QA Program and to assess its effectiveness.

The achievement of designated process, product or service parameters are to be reviewed by personnel not involved in performing or supervising the work being verified. Any or all of this work may be delegated in writing to others but the ultimate responsibilities shall remain as described in the organizational structure as shown in LA, Revision B Chapter 2 Section 2.2 "Key Management Positions, Responsibilities and Qualification" and this QA Program Description.

A.1.4 Quality Assurance General Practices

QA, as addressed by IIFP, is a set of practical methodologies: 1) personnel qualifications and assignments and 2) operating practices that ensure the safe operation of the facility and attainment of required product and service quality.

The IIFP COO is responsible for having policies in place for ensuring that:

- Performance of QA functions complies with requirements of applicable regulations, codes and standards
- Appropriate incorporation of ESH and quality aspects and requirements into applicable procedures
- Direct work performed by qualified individuals
- The quality of work performed by personnel satisfies defined quality standards
- Verification of work quality accomplished; reports documented
- Records maintained in accordance with the necessary requirements

The Plant Manager or the QA Manager serves as the point of contact between IIFP and the customers for quality-related matters.

The Plant Manager (or during design and construction, the COO), ESH Manager, Engineering Manager and QA Manager have the overall responsibilities and authority to ensure the identification and correction of quality deficiencies related to ESH and to work for which IIFP is responsible. This includes, when necessary, the authority to stop work in order to prevent further performance of work involving ESH or quality concerns.

The QA Manager may designate a QA lead to direct the QA effort within the production line organizations and to exercise the necessary authority to fulfill all organizational quality requirements. When such delegation of authority is made, the assigned QA lead's specific responsibilities include, as assigned:

- Serve as the contact between the customer and IIFP for quality related matters
- Ensure identification and documentation of all applicable quality-related requirements pertaining to the customer's activities for which IIFP has been contracted, including identification of any requirements differing from currently accepted practices
- Assign appropriately qualified personnel to specific tasks
- Determine the need for and provide any required job instruction or training
- Determine the need for and where required ensure the adequacy and appropriateness of checklists, plans, guides, procedures or other documents
- Review the work performed by IIFP personnel to ensure acceptability and conformance to contractual obligations

A.2 QUALITY ASSURANCE PROGRAM

A.2.1 Program

The IIFP QA Program and its implementing procedures comprise the management system established to ensure that IIFP operations, products and services are safe and reliable and that those products and IIFP services meet or exceed customers' requirements.

The QA Program applies to all IIFP products and services and uses a graded approach, in accordance with the applicable contract and at the earliest time consistent with the project schedule. The establishment of the QA Program shall include consideration of the technical aspects of the activities affecting quality.

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 ensuring the quality-related aspects 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 sets forth the minimum requirements for those items, activities and services within the scope of this QAPD. This QAPD is established, maintained and executed as described in this document. Project-specific quality standards/requirements not addressed in this QAPD, Revision B may be implemented in supplementary implementing QA procedures, other procedures and instructions.

A.2.1.1 Program Basis

IIFP has developed a QA Program that applies to the design, construction, operations and decommissioning of the IIFP Facility. IIFP will ensure the Quality Assurance Program complies with necessary regulatory requirements in 10 CFR Part 40 (CFR, 2009). Application of the QA Program is mandatory for SSCs, equipment and activities identified as IROFS in accordance with 10 CFR Part 70, Subpart H (CFR, 2009a) and 10 CFR 21, "Reporting of Defects and Noncompliance" (CFR, 2009b). 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.2.1.2 QA Program Implementation

This QA Program is implemented through a quality management system including, but not limited to, policies, procedures, instructions, specifications, drawings, procurement documents, contractual documents and other appropriate documents. Procedures are established to ensure that documents are consistent with the requirements of this QA Program, the ISA Summary, Revision B and applicable regulatory requirements. These documents also provide measures that ensure activities within the scope of the QA Program are planned and accomplished and monitored under conditions which ensure the accomplishment of project goals.

Specific processes and controls, which implement the provisions for product and QA Program requirements, are delineated in approved written procedures. When work cannot be accomplished as specified in the implementing procedures, the work is stopped until proper corrective action is taken. If procedures cannot be used as written, the work must be stopped until the procedure is modified, reviewed

for quality and safety and approved appropriately. Temporary process change requests must be approved by the same organizations responsible for the original documentation and process controls.

The documents shall provide details needed to accomplish quality-related activities under suitably controlled conditions. Examples of conditions to address include use of appropriate equipment, environmental restriction and verification that necessary prerequisites for the IIFP activities have been met.

A.2.1.3 Graded Application

This section describes 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-based assessment decision process. Risk analysis reviews are performed to determine the appropriate elements and principles for ensuring the necessary quality-related aspects of the facility are implemented. The extent of the graded approach application is discussed below.

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 (QL)-1 or QL-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 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 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-1 or 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

By appropriately balancing considerations of importance and process capability, an appropriate level of quality is achieved commensurate with the item's importance to safety. The results of the application of the graded approach to quality are incorporated into design requirement documents, specifications, procedures, instructions, drawings, inspection plans, test plans, procurement documents and other documents that establish the requirements for items or activities.

For contractors, the QL-1 and QL-2 requirements shall be described in IIFP approved documents.

A.2.1.4 Indoctrination and Training

Personnel performing or managing activities affecting quality shall receive training/indoctrination to ensure that they are knowledgeable of the applicability, purpose, scope and implementation of the QA Program and the applicable policies and procedures. Such indoctrination may be by formal classes, supervised on-the-job training (OJT) and evaluation or through completion of required reading or self-study.

Training shall be provided as needed to achieve initial proficiency, maintain proficiency and adapt to changes in the technology, methods or job responsibility. Formal training, when applicable, includes instruction in principles and techniques of the activity being performed to the extent necessary to ensure competence in the activity. Indoctrination and training shall be documented.

The QA Manager is responsible for indoctrinating appropriate IIFP management and supervisory personnel in the basis for, objective of and methods for ensuring quality of IIFP work. The IIFP management team is responsible to work together to determine the appropriate methods of indoctrinating and training company personnel.

A.2.1.5 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. In achieving that, managers should encourage the development and exploration of new ideas. Managers are expected to increase the awareness of all employees of the importance of quality. Managers must also emphasize the need for enhancing product and process safety and reliability, in addition to the identification of nonconforming items as potential areas for improvement.

Processes have been established by IIFP to detect and prevent quality problems and to verify implementation of quality improvement. Management is regularly informed of process trends and lessons learned which are incorporated as a result of audit reports, surveillance reports, corrective action reports, management assessments, etc. Corrective actions are initiated as necessary.

