International Isotopes Fluorine Products, Inc.
(IIFP)

A Wholly Owned Subsidiary of
International Isotopes, Inc.

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

Appendix A
Quality Assurance Program Description

Revision A

December 23, 2009

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APPENDIX A. QUALITY ASSURANCE PROGRAM DESCRIPTION

A.1.0 Introduction

International Isotope Fluorine Products (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 uranium oxides. Depleted uranium hexafluoride, referred to as "tails", is the by-product of the uranium enrichment industry.

The proposed licensed action is the issuance of an NRC license under Title 10 Code of Federal Regulations (CFR) Part 40, Domestic Licensing of Source Material (CFR, 2009) for the IIFP plant. Although 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 is completed and is being submitted. This ISA is prepared 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, 2000).

The IIFP project is currently in its development, initial conceptual design and licensing application phase. The provisions contained in this QA Program Description are applicable during design and construction of the IIFP Facility for design activities taking place beginning on the date the DB contactor assumes the detailed design and engineering role and establishes the design organization and controls. An equivalent Quality Assurance Program provided by the DB contractor may be used during the design and construction phase upon review and evaluation by the IIFP Regulatory Affairs and Quality Assurance staff and approval of the IIFP Chief Operations Officer/Commercial Facility Project Director (COO/CFPD) or the INIS President/CEO.

Once the design, engineering and construction phase of the FEP/DUP project begins, the IIFP COO/CFPD, appointed by the President and CEO and reporting to the INIS President/CEO, is responsible for implementing the safe design and construction in accordance with the graded QA Program as applicable (See Figure A-1, IIFP Organization during Design and Construction). Upon start up of the facility operations, the provisions of the IIFP Quality Assurance Program (QAP), or its approved revisions, remain in effect. The IIFP Chief Operating Officer/Plant Manager is responsible for assuring implementation of the IIFP QAP and its provisions for Facility operations.

The IIFP licenses application and supporting documentation addresses construction and operation of an initial (Phase 1) Fluorine Extraction Process and Depleted Uranium De-conversion Plant (FEP/DUP) in Lea County, New Mexico. The facility will utilize depleted uranium hexafluoride (DUF_6) to produce high-purity inorganic fluorides, uranium oxides, and anhydrous hydrofluoric acid. 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 a Phase 2 plant approximately 4 years after start up of the Phase 1 plant. Amended licensing and revisions to the ISA will be developed and submitted at an appropriate time during the licensing process of the Phase 2 project. The Phase 2 will consist of the additional processing equipment to convert DUF_6 directly into uranium oxide.

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 Quality Assurance

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Program (QAP) description is applicable to the detailed design, construction, operation and de-commissioning of the both the Phase 1 and Phase 2 facilities. The QAP may be updated for the Phase 2 expansion in the timeframe during which the Phase 2 project materializes.

A.1.1 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 INIS President and Chief Executive Officer (CEO) is the senior executive responsible for corporate quality assurance and is the highest level of responsibility for QA policies and quality-related goals and objectives.

A.1.1.1 Quality Assurance (QA) Responsibilities during Project Design and Construction

The project design and construction organization is shown in Figure A-1. Responsibilities for key management positions during this stage of the project are given in the IIFP license application Chapter 2, Organization and Administration. The INIS President and Chief Executive Officer (CEO) has responsibility and authority for ensuring that appropriate QA policies and organizations are in place to effectively implement the QAP during detailed design and construction; referred to as the design/build (DB) stage of the FEP/DUP facility.

