International Isotopes Inc.

March 15, 2011

ATTN: Document-Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Submittal of Responses to Requests for Additional Information (RAI) TAC L32739.

To Whom it May Concern,

The following document is provided as a response to the US Nuclear Regulatory Commission RAIs pertaining to the International Isotopes Fluorine Products Inc. December 30, 2009 application to license a depleted uranium hexafluoride de-conversion and fluorine extraction process facility.

(1) Organization & Administration

Please contact me by phone at 208 524-5300 or email at jjmiller@intisoid.com if you have any questions regarding this letter or require additional information.

Sincerely,

John J. Miller, CHP
Radiation Safety Officer

JJM-2011-18

Enclosure as Stated

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ORGANIZATION AND ADMINISTRATION

OA-1 Correct the typo in the first sentence of LA Section 2.1.2. This sentence indicates that the IIFP management owns and operates the plant.

RESPONSE: Chapter 2 of the IIFP License Application, Revision A has been removed and will be replaced with the Revision B of Chapter 2 in its entirety. In the revision the wording is removed that indicates IIFP management is the owner and operator of the plant.

License Documentation Impact: The revised LA, Chapter 2 (Revision B) Section 2.1.2, first paragraph will read as follows:

~~As the owner and operator of the plant,~~ IIFP management is responsible with delegated authority from the INIS President/CEO for the design, engineering, construction, startup, operation, maintenance, modifications, testing and final facility decommissioning.

ORGANIZATION AND ADMINISTRATION

OA-2 The acronym Environmental Safety and Health (ESH) is used on LA Page 31 before it is defined on LA Page 67. Ensure that ESH is defined at its first use.

RESPONSE: The acronym ESH will be defined at its first occurrence in Section 1.1.2.2, subheading Process Offices/Laboratory of the IIFP License Application

License Documentation Impact: Section 1.1.2.2, subheading "Process Offices/Laboratory" of the IIFP License Application (LA) Chapter 1 will be revised to clarify the subheading title and to define the first occurrence of the acronym for ESH and to read as follows:

Process Offices~~/~~ and Laboratory

The Process Office Building is located adjacent to, and north of the DUF_4 equipment access pad. This building contains the offices for the engineering, technical, Environmental, Safety and Health (ESH) and plant management ~~production~~ supervisory staff. The north side of this building contains the Laboratory that is furnished with work benches, equipment, analytical instrumentation, fume hoods, containment devices and exhaust systems with vent streams exiting to an outdoor scrubber on a containment pad just east of the Laboratory area. The Laboratory area provides areas that receive, prepare, and store various samples as follows:

- Radiological Protection (Health Physics)~~Health Physics~~ Lab for calibrating instrumentation and counting samples,
- Chemical Laboratory for the analyses of process and product samples, and
- Environmental Monitoring Lab for the process of environmental/regulatory analysis.

ORGANIZATION AND ADMINISTRATION

OA-3. The last sentence on LA Page 2-4 indicates that the plant organization is responsible for system maintenance. Clarify the intent of this sentence and define in the application what is meant by the phrase "plant organization."

RESPONSE: After turnover from the Design and Construction organization structure shown in Figure 2-1, the plant organization transitions to the Plant Operation Organization as shown in Figure 2-2. The fourth paragraph in which the subject sentence appears will be rewritten to clarify the intent of the plant organization during this turnover.

License Documentation Impact: Remove Chapter 2 of the IIFP License Application, Revision A and insert the Revision B of Chapter 2 in its entirety. The 4th paragraph of Section 2.1.3 of the License Application Chapter 2 Revision B will read as follows:

When construction of the ~