IIFP products, services and processes that do not meet established requirements shall be identified and controlled in accordance with Section A.15 "Control of Nonconforming Items". The severity and impact of the nonconformance shall be evaluated to determine if a corrective action must be initiated. The Corrective Action Program documented in Section A.16 shall be utilized to evaluate and document the corrective action. The process of correction includes identifying the root cause of nonconformance and determining actions necessary to prevent 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 ensuring 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.

The Plant Manager is responsible for managing production process quality and identifying potential improvements. Where specific training is being conducted for quality improvement projects, the PM shall emphasize the responsibility of each project team member to understand how their contributions affect the success of the overall project.

A.2.1.6 Review and Assessment

Managers of organizations that implement QA Program elements shall regularly assess the adequacy of that part of the QA Program. They may be assigned to audit sections of the QA Program for which they are not responsible. Responsible managers shall address any audit findings in their area by implementing appropriate corrective action and ensuring its effective implementation in accordance with applicable procedures.

The QA Manager is responsible for the performance of internal and external audits in accordance with the requirements of Section A.18. Audits determine the performance and effectiveness of activities required

by the QA Program. Audit findings identify the need for any revision to the QA Program or process procedures. The results of audits are reported to responsible management as described in Section A.18.3.6 and incorporated into facility procedures.

A.2.2 Qualification and Certification of Personnel

A.2.2.1 General

The principle objective of the Training Program is to ensure job proficiency of all personnel through effective training and qualification. The Training Program system will be designed to meet commitments complying 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 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 and IIFP. A graded approach to systematic training will be used when applied to the level of detail needed relative to safety. This graded approach incorporates methods to accomplish the analysis, design, development, implementation and evaluation of training.

A.2.2.2 Responsibilities

Managers have responsibility for and authority to develop and effectively conduct training for their personnel.

The Training organization provides support to line managers by facilitating the planning, directing, analyzing, developing, conducting, evaluating and controlling the training process.

The QA Manager is responsible for ensuring that personnel performing quality-related activities in accordance with this QA Program and applicable requirements of each particular project are adequately trained in activities associated with their work assignment.

A.2.2.3 Requirements

Indoctrination shall include the technical objective and requirements of the applicable codes and standards and the QA Program elements that are to be employed. Documentation of the QA Program indoctrination shall be retained in the appropriate IIFP personnel and qualification file.

On-the-job training will be a systematic method of providing the required job-related skills and knowledge for a position. This training will be conducted in an environment as close to the work environment as feasible. Applicable tasks and related procedures make up the OJT qualification requirements for each technical area.

Continuing training is any training not provided as initial qualification or basic training that maintains and improves job-related knowledge and skills. Continuing training shall be conducted as required.

Quality Assurance/Quality Control (QA/QC) inspections, examinations, surveillances and nondestructive examinations (NDE) shall be performed by QA/QC specialists, technical specialists, engineers, or NDE

technicians, who are qualified and certified in the discipline and/or method in which the activity is being performed.

Special processes that control or verify quality, such as those used in welding, heat treating and nondestructive examination, are performed by qualified personnel using qualified procedures in accordance with specified requirements.

Training, testing, qualification and certification requirements are specified for personnel who perform or inspect special process operations such as nondestructive examinations.

For special processes not covered by existing codes and standards or where quality requirements specified for an item exceed those of existing codes or standards, the necessary requirements for qualifications of personnel, procedures and equipment shall be specified or referenced in the procedures or instructions.

The QA Manager, or Designee, will periodically assess activities to ensure compliance with these QA Program requirements.

A.2.3 Work Control

A.2.3.1 General

This QA Program Description establishes requirements and defines the procedures for controlling work activities for maintenance and future projects after the IIFP Facility operations begin to ensure that they comply with the requirements of both the applicable contract and this QA Program.

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 procedure is commensurate with the risk associated with the work being performed and specific customer requirements.

A.2.3.2 Responsibilities

Managers ensure that adequate controls are established over activities and that personnel are properly trained, qualified and have the proper tools available prior to performing the work. Procedures and instructions are prepared with a level of detail commensurate with the complexity and importance of the work or activity. To provide a smooth transition in work processes involving more than one organization, process documents shall define organizational interfaces and responsibilities, intermediate process steps and expectations of the organizations.

Managers are involved in the work and the work processes which enables management to stay current and to create an environment that encourages employees to improve the quality of the work and work processes. To meet work performance objectives and expectations, each individual must focus on his or her specific tasks and take responsibility for the quality of the work performed.

A.2.3.3 Requirements

Activities involving licensed materials or IROFS are conducted in accordance with approved procedures. Procedures are used to control activities to ensure the activities are carried out in a safe manner and in accordance with regulatory requirements.

Procedures utilized to control activities shall be reviewed by line managers, the QA Manager, production staff and the Radiation Protection staff prior to their use to ensure that the procedures meet the applicable contractual, technical and quality requirements, including these QA Program requirements.

Applicable safety limits and IROFS are identified in procedures. IIFP will utilize standardized methods for identifying, developing, approving, implementing and controlling operating procedures. Identifying needed procedures will include consideration of the ISA Summary, Revision B results.

Maintenance of facility IROFS is performed in accordance with written procedures, documented instructions, checklists or drawings appropriate to the circumstances that conform to applicable codes, standards, specifications and other appropriate criteria.

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

Procedures developed for specific products shall comply with the requirements of the applicable portions of this QA Program. New procedures and procedural revisions shall be reviewed and approved, as a minimum, by the Plant Manager, the QA Manager and the ESH Manager prior to implementation.

A.3 DESIGN CONTROL

A.3.1 General

The design control provisions contained in this QA Program Description, Revision B are applicable during design and construction of the IIFP Facility for activities taking place beginning on the date the DB Contactor assumes the detailed design and engineering role and establishes the design organization and controls. Reconstitution of the any prior conceptual design is not required; however if a deviation to the design is discovered, engineering shall resolve the deviation and the affected as-built drawings, if necessary. The design control provisions remain in effect after the IIFP Facility becomes operational.

This section addresses the requirements and controls that ensure new design and design change activities are carried out in a planned, controlled and orderly manner. The design requirements and controls ensure that design basis, regulatory requirements and appropriate quality standards are correctly translated into design output, procurement requirements and procedural documents. These controls also establish provisions for verifying or checking the technical adequacy of design documents including computer codes.

A.3.2 Responsibilities

The COO (or the IIFP Engineering Manager once the positioned is filled) is the design authority having responsibility for implementation and execution of the design control system in accordance with this section for the IIFP during design, engineering and construction. Appropriate design authorities are delegated to the DB Engineering Manager by the COO or IIFP Engineering Manager.