As shown in Figure A-1, the IIFP COO/CFPD reports to the INIS President/CEO. The COO/CFPD is responsible for managing the design, engineering, construction, quality assurance, environmental, safety and health (ESH), configuration management, procurement and initial start-up activities. The IIFP QA Coordinator reports to and supports the COO/CFPD. The QA Coordinator also has a matrix reporting relationship to the INIS Regulatory Affairs/QA Director; allowing for objective audit, review, and control activities. When the project transitions from the development and conceptual design stage to the DB stages, the preparation of engineering and construction documents and the construction, is performed utilizing qualified contractors. DB is performed in accordance with the IIFP QA Program, or an approved equivalent program. 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 plant DB project is generally performed by the DB contractor, but in some cases may be performed by IIFP or its contractors. The IIFP QA function ensures that evaluation and pre-approval of vendor qualification is performed or increased inspection requirements are implemented where the procurement involves items-relied-on-for-safety (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 Quality Assurance Program. Likewise, the IIFP QA function ensures reviews of vendor performance in accordance with the IIFP QAP, where the procurement systems, structures and components involve IROFS as identified by the IIFP QAP procedures.
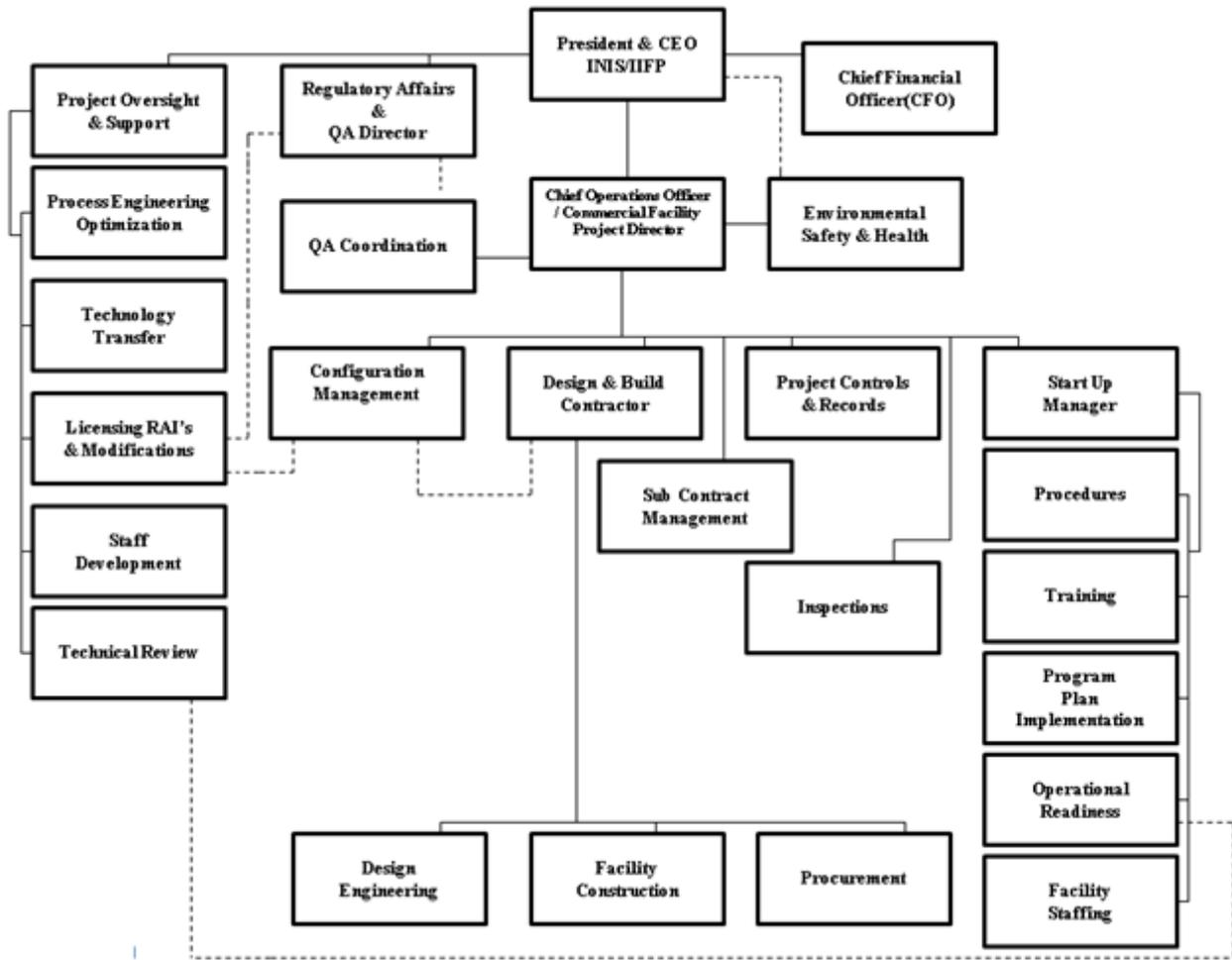
Figure A-1 IIFP Organization during Design and Construction

The IIFP QA Coordinator is responsible for ensuring compliance of the IIFP QA Program Plan (QAPP) and procedures. The QA Coordinator is responsible for verifying compliance to the QA Program during design and construction of the IIFP facility. The QA Coordinator reviews the DB contractor qualified QA programs in accordance with the IIFP QAPP. Approval of vendor, DB contractor and sub-contractor QA programs, where required, shall be obtained prior to commencing with the DB and procurement work activities.