After the IIFP Facility is approved for operation, the IIFP Engineering Manager is the facility design authority having responsibility for the implementation and execution of the design control system in accordance with the requirements of this section.

Design changes and new designs are authorized by responsible management. Management is responsible for ensuring that completed facility changes are tested and for ensuring that personnel affected by the change are adequately trained as described in procedures.

A.3.3 Requirements

A.3.3.1 Design Inputs

Design inputs are identified and documented. Design input selection is reviewed and approved by the responsible design organization. Design inputs are those criteria, parameters or other design requirements upon which the final design is established. Inputs such as performance requirements, regulatory requirements, codes, standards, environmental conditions and regulations, safety classes and interfaces with new or existing structures/equipment are considered.

Applicable design inputs shall be appropriately specified and correctly translated into design documents. Design inputs are specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures and evaluating design changes.

Changes to approved design inputs, including the reason for the changes, shall be identified, approved, documented and controlled prior to implementation.

A.3.3.2 Design Process

Design documents shall be adequate to support facility design, construction and operation.

Appropriate quality standards are identified and documented and their selection reviewed, approved and controlled. Changes from specified quality standards and reasons for the changes shall be identified, approved, documented and controlled prior to implementation.

Design methods, materials, parts, equipment and processes that are essential to the function of the IROFS are selected and reviewed for suitability of the application.

The outputs of design and development shall be provided in a format that enables verification against the design and development input requirements. Output results shall be reviewed and approved prior to design release. Design and development outputs shall meet the input requirements for design and development; provide appropriate information for purchasing, production and for service provision; contain or reference product acceptance criteria; and specify the characteristics of the product that are essential for its safe and proper use.

A.3.3.3 Design Analyses

Design analyses are performed in a planned, controlled and documented manner. Design analyses documents are legible and in a form suitable for reproduction, filing and retrieval.

Design analyses documents contain sufficient detail description to define the purpose, method, assumptions, design input, references and units, such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.

Calculations are identifiable by subject, originator, reviewer and date or by other data such that the calculations are retrievable.

A.3.3.4 Design Verification

Design requirements and associated design basis are established and maintained by the design engineering organization as designated by the DB Engineering Manager or the delegated Configuration Management Manager (CMM) and approved by the IIFP Engineering Manager (or COO until the position is filled) during the design/construction stage and as designated and approved by the Engineering Manager after operations begin. The configuration management controls on design requirements and the integrated safety analysis of the design basis are described previously in this section.

The design basis is documented in the ISA Summary, Revision B and the design requirements are derived from the design basis. Design requirements are documented in design requirements documents (i.e. calculations, safety analysis, design criteria, engineering drawings, system descriptions, technical documents and specifications). The design requirements and basis of design documents are controlled under the design control provisions of the Configuration Management 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. Analyses constituting the integrated safety analysis of the design basis, after the basis is established and verified, are subject to the same requirements. 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 Integrated Safety Analysis 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 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 document. The CMM ensures that the designated engineering organization documents the entire review process in accordance with approved procedures. These procedures include provisions to ensure 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 ensuring conformance with applicable codes, standards and license application design commitments. The individuals in engineering assigned to perform the check and review of a design requirements documents (calculations, safety analysis, design criteria, engineering drawings, system descriptions, technical documents and specifications) 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, theories, examples, tables, codes

and computer programs must be referenced in the design document and their application verified during the check and review process. 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 performing design verification. Verification may be performed by the supervisor of the individual performing the design, provided this need is documented, approved in advance by the supervisor's management and the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design or, provided 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 requirements 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 actions procedures. In accordance with these procedures, the report 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.

A.3.3.5 Design Changes

Configuration control and design control are 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: 1) need for inspection, identification of inspection personnel, 2) documentation of inspection result and 3) 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.

Human Factors Engineering (HFE) will be included in a facility modification procedure as a review/evaluation activity for any modifications that may impact Human System Interfaces (HSI).

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.

Changes to final designs, field changes, modifications and disposition of nonconforming items (use-as-is or repair) must be justified, documented and evaluated against criteria established by the Engineering Manager, QA Manager and ESH Manager.

A.3.3.6 Design Interfaces

Internal and external design interfaces are identified and controlled. Design change efforts are coordinated among participating organizations.

The responsibilities for the preparation, review, approval, release, distribution and revision of documents involving design changes require cross-functional team evaluation and must follow the standard document and configuration control requirements.

Design information transmitted across interfaces is documented and controlled.

A.3.3.7 Design Documentation and Records

Design documentation and records that provide evidence that the design and design verification processes were performed in accordance with the QA Program requirements, shall be collected, stored, and maintained in accordance with documented retention policies and procedures.

The documentation shall include not only final design documents, such as drawings and specifications, and revisions, but also documentation that identifies the important steps, including sources of inputs that support the final design.

Prior to modification or extensive repair on equipment or systems, configuration management requirements must be followed to approve the planned as-built condition is documented correctly and completely shown on the drawings, specifications, engineering change notices, and other equipment or systems descriptions prior to implementing the change.

A.4 PROCUREMENT DOCUMENT CONTROL

A.4.1 General

The Procurement System requirements ensures that applicable regulatory requirements, drawing and technical requirements, along with QA Program requirements are included or referenced in procurement documents for the procurement of items and services for QL-1 and QL- 2 control items. This system also establishes provisions for the preparation, review, approval and control of procurement documents, including changes.

A.4.2 Responsibilities

Engineering is responsible for the preparation and maintenance of design specifications (including specifications for spare and replacement parts) and for identifying the technical and quality requirements

necessary to ensure item acceptability. These specifications are subject to the requirements of Section A.3 of this QAPD. Engineering is also responsible for development of procedures that define these activities, including the criteria for developing the necessary technical and quality requirements for procurement.

A.4.3 Requirements

A.4.3.1 Procurement Document Contents

Procurement documents shall contain a statement of work for procurement of services, or an engineering specification for the procurement of items for QL-1 and QL-2 items.

Procurement documents shall include technical requirements by specific reference to drawings, specifications, codes, standards, regulations, procedures or instructions, including revisions, which describe the items or services to be furnished for QL-1 and QL-2 items.

Procurement documents shall specify special instructions and requirements for designing, fabricating, erecting, packaging, shipping, handling, storing, testing, inspecting and accepting, if required.

Procurement documents shall require the supplier have a documented Quality Assurance program consistent with the applicable requirements of the IIFP QA Program, other applicable codes and standards. The extent of the program required is dependent upon the type and use of the item or service being procured and its importance to safety.

Procurement documents shall require suppliers of non-commercial grade items and services to evaluate their lower-tier suppliers that supply IROFS items or services within the scope of the Statement of Work or Engineering Specification.

Procurement documents shall identify the documentation required to be submitted for information, review, or approval as well as the time of submittal, where applicable.

Procurement documents shall specify the requirements for reporting and obtaining disposition of nonconforming items and services, as appropriate.

A.4.3.2 Procurement Document Review

Reviews are documented to provide objective evidence of satisfactory accomplishment prior to contract award.

Changes made as a result of the bid evaluation or pre-contract negotiations are incorporated into procurement documents prior to contract award.

The reviews and approvals required by this section are performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and the procurement documents.

Procedures ensure that procurement document changes are subject to the same degree of control as utilized for the preparation of the original procurement document.

A.5 INSTRUCTIONS, PROCEDURES AND DRAWINGS

A.5.1 General

The requirements for instructions, procedures and drawings are applied to quality and process-related activities and services. Measures are in place to ensure that activities affecting quality are prescribed by documented procedures, drawings and instructions, appropriate to the circumstances and are accomplished in accordance with these documents. These documents also include quantitative and qualitative acceptance criteria to ensure that important operation evaluations which may affect IROFS have been satisfactorily accomplished.

A.5.2 Responsibilities

The Training Manager or QA Manager is responsible to review the approval and use of procedures and instructions in accordance with the management oversight requirements defined in this section.

The IIFP President (or the COO where delegated by the IIFP President) is responsible for approving all policy level documents.

Engineering is responsible for the system of preparation, review and approval of drawings in accordance with the requirements of this section.

Line and functional managers are responsible for developing and approving procedures which control functions or activities within their area of responsibility.

All personnel are required to use and adhere to the requirements of applicable procedures, instructions and drawings for activities.

A.5.3 Requirements

Activities that require skills normally possessed by qualified personnel are performed in accordance with work instructions, procedures or drawings of a type appropriate to the circumstances for the control of maintenance and modification work. The types of activities otherwise known as "skill-of-the-craft" do not require detailed step-by-step procedures.

Written procedures shall be prepared, reviewed, approved, implemented and maintained in accordance with the IIFP document control process.

A.6 DOCUMENT CONTROL

A.6.1 General

A Document Control Program (System) is established to maintain policy, procedure, work instruction and any other documentation which relates to the activities and services provided by IIFP. This program ensures that documents defining the performance of process and quality-related activities are controlled so only current and correct information is available at the location where the activity is performed prior to commencing the work. See also Section A.11 for specific information on the Records Management Program.

A.6.2 Responsibilities

An assigned Records/Document Control lead person will have the overall responsibility for the development and implementation of the Records Management and Document Control Programs.

Managers are responsible for: 1) identifying documents to be included in the Document Control System, 2) ensuring instructions, procedures, drawings and other specified documents are reviewed for adequacy and approved for release, 3) complying with document distribution requirements and 4) ensuring these documents are maintained and used by personnel performing the prescribed activity.

A.6.3 Requirements

Procedures for the control of document preparation, review, approval and issuance are established to ensure the following:

- Identification of documents to be controlled and their specified distribution
- Identification of assignments of responsibility for preparing, reviewing, approving and issuing documents
- Review of documents for adequacy, completeness and correctness prior to approval and issuance

Drawings depicting as-built conditions, including changes and related documentation are prepared in a timely manner and accurately reflect the actual design.

Document controls used to specify the current revision and any changes to instructions, procedures, specifications, drawings and procurement documents are identified. This Document Control System has provisions for updating and for distribution to predetermined personnel.

Except for minor changes, changes to documents are reviewed and approved by the same organization that performed the initial review and approval or are delegated to other qualified organizations. The reviewing organization has access to pertinent background data or information upon which to base their approval.

Minor changes to documents, such as inconsequential editorial corrections do not require that the revised documents receive the same review and approval as the original documents. The review and approval for minor changes are specified in procedures.

Obsolete or superseded documents are removed and/or replaced in a timely manner.

A.7 CONTROL OF PURCHASED ITEMS AND SERVICES

A.7.1 General

A system for the control of purchased items and services is established within the scope of this QA Program Description. 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.

A.7.2 Responsibilities

The QA Manager is responsible for providing the necessary QA functions to support procurement. These QA functions include review of supplier quality documentation, evaluation of supplier's QA capability, supplier audits and for the development and maintenance of an approved suppliers list. The QA Manager provides support functions such as source verification or surveillance, receipt inspections, installation inspections and review of procurement documents during receipt inspections. The QA Manager is also responsible for developing and implementing procedures which meet the requirements of this section of the QAPD.

The Engineering organization is responsible for assisting the QA Manager by performing evaluations of supplier technical capabilities and determining the methods of acceptance to be applied to purchased items and services. Engineering is responsible for the approval of dispositions and technical evaluations for supplier-generated nonconformances for items and services. Engineering or Quality Assurance is also responsible for providing measures which ensure the proper selection, application, methods of acceptance and use of items.

A.7.3 Requirements

A.7.3.1 Procurement Planning

Procurement activities are planned and documented to ensure a systematic approach to the procurement process. Procurement planning results in the documented identification of procurement methods and organizational responsibilities.

A.7.3.2 Supplier Selection

Procedures are established for the selection of suppliers. The selection of suppliers is based upon evaluation of the supplier's capability to provide items or services in accordance with the requirements of the procurement documents prior to award of contract. An assessment of the potential supplier's technical and quality capability is performed and documented in accordance with one or more of the following:

- Evaluation of the supplier's history of providing an identical or similar product which performs satisfactorily in actual use. The supplier's history shall reflect current capability.
- The supplier's technical and quality capability is determined by an evaluation of his facility and personnel and the implementation of the supplier's quality assurance program.
- The supplier implements an International Organization for Standardization (ISO) accepted quality assurance program.
- The supplier maintains a valid ISO certification for the item or service being provided.

Upon an acceptable evaluation using any of the above methods, the supplier may be placed on the Approved Suppliers List (ASL).

Source Verification

When this method is utilized, it is performed at intervals consistent with the importance to safety and complexity of the item or service; and it shall be implemented to monitor, witness, or observe activities. This method provides plans to perform inspections, examinations, or tests at predetermined points. Upon purchaser acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, to the purchaser and to the supplier.

Receiving Inspection

This method is utilized for all purchased items to verify conformance to procurement documents. This method verifies by objective evidence such features as proper configuration; identification; dimensional, physical, or other characteristics; freedom of damage from shipping; cleanliness; and review of supplier documentation when procurement documents require the documentation to be furnished. Upon completion of receipt inspection, acceptable items are released for storage or issued for installation or use. Items determined to be nonconforming after completion of the receipt inspection are documented and processed.