A.1.1.2 Operating Organization QA Responsibilities

Once the operating organization is established and the project enters into the operations start-up mode, the IIFP Chief Executive Officer/Plant Manager (COO/PM) has the overall responsibility for implementation of the QA policies and programs. The COO/PM reports to the INIS President/CEO.

The IIFP Plant QA Coordinator reports then to the COO/PM directly and also has a QA reporting matrix responsibility to the INIS Regulatory Affairs and Quality Director who reports directly to the INIS President. See Figure A-2, IIFP Facility Operating Organization.

Management responsibilities and qualifications are provided in the IIFP license application Chapter 2, Organization and Administration.

The IIFP Plant QA Coordinator is responsible for maintaining and complying with the corporate quality management system. The INIS President/CEO is ultimately responsible for approval of company policies that could impact the quality system. The President/CEO may delegate approval authority to the Regulatory Affairs and Quality Director or the IIFP COO/Plant Manager. The responsibility for performing specific activities is assigned within the individual procedures or work instructions.

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

Figure A-2 IIFP Facility Operating Organization

managers are required to address identified quality problems, 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 COO/Plant Manager, where

necessary.

The QA Coordinator 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 correc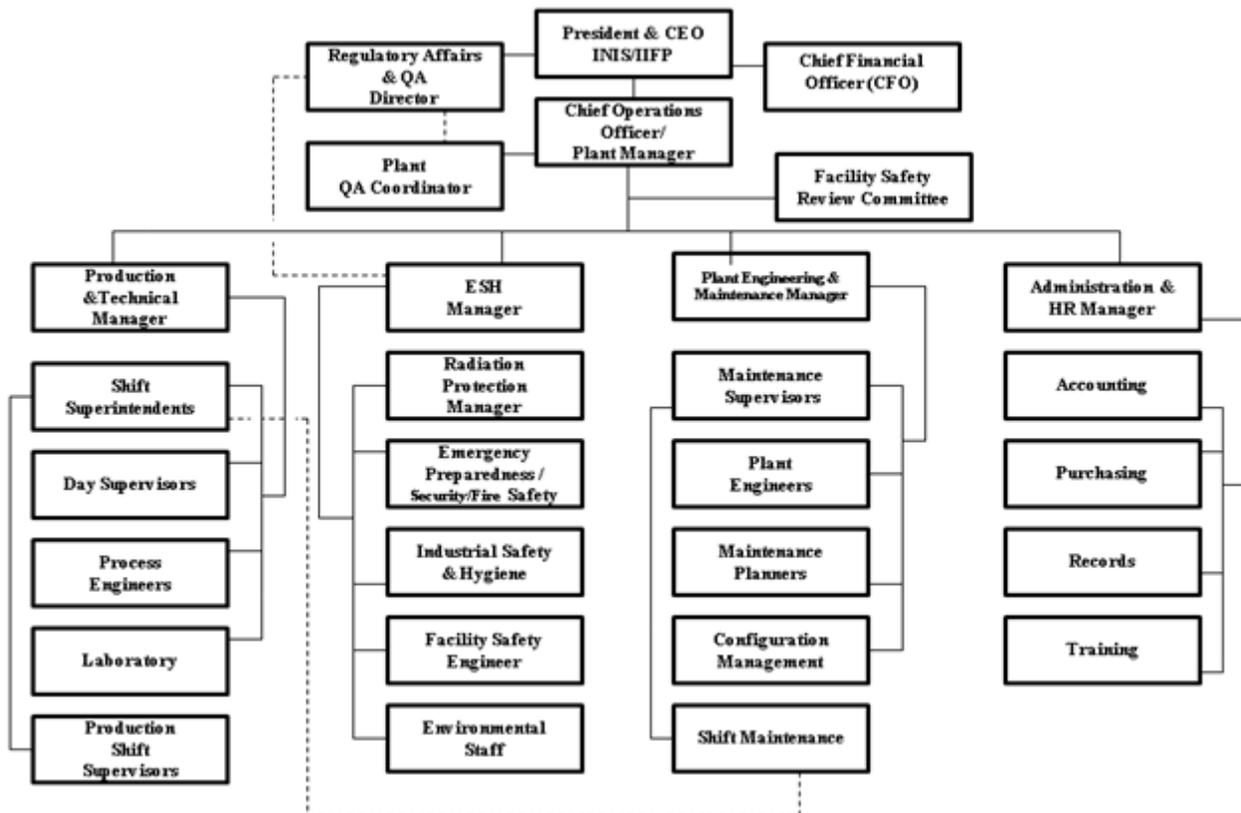tive action are completed and verified. While providing oversight for the corrective action, the QA Coordinator will not be directly involved in the affected project or production performance assignments.