Post-Installation Testing

When this method is utilized for acceptance of non-commercial grade items, post-installation test requirements and acceptance documentation are established by the purchaser and supplier.

A.7.3.3 Commercial Grade Items

Methods shall be established for determining whether an item can be purchased as commercial grade and dedicated for use in an IROFS application. The criteria and methods shall identify the critical characteristics that are essential to ensure that the item will perform its intended IROFS function.

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. The dedication process is described below.

In accordance with 10 CFR 21 (CFR, 2009b), 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 ensure critical characteristics will be met. Those requirements for verifying acceptability of critical characteristics could encompass inspection, tests or analyses after delivery, supplemented as necessary by one or more of the following:

- Commercial grade surveys
- Product inspections or witness at hold-points at the manufacturer's facility
- Analysis of historical records for acceptable performance

As a minimum for acceptance of commercial grade items, receipt inspection will be performed to provide reasonable assurance that the item received is the item ordered. Receipt inspections are performed:

- To determine that damage was not sustained during shipment
- That the item received is the item ordered
- That inspection and testing was performed by the supplier as required by Engineering
- To ensure conformance with manufacturer's published requirements
- To ensure that required documentation is received and is acceptable

Commercial grade items are identified in the contract or purchase order by the manufacturer's published product description. Alternate commercial grade items are allowed provided Engineering provides verification that the alternate commercial grade item will perform its intended IROFS function.

A.8 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

A.8.1 General

A system is established for the identification and control of IROFS items within the scope of the QAPD, Revision B. 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 stores for use. Configuration management provides for parts traceability after they are installed in the plant.

A.8.2 Responsibilities

The Engineering organization is responsible for specifying requirements for identification methods, traceability, shelf life and operating life of items when required by codes, standards or specifications. Engineering specifies these requirements during the generation of specifications, drawings, procurement documents or other documents appropriate to the circumstances.

The QA Manager is responsible for verifying that items are correctly identified through receipt inspection.

Managers are responsible for maintaining and implementing identification, traceability, and shelf life and operating life requirements for items under their jurisdiction.

The Purchasing organization is responsible for receipt, delivery, storage, traceability, identification and control of materials.

A.8.3 Requirements

Managers shall ensure that procedures are established depicting requirements to be implemented for the identification, traceability, and control of materials, parts and components, including partial fabricated assemblies or subassemblies.

These procedures shall include requirements, for but shall not be limited to, the following:

- Where practical and required by codes, standards or contractual documents, identification maintained on items or in documents traceable to them in a manner which ensures that identification is established and maintained
- When physical identification is either impractical or insufficient to control the item, physical separation, procedural controls or other means employed

- Preventing the use of defective, unapproved, incorrect or incomplete materials equipment, and precluding use of items whose shelf life or operating life has expired
- Unique identification and traceability of items by serial number, part number, batch, lot, or specified inspection, test, records, or other appropriate means
- Production of an item at any stage from initial receipt through fabrication, installation, repair, modifications and use traced to records such as applicable drawings, specifications, purchase orders, manufacturing and inspection documents, deviation reports, certified material test reports, or other pertinent applicable design specifying documentation
- Permanent physical identification on an item itself to the maximum extent possible, in a manner and location that will not impair or negate its intended use, quality, function or service life (When markings are used, measures are established to ensure the markings are clear, legible or machine readable. 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.)
- Use of physical separation, procedural control or other appropriate means where physical identification on the item is impractical or not sufficient
- Correct identification of materials, parts, and components verified and documented on appropriate release documents, work packages, or controlling documents, and on materials prior to subdividing an item or material, and prior to release for fabrication, assembly, shipping and installation
- Trained personnel performing quality activities, as required, ensuring understanding and proper implementation of this procedure and use of approved procedures to ensure that improper, uncontrolled, damage, incorrect or nonconforming material or items are not used or installed
- Audits, inspection and surveillances performed to ensure compliance to established procedures
- Quality records maintained in accordance with design, procurement and process documents establishing and attesting to proper identification of IIFP furnished items

A.9 CONTROL OF SPECIAL PROCESSES

A.9.1 General

A system is established for the control of special processes within the scope of the QA Program Description, Revision B. This system establishes the requirements for the control of special processes.

A.9.2 Responsibilities

The engineering discipline is responsible for determining special processes, providing technical requirements for identified special processes, and reviewing and concurring with all special process procedures including the utilization and application of NDE procedures.

The QA Manager is responsible for the qualification on NDE personnel, including welder/brazing qualifications.

Line managers ensure that identified special processes are performed by qualified personnel, using qualified and approved procedures or documents of a type appropriate to the circumstances.

A.9.3 Requirements

Special processes affecting quality of items and services such as welding, heat treating and nondestructive examination are controlled.

Policies, plans, procedures, instructions, drawings, checklists, travelers, work orders or other appropriate means are used to control special processes.

These special processes ensure special process parameters are controlled and specified environmental conditions are maintained.

Special processes that control or verify quality (that is, those used in welding, heat treating and nondestructive examination) are performed by qualified personnel using approved written policies, plans and/or procedures in accordance with specified requirements, codes or standards.

When the outcome of the process is highly dependent on personal skills, such individuals are certified in accordance with specified requirements.

When the outcome is highly dependent on control of process parameters, the process and equipment are pre-qualified in accordance with specified requirements.

Special process policies, plans and/or procedures prescribe the necessary equipment, process parameters, calibration and acceptance criteria.

Records are maintained of currently qualified personnel, processes and equipment for special processes.

A.10 INSPECTION

A.10.1 General

A system is established for inspection of IROFS. This system provides measures to ensure that maintenance, repair or modification work is completed satisfactorily. 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.

Requirements for the certification of personnel who perform inspection, examination, surveillance and testing are identified.

A.10.2 Responsibilities

The QA Manager is responsible for inspection planning, for ensuring inspections are performed, and for utilizing qualified and certified inspection personnel.

Engineering or Quality is responsible for specifying "hold" and "witness" points for inclusion in applicable work control documents. Such work control documents are developed from approved design documents, which specify the criteria for acceptance of the work.

Management establishes measures to ensure that the requirements of this section of the QAPD are met.

A.10.3 Requirements

Inspections are required to verify conformance of an item or activity to specified requirements and shall be planned and executed. Characteristics to be inspected and inspection methods to be employed shall be specified.

Inspection results shall be documented and inspection records shall identify the following:

- Item inspected
- Date of inspection
- Inspector
- Type of observation
- Results or acceptability
- References to information on action taken in connection with nonconformances

Inspection personnel shall not report directly to the immediate supervisors who are responsible for performing the work being inspected.

If mandatory inspection hold points are required beyond which work shall not proceed without the specific consent of the designated representative, the specific hold points shall be indicated in appropriate documents. Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point.

Planning for inspection activities shall be accomplished and documented. The documentation shall identify characteristics to be inspected, responsibility, methods, measuring and test equipment, acceptance criteria, and referenced instructions and design documents. Planning for inspection activities provides for recording objective evidence of inspection results.

Inspection of items in-process or under construction shall be performed to verify quality for certain work activities where necessary.

A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to ensure that the specified requirements for control of the process and quality of the item are being achieved throughout the duration of the process. Controls, where required, shall be established and documented for the coordination and sequencing of these activities at established inspection points during successive stages of the conducted process or construction.

Final inspections shall include the following:

- A records review is performed of the results and resolution of nonconformances identified by prior inspections. The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements.
- Completed items shall be inspected for completeness, markings, calibrations, adjustments, protection from damage, or other characteristics as required to verify the quality and conformance of the item to specified requirements. Quality records shall be examined for adequacy and completeness, if not previously examined.

- The acceptance of the item shall be documented and approved by authorized personnel.
- Modifications, repairs, or replacement of items performed subsequent to final inspection shall require re-inspection or retest, as appropriate, to verify acceptability.

Required in-service inspection or surveillance of structures, systems or components shall be planned and executed by, or for the organization responsible for construction or operation as specified in the QAPD, Revision B or the ISA Summary, Revision B. Inspection methods shall be established and executed to verify that the characteristics of an item continue to remain within specified limits. Inspection methods shall include evaluation of performance capability of essential emergency and safety systems and equipment, verification of calibration and integrity of instruments and instrument systems and verification of maintenance, as appropriate.

The depth and extent of inspections are determined by the significance of the IROFS and the complexity of the item or activity.

The identification of inspection activities and attributes is based on the complexity of the item or activity to be inspected, on mandatory inspections required by codes, standards, regulatory requirements or commitments. The inspection requirements are established by the Plant Engineering and Maintenance Manager with consideration of the quality history of the process.

A.11 TEST CONTROL

A.11.1 General

A system is established for design verification testing, acceptance testing, pre-operational and operational testing of IROFS as described in the IIFP LA, Revision B Chapter 11 Section 11.2.2. This system provides measures to ensure that this testing is completed satisfactorily.

Requirements for the certification of personnel who perform design verification testing, acceptance testing, pre-operational and operational testing of IROFS are identified.

A.11.2 Responsibilities

The Engineering organization is responsible for providing technical criteria for testing, evaluation of test results and resolution of deficiencies identified from these tests.

Line managers are responsible for the conduct of testing activities under their cognizance which are in accordance with procedures consistent with these requirements.

A.11.3 Requirements

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 required to collect data, such as for site testing or design input, shall be planned, executed, documented and evaluated.

Tests include design verification tests, acceptance tests, pre-operational and operational tests, post-maintenance tests and special tests. Planning for tests may include mandatory hold points, as required.

Test policies, plans and/or 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 prerequisites for a given test 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
- Maintained and available adequate instrumentation and suitable environmental conditions
- Provisions for documenting and evaluating the test results for conformance with acceptance criteria
- Qualifications for test personnel

In lieu of test policies, plans and procedures, appropriate methods of related documents [such as American Society for Testing and Materials (ASTM), external manuals, maintenance instructions or approved drawings may be used. Such documents must include adequate instructions to ensure the required quality of work.

Test records contain the following information:

- Item tested; test date
- Tester or data recorder
- Type of observation
- Test policy, plan, procedure, or reference
- Results and acceptability
- Actions taken in connection with any deviations noted
- Person evaluating the results

A.12 CONTROL OF MEASURING AND TEST EQUIPMENT

A.12.1 General

A system is established for the control of measuring and test equipment (M&TE) used for measurement, test and calibration items within the scope of this QA Program requirements. 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.

This system also establishes measures to ensure that devices and standards used for measurements, tests, and calibration activities are of the proper type, range, accuracy and tolerance to accomplish the function of determining conformance to specified requirements.

A.12.2 Responsibilities

The Plant Engineering and Maintenance Manager has the overall responsibility for the Calibration Control System for M&TE.

Line managers are responsible for implementation of the Calibration Control System for M&TE under their cognizance.

A.12.3 Requirements

A list of devices (and their assigned location) 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. Calibration controls are not necessary for rulers, tape measures, levels and other such devices if the commercial equipment provides adequate accuracy.

M&TE is calibrated at specified intervals or prior to use against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standard exists, the bases for calibration are documented.

The method and interval for calibration for each item shall be defined, based on the type of equipment, stability characteristics, required accuracy, intended use and other conditions affecting measurement control.

When M&TE is found to be out of calibration, 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 recalibrated. When M&TE is consistently found to be out of calibration, it is repaired or replaced. Also, calibrations are performed when the accuracy of the equipment is deemed suspect by personnel performing measurements and tests.

M&TE is properly handled and stored to maintain accuracy. The following M&TE items are included in 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

Records are maintained and equipment is suitably marked to indicate its calibration status.

A.13 HANDLING, STORAGE AND SHIPPING

A.13.1 General

A system is established for the handling, storage and shipping of IROFS items in accordance with design and procurement requirements to protect against damage, deterioration or loss. Special handling tools and equipment are provided where necessary to ensure IROFS items can be handled safely and without damage. Operators of special equipment are experienced and trained as required.

A.13.2 Responsibilities

The Engineering organization is responsible for specifying requirements for handling, storage and shipping of IROFS items when required by codes, standards or specifications.

The QA Manager is responsible for verifying that handling, storage and shipping requirements are incorporated into procedures and assessing compliance to those procedures.

Managers are responsible for maintaining and implementing handling, storage and shipping requirements for IROFS items under their jurisdiction.

A.13.3 Requirements

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, 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 A.8, "Identification and Control of Materials, Parts and Components" and Section A.10, "Inspection." Operators of special handling and lifting equipment shall be experienced or trained in the use of the equipment.

A.14 INSPECTION, TEST AND OPERATING STATUS

A.14.1 General

A system establishes requirements 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.

A.14.2 Responsibilities

The Quality Assurance Manager is responsible for providing a status-indicating system for inspections performed in accordance with these requirements.

Line managers participating in testing and operational activities are responsible for the development and implementation of status-indicating systems consistent with these requirements.

A.14.3 Requirements

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. This activity is required when

it is necessary to ensure that required inspections and tests are performed and to ensure items that have not passed the required inspections and tests are not inadvertently installed, used or operated.