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 Coordinator 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 and QA plan description.

A.1.1.3 Quality Assurance Practices

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

The Production and Technical Manager are responsible for ensuring that:

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

The Production Manager, Technical Manager, or the QA Coordinator serves as the point of contact between IIFP and the customer for quality-related matters.

The Production/Technical Manager (or during design and construction, the COO/CFPD, ESH Manager and QA Coordinator have the responsibility 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 safety or quality concerns.

The QA Coordinator 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.2.1 Quality Assurance Program

A.2.1.1 Program Applicability

The IIFP QA Program (QAP) and corporate quality management system 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 using a graded approach, in accordance with the applicable contract, and at the earliest time consistent with the project schedule. The establishment of the program shall include consideration of the technical aspects of the activities affecting quality.

This QA Program sets forth the minimum requirements for those items, activities, and services within the scope of this QAP description. This QAP is established, maintained, and executed as described in this document. Project-specific quality standards/requirements not addressed in this Program description may be implemented in supplementary manuals, procedures, and instructions.

A.2.1.2 Program Basis

INIS is using ISO 9001 in the existing Quality Management System (QMS) and is planning to have the corporate office and Idaho production facility achieve ISO 9001 certification by mid-year 2010. Corporate processes and procedures for the IIFP de-conversion facility will be incorporated into the IIFP quality program.

IIFP will also incorporate a graded approach into the Quality Assurance Program that will ensure compliance with necessary regulatory requirements in 10 CFR Part 40 (CFR, 2009). The QA Program graded levels are applied based on an item's importance to safety. This approach provides the level of rigor necessary to satisfy the requirements of assuring safety and reliability of items-relied-on-for-safety (IROFS) that have been identified the IIFP license application Integrated Safety Analysis (ISA) Summary.

A.2.1.3 QA Program Implementation

This QA Program is implemented through 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 Integrated Safety Analysis (ISA), and 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.

Quality-related activities shall be controlled and conducted using documented procedures including instructions, drawings, process diagrams, or other appropriate documents. 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.2.1.4 Graded Application

This section describes the graded application of the IIFP QA Program.

Risk analysis reviews are performed to determine the appropriate elements and principles for assuring the necessary quality-related aspects of the facility are implemented. A risk-based quality approach is the fundamental consideration in determining what extent the requirements of 10 CFR 70 Subpart H apply. Certain activities, items, or processes may require extensive control measures while others may require only a limited degree of control. The control measures that must be included are document control, configuration management, approval level requirements, qualification and training, record keeping peer reviews surveillance audits, and assessments.

Three QA levels are established in the graded approach as defined below.

A.2.1.4.1   QA Level 1 Requirements

The QA Level 1 Requirements shall conform to the criteria established in 10 CFR 70, Subpart H (CFR, 2000).

The ISA provides the methodology utilized to establish the items relied on for safety (IROFS) listing. The IROFS are comprised of specific structures, systems and components (SSC) and administrative controls. The QA Level 1 requirements shall be applied to a single IROFS (sole IROFS) preventing or mitigating a high consequence event. All QA Program requirements are applied to QA Level 1 IROFS.

A.2.1.4.2 QA Level 2 Requirements

The QA Level 2 requirements are 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. QA Program requirements are applied to QA Level 2 IROFS using a graded approach. The QA Program graded approach is implemented through approved written procedures taking into consideration the factors delineated in section A.2.1.4 above and the following:

- Risk significance,
- Relative importance to ESH, safeguards and security,
- Applicable regulations, industry codes, and standards,
- Complexity or uniqueness of an item/activity and the environment in which it has to function,
- Quality or safety 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, and
- 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 QA Level 1 and QA Level requirements shall be described in IIFP approved documents.