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 (for example, tagging valves and switches) to prevent inadvertent operation. Authority for the application and removal of tags, markings, labels and stamps is specified.

A.15 CONTROL OF NONCONFORMING ITEMS

A.15.1 General

A system is established for the control of nonconforming materials and related activities and services within the scope of the QA requirements. 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 disposition made 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.

A.15.2 Responsibilities

Personnel participating in quality-affecting activities within the scope of Quality System requirements are responsible for reporting and documenting nonconforming items or related activities and services.

The QA Manager is responsible for implementation of the Nonconformance Control System for materials that do not meet the established specifications or technical requirements.

The Engineering, ESH and Quality Assurance organizations are responsible for providing documented technical justification for the acceptability of disposition of nonconforming items ("use-as-is" or "repair") and are also responsible for applying the design control measures of Section A.3 of this QAPD to those nonconformances. Engineering ensures that as-built records reflect the accepted change.

A.15.3 Requirements

Nonconforming items are identified in a manner that does not adversely affect the end use of the item, by markings, tagging and other appropriate methods. The identifications shall be legible and easily recognizable. When identification of the item is not practical, the container, package or segregated storage area is identified.

Nonconforming items are segregated, when practical, by placing them in a clearly identified and designated area until disposition is decided. When segregation is impractical or impossible due to physical conditions such as size, weight or access limitations, other measures are employed to preclude inadvertent use of the item.

Nonconforming characteristics are reviewed and dispositions are recommended. Further processing, delivery, installation or use of the nonconforming item is controlled pending an evaluation and approved disposition by authorized personnel; and notification to affected organizations is provided and approved.

Nonconforming items or services are evaluated to determine whether reporting is required.

Nonconforming items or services identified by suppliers are reviewed to determine applicability and to initiate corrective action if required.

The responsibility and authority for the evaluation and disposition of nonconforming items is defined. The personnel performing evaluations to determine the disposition have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements and have access to pertinent background information.

The disposition of nonconforming items is identified and documented. Technical justification for the acceptability of nonconforming items with a disposition of "repair" or "use-as-is" is also documented. Nonconformance disposition as "repair" or "accept" shall be subject to design control measures commensurate with those applied to the original design. The as-built records, if such records are required, shall reflect the accepted deviations.

Repaired or reworked items are reexamined in accordance with applicable procedures and with the original acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.

Nonconformance documentation identifies the nonconforming item, describes the nonconformance, contains the disposition and any re-inspection requirements and contains the appropriate signatures approving the disposition.

When a nonconformance is identified subsequent to product being shipped to a customer or recipient, management shall evaluate whether the nonconformance is potentially reportable to the NRC under Part 21 (CFR, 2009b) of the NRC Rules and Regulations. Notification shall also be made to the customer or recipient.

A.16 CORRECTIVE ACTION

A.16.1 General

A Corrective Action Program is established for those activities and services that are determined to have an adverse effect on the customer or have potential for recurrence. This program establishes measures which ensure that conditions adverse to quality are identified and corrected as soon as practical. The program also ensures that a root cause analysis and Corrective Action Report will be generated to Document Control and report the analysis and action to the appropriate levels of management. The program also ensures that follow-up actions are taken to verify implementation of the corrective action.

A.16.2 Responsibilities

The QA Manager is responsible for maintenance and implementation of the Corrective Action Program. This manager is also responsible for verifying that adverse conditions are reviewed and assessed by appropriate levels of management.

Managers are responsible for ensuring evaluation and performance of assigned corrective actions in a timely manner in accordance with procedures that implement the requirements of this section of the QAPD. They are also responsible for ensuring the identification and documentation of conditions adverse to quality in accordance with applicable procedures.

A.16.3 Requirements

Conditions adverse to quality are promptly identified and corrected as soon as practical. Conditions adverse to quality are defined as failures, malfunctions, deficiencies, deviations, defective material and equipment and nonconformances. Conditions adverse to quality shall be documented and reported to the appropriate levels of management.

For significant conditions adverse to quality, the cause of the condition is determined and corrective action is taken to preclude recurrence. Significant conditions adverse to quality are defined as:

- A deficiency that would seriously impact an item, activity or service from meeting or performing its intended function or output of ensuring public health and safety
- A deficiency in design that has been approved for fabrication or construction where the design deviated extensively from design criteria and bases
- A deficiency in the fabrication or construction of, or significant damage to, SSCs that require extensive evaluation, re-design or repair in order to establish the adequacy of the SSCs to perform its intended function of ensuring public health and safety
- A deviation from performance specifications that shall require extensive evaluation, re-design, or repair to establish the adequacy of the structure, system or component to perform its intended function
- A significant error in a computer program used to support activities affection quality after it has been released for use
- A deficiency, repetitive in nature, related to an activity or item subject to the IIFP QA Program
- A condition that, if left uncorrected, has the potential to have a serious negative impact on activities or items subject to the IIFP QA Program controls

Significant conditions adverse to quality shall be evaluated for stop work condition to determine if stopping work is warranted.

The identification, cause and corrective action for significant conditions adverse to quality are documented and reported to appropriate levels of management and follow-up action is taken to verify implementation of the corrective action.

Nonconformances and deficiencies that relate to procedural or programmatic breakdowns identified by an audit or surveillance performance by management shall be documented and the responsible area manager must complete the corrective action(s) to resolve the systemic problem.

Actions to correct IIFP system deficiencies are the responsibility of the official immediately in charge of the function in which the action is required.

The QA Manager is responsible for maintaining an orderly file of all audit findings and nonconformances related to products and services. Each area manager is responsible to determine the cause of each

deficiency, document it as a nonconformance, determine necessary action to be taken and report actions in a Nonconforming Report or in the Corrective Action Report depending on the severity of the issue.

Deficiencies identified by a customer audit or assessment shall be reviewed by the QA Manager, who shall be responsible for ensuring that as a minimum the requirements of the customer and of the procedure are met. The QA Manager shall evaluate any corrective action suggestions from the customer and ensure that such suggestions are appropriately addressed either by implemented change or resolution with the customer.

The QA Manager shall review and evaluate corrective action effectiveness. The affected management, including the COO when appropriate, shall be advised of the trends and if additional remedial action is needed.

A.17 QUALITY ASSURANCE RECORDS

A.17.1 General

A Records Management Program is established and related activities and services are defined within the scope the QA Program. The Records Management Program provides measures to control Quality Assurance records.

A.17.2 Responsibilities

Records Management/Document Control is responsible for the maintenance and implementation of the Records Control Program consistent with the requirements set forth in the QA Program.

Managers are responsible for: 1) identifying quality assurance records initiated by their organization including those received from suppliers of items and services, 2) controlling the records within their jurisdiction and 3) transferring records, for which their group has copy responsibility, to the records management organization for retention consistent with governing procedures meeting the requirements established the QA Program.

A.17.3 Requirements

QA records shall be identified, prepared, stored, maintained, preserved and kept safe in appropriate facilities, which allow the records to be retrievable. Measures shall be established to preclude entry of unauthorized personnel into record storage locations and to guard against larceny and vandalism. Records shall be protected against damage, deterioration or loss.

Records shall be stored in authorized facilities or containers providing protection from fire hazards, natural disasters, adverse environment, insect infestation, mold or rodents. Storage facilities shall be maintained to ensure continuous protection of the records. Requirements shall be specified for both permanent and temporary storage of records. Specific requirements and responsibilities for generation, classification, retention, receiving, storage and preserving of QA records are established in approved written procedures.

Applicable design specifications, procurement documents, test procedures, operational procedures or other documents specified as records, which require retentions shall be legible, accurate and complete.

Documents shall be considered valid records only if stamped, initialed or signed and dated by authorized personnel or otherwise authenticated.

Records shall be properly identified, indexed and maintained to ensure the records can be retrieved.

Methods are established to permit identification between the record and the item(s) or activity (ies) to which it applies.

Records Management Program requirements for goods or services procured from outside suppliers shall be specified in the applicable procurement documents.

Corrections to records are approved by the originating organization and the corrections include the date and the identification of the individual authorized to issue the correction.

QA records shall be classified as “lifetime” or “non-permanent.” Lifetime records are required to be maintained for the life of the particular item. Record retention requirements are defined in the IIFP record retention policy.

Lifetime records shall meet one or more of the following criteria:

- Records that would be of significant value in demonstrating that manufactured products meet requirements
- Records that would be of significant value in maintaining, reworking, repairing, replacing or modifying critical items with the plant or manufactured products
- Records that would be of significant value in determining the cause of an accident or malfunction of an item with the plant

A.18 AUDITS

A.18.1 General

An audit system is established for 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 system 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.

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 ensure that audits of activities are completed within specified time periods.

External audits of selected suppliers and service contractors are performed to verify and evaluate their Quality Assurance programs, procedures and activities to ensure that they are complying with applicable aspects of the IIFP QA Program and procurement requirements. This may include verification that the suppliers and contractors similarly review and audit the QA programs of their suppliers as required depending on the QA level of the product or service.

A.18.2 Responsibilities

The QA Manager is responsible for the development, maintenance, scheduling and performance of the internal audit and external supplier audit system consistent with the requirements of the QA Program.

Audited organizations are responsible for providing assistance as required during the planning and performance of audits, for providing access to facilities, personnel, documents and records, as required, and for ensuring that requests for corrective action are promptly answered and that actions taken to correct any discrepancy are adequate and timely.

A.18.3 Requirements

A.18.3.1 Training and Qualification

Audit personnel shall be properly trained such that they are competent to perform the required audits. Technical specialists may participate as audit team members provided they receive the required indoctrination and guidance during the audit.

A.18.3.2 Scheduling

Internal and external audits are scheduled in a manner to provide coverage and coordination with ongoing QA Program activities. Audits are scheduled at a frequency commensurate with the status and importance of the activities. The audit schedules are reviewed periodically and revised as necessary to ensure coverage is maintained current.

Regularly scheduled audits are supplemented by additional audits or surveillance (assessment) of specific subjects when necessary to provide adequate coverage.

An implementation audit for initial evaluation of suppliers may be scheduled and performed after award of the contract when sufficient time has lapsed for implementing their QA program and they are performing the functions as defined in their QA program, codes, standards and other contract documents.

External audits of approved non-commercial grade suppliers are scheduled and performed based on supplier certification program and established quality performance parameters. Suppliers of services do not require external audits if they perform work in accordance with IIFP QA Program (i.e., QAPD and its implementing procedures) under IIFP supervision. External audits are required for suppliers of services based on supplier quality certification program, established quality performance parameters and the Quality level of the service provided.

A.18.3.3 Audit Plan

The auditing organization shall develop and document an audit plan for each audit. The plan is required to identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule and applicable written procedures or approved checklists of questions covering the items to be audited.

A.18.3.4 Personnel and Selection of Audit Team

Measures are established for the selection of the audit team and audit team familiarization prior to the beginning of each audit. These measures ensure consideration is given to special abilities, specialized technical training, prior experience, personal characteristics and education when personnel are selected as audit team members.

The audit team shall contain one or more auditors and shall have an individual appointed to lead the team who organizes and directs the audit, coordinates the preparation and issuance of the Audit Report and evaluates the responses. The selected auditors shall be independent of any direct responsibility for performance of the activities which they will audit.

Expected audit deliverables are established for audit team preparation prior to initiation of the audit; particularly that pertinent information (policies, procedures, standards, instructions, codes, regulatory requirements and prior audit reports) is available for review by the auditors for formulation of the checklist and the conduct of the audit.

A.18.3.5 Auditing

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(s) are reported immediately to the management of the audited organization.

A.18.3.6 Reporting

The audit report is signed by the audit team leader. The report should be issued generally within thirty (30) days of the post-audit conference. The audit report is distributed to responsible management of both the auditing and the audited organizations.

The audit report shall include the following information, as appropriate:

- Description of the audit scope
- Identification of the auditors
- Identification of persons contacted during audit activities
- Summary of audit results, including a statement of the implementation effectiveness of the Quality Assurance Program elements which were audited
- Description of each reported adverse audit finding in sufficient detail to enable corrective actions to be taken by the audited organization

A.18.3.7 Response and Follow-Up Action

Management of the audited organization or activity shall ensure that an investigation is conducted of adverse audit findings, and that corrective actions and measures are identified and scheduled to prevent recurrence and to notify the appropriate organization in writing of the actions taken or planned. The adequacy of the written audit responses is evaluated by or for the auditing organization. Follow-up action shall be taken to verify that corrective action is completed as scheduled.

A.18.3.8 Records

Audit records include audit plans, audit reports, written replies and documented completion of corrective actions.

REFERENCES

- CFR, 2009 Title 10, Code of Federal Regulations, Part 40, "Domestic Licensing of Source Material," U.S. Nuclear Regulatory Commission, 2009.
- CFR, 2009a Title 10, Code of Federal Regulations, Part 70, Subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material," U.S. Nuclear Regulatory Commission, 2009.
- CFR, 2009b Title 10, Code of Federal Regulations, Part 21, "Reporting of Defects and Noncompliance," U.S. Nuclear Regulatory Commission, 2009.