A.2.1.4.3 QA Level 3 Requirements

The QA Level 3 requirements are considered to follow standard commercial practice. A documented Quality Management System including document control, system and component traceability, record keeping, and training elements are not required for QA Level 3 items

A.2.1.5 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 Quality Management System and the appropriate implementing procedures. Such indoctrination may be by formal classes, supervised on-the-job training 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 Coordinator is responsible for indoctrinating appropriate IIFP management and supervisory personnel in the basis for, objective of, and methods for assuring 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.2.1.6 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.11.1, "Control of Nonconforming Items". The severity and impact of the non-conformance shall be evaluated to determine if a corrective action must be initiated. The Corrective Action Process documented in Section A.12.1.1 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 Coordinator shall establish procedures to periodically perform a trend-analysis of non-conformances and corrective actions.

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 Production Manager and Technical Manager are responsible for managing process quality and identifying potential improvements to the Plant Manager. In project-specific training, the Production and Technical Managers shall emphasize the responsibility of each project team member to understand how their processes contribute to the success of the overall project.

A.2.1.7 Review and Assessment

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

The QA Coordinator is responsible for the performance of internal and external audits in accordance with the requirements of Section A.14.1. Audits determine the performance and effectiveness of activities required by the QMS. 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.14.1.3.5 and incorporated into plant procedures.

A.2.2   Qualification and Certification of Personnel

A.2.2.1 General

The principle objective of the training program system 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, and 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 Coordinator 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 (OJT) 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 qualifications program 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.

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 Coordinator 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 procedure for controlling work activities for maintenance and future projects after the 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 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 involved in the work and the work processes 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 the Line Managers, QA Coordinator, 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 the requirements of these QA Program requirements.

Applicable safety limits and IROFS are identified in the procedures. IIFP will utilize standardized methods for identifying, developing, approving, implementing, and controlling operating procedures. Identifying needed procedures will include consideration of ISA 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 Production and Technical Manager and the QA Coordinator and ESH Manager prior to implementation.

A.3.1 Design Control

A.3.1.1 General

The design control provisions contained in this QA Program Description are applicable during design and construction of the IIFP Facility for design 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 as-built the 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. The design control provisions contained in this QA Program are applicable to design activities during the design, construction, and operation of the facility. Reconstitution of the design is not required; however if a deviation to the design is discovered, engineering shall resolve the deviation and establish as-built the drawings, if necessary.

A.3.1.2 Responsibilities

The COO/CFPD, with appropriate delegation of authorities to the DB Design Engineering Manager, is the design authority having responsibility for implementation and execution of the design control system in accordance with this section for the IIFP during the design, engineering and construction phase as defined above in A.3.1.1.

The Plant Engineering and Maintenance Manager is the plant 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 plant changes are tested and for assuring that personnel affected by the change are adequately trained as described in procedures.

A.3.1.3 Requirements

A.3.1.3.1   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.3.1.3.2   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.3.1.3.3 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.3.1.3.4 Design Verification

Design requirements and associated design basis are established and maintained by the design engineering organization (designated by the Configuration Manager and approved by the COO/CFPD) during the design/construction phase and designated/approved by the Plant Engineering/Maintenance 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, and the design requirements are derived from the design basis. Design requirements are documented in design requirement documents i.e. calculations, safety analysis, design criteria, engineering drawings, system descriptions, technical documents, and specifications. The design requirements and basis of 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 QA Level 1 or Level 2 (see Section 11.8). The associated design documents are subject to interdisciplinary reviews and design verification. Analyses constituting the integrated safety analysis of the design basis 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. 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 Configuration Manager ensures that the designated engineering organization documents the entire review process in accordance

with approved procedures. These procedures include provisions to assure that appropriate quality standards are specified in design documents, including quantitative or qualitative acceptance criteria. The QA Coordinator conducts audits on the design control process using independent technically qualified individuals to augment the QA audit team.

During the check and review, emphasis is placed on assuring conformance with applicable codes, standards and license application design commitments. The individuals in engineering assigned to perform the check and review of a document 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 check and review. Model tests, when required to prove the adequacy of a concept or a design, are reviewed and approved by the responsible qualified individual. Testing used for design verification shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. The tests used for design verification must meet all the design requirements.

Qualified individuals other than those who performed the design may be from the same organization 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 document 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 Coordinator 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.3.1.3.5   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:

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

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 Plant Engineering and Maintenance Manager, Quality coordinator, and EHS Manager.

A.3.1.3.6   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.3.1.3.7   Design Documentation and Records

Design documentation and records that provide evidence that the design and design verification processes were performed in accordance with the 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 control system 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/systems descriptions prior to implementing the change.

A.4.1 Procurement Document Control

A.4.1.1 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 QA Level 1 and QA level 2 control items.. This system also establishes provisions for the preparation, review, approval, and control of procurement documents, including changes.

A.4.1.2 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.3.1 of this QA Program Description. 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.4.1.3 Requirements

A.4.1.3.1 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 QA level 1 and QA level 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 QA level 1 and QA level 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 this 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.4.1.3.2 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.5.1 Instructions, Procedures, and Drawings

A.5.1.1 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.5.1.2 Responsibilities

The Training/Procedures Support Manager or Quality Coordinator is responsible to review, the approval and use of procedures and instructions in accordance with the management oversight requirements defined in this section.

CEO/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.5.1.3 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.6.1 Document Control and Records Management

A.6.1.1 General

A document control and records management system is established to maintain policy, procedure, work instruction and any other documentation which relates to the activities and services provided by IIFP. This system ensures that documents and records 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.

A.6.1.2 Responsibilities

The Records Manager has the overall responsibility for the development and implementation of the records management and document control system.

Managers are responsible for (1) identifying documents to be included in the controlled document 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.6.1.3 Requirements for Document Control

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, and
- 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 is specified in procedures.

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

A.6.1.4 Requirements for Records Management

The records management program provides direction for the handling, transmittal, storage, and retrieval of records. Records media may include microfilm, electronic, or hard copy. Records shall be categorized and handled in accordance with their relative importance to safety and storage needs. Special provisions shall be made for handling contaminated records and ensuring their inclusion in the program. This program will be implemented through procedures that provide guidance for the following elements:

- Documents designated to become records shall be legible, accurate, complete, and contain an appropriate level of detail commensurate with the work being performed and the information required for that type of record.
- Records clearly and specifically identify the items or activities to which they apply.
- Methods shall be specified for indexing, filing, and locating records within the record system to ensure the records can be retrieved in a timely manner.
- Records retention times shall be specified in a retention schedule. The process for disposition of records that have reached the end of their retention lifetime will be specified by procedures and conforms to applicable requirements.
- Corrections to records shall be approved by the organization which created the record unless other organizations are specifically designated.
- Controls shall be established for protection of records from deterioration, loss, damage, theft, tampering, and/or unauthorized access for the life of the record.
- 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.
- Records management requirements for goods or services procured from outside suppliers shall be specified in the applicable procurement documents.

A.7.1 Control of Purchased Items and Services

A.7.1.1 General

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

A.7.1.2 Responsibilities

The QA Coordinator 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 Coordinator provides support functions such as source verification or surveillance, receipt inspections, installation inspections, and review of procurement documents during receipt inspections. The QA Coordinator is also responsible for developing and implementing procedures which meet the requirements of this section of the QA Program Description.

Engineering is responsible for assisting the QA Coordinator by performing evaluations of supplier technical capabilities and determining the methods of acceptance to be applied to purchased items and services. Engineering or Quality Assurance is responsible for the approval of dispositions and technical evaluations for supplier-generated non-conformances 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.7.1.3 Requirements

A.7.1.3.1 Procurement Planning

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

A.7.1.3.2 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 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.7.1.3.3   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.

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, and
- 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.8.1 Identification and Control of Materials, Parts, And Components

A.8.1.1 General

A system is established for the identification and control of IROFS items within the scope of the QA Program Description. This system establishes the requirements for the identification and control of such items and associated materials, parts, spare parts, components, and sub-assemblies.

A.8.1.2 Responsibilities

Engineering 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 Coordinator 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 Manager is responsible for receipt, delivery, storage, traceability, identification, and control of materials.

A.8.1.3 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 shall be maintained on items or in documents traceable to them in a manner which ensures that identification is established and maintained.
- 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.
- Productions of an item at any stage from initial receipt through fabrication, installation, repair, modifications, and use can be 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.
- 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.
- Train 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 install.
- Perform audits, inspection and surveillances, to ensure compliance to established procedures.
- Maintain as quality records in accordance with design, procurement and process documents establishing and attesting to proper identification of IIFP furnished items.

A.9.1 Inspection

A.9.1.1 General

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

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

A.9.1.2 Responsibilities

The QA Coordinator 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 QA Program Description are met.

A.9.1.3 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, and
- references to information on action taken in connection with non-conformances

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, methods, and acceptance criteria and provide 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 assure 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 non-conformances 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 required 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 QA Program Description or the ISA. 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; and inspection requirements established by the Plant Engineering & Maintenance Manager.

A.10.1   Control of Measuring and Test Equipment

A.10.1.1   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 measurement, tests, and calibration activities are of the proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements.

A.10.1.2   Responsibilities

The Plant Engineering and Maintenance Manager has the overall responsibility for the calibration control system for M&TE.

Managers are responsible for implementation of the calibration control system for M&TE under their cognizance.

A.10.1.3   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.

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

A.11.1   Control of Non-Conforming Items

A.11.1.1   General

A system is established for the control of nonconforming materials and related activities and services within the scope of the Quality System 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.

A.11.1.2   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 Coordinator is responsible for implementation of the nonconformance control system for materials that do not meet the established specifications or technical requirements.

The Plant Engineering, ESH, and Quality organizations are responsible for providing documented technical justification for the acceptability of disposition- nonconforming items (use-as-is or repair) and is also responsible for applying the design control measures of Section 3.1 of this QA Program Description to those non-conformances. Engineering ensures that as-built records reflect the accepted change.

A.11.1.3   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.

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

A.12.1 Corrective Action

A.12.1.1 General

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

A.12.1.2   Responsibilities

The QA Coordinator is responsible for maintenance, and implementation of the corrective action system. This manager is also responsible for verifying that adverse conditions are reviewed and assessed by appropriate levels of management.

Managers are responsible for evaluating and performing assigned corrective actions in a timely manner in accordance with procedures that implement the requirements of this section of the QA Program Description. They are also responsible for assuring the identification and documentation of conditions adverse to quality in accordance with applicable procedures.

A.12.1.3   Requirements

Conditions adverse to quality are promptly identified and corrected as soon as practical.

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 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; follow-up action is taken to verify implementation of the corrective action.

Non-conformances 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 a corrective action 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 Coordinator is responsible for maintaining an orderly file of all audit findings and non-conformances related to products and services. Each area manager is responsible to determine the cause of each deficiency, document it as a non-conformance 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 Coordinator, who shall be responsible for ensuring that as a minimum the requirements of the customer and of the procedure are met. The QA Coordinator 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 Coordinator shall review and evaluate corrective actions effectiveness. This evaluation will encompass the actions taken, and validation data analysis. The affected management, including the COO/Plant Manager when appropriate, shall be advised of the trends and if additional remedial action is needed.

A.13.1   Quality Assurance Records

A.13.1.1   General

A records management system is established and related activities and services are defined within the scope the QA Program. The records management system provides measures to control quality assurance records.

A.13.1.2   Responsibilities

Records Management/Document Control is responsible for the maintenance, and implementation of the records control system 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 Manager for retention consistent with governing procedures meeting the requirements established the QA Program.

A.13.1.3   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.

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.

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.14.1   Audits

A.14.1.1   General

An audit system is established for activities and services within the scope of this QA Program. This system establishes planned and periodic audits to verify the compliance and the effectiveness of this 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 assure 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 QA Program and procurement requirements. This may include verification that the suppliers and contractors similarly review and audit the quality assurance programs of their suppliers as required depending on the Quality Level of the product or service.

A.14.1.2   Responsibilities

The QA Coordinator 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.14.1.3   Requirements

A.14.1.3.1   Training and Qualification

Audit personnel shall be properly training 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.14.1.3.2   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 assure 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 audit if they perform work in accordance with IIFP QA Program and procedures under IIFP supervision. External audit is required for suppliers of services based on supplier quality certification program, established quality performance parameters, and the Quality Level of the service provided.

A.14.1.3.3   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.14.1.3.4   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 including 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.14.1.3.5   Reporting

The audit report is signed by the audit team leader. The report should be issued generally within 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.14.1.3.6 Response and Follow-Up Action

Management of the audited organization or activity shall investigate adverse audit findings, identify and schedule corrective action, identify and schedule measures to prevent recurrence, and 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.14.1.3.7 Records

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

A.15.0 References

CFR, 2000. 10 Code of Federal Regulations, 70, Subpart H, Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material, 2000.

CFR, 2009. Title 10 Code of Federal Regulations, Part 40, Domestic Licensing of Source Material, 2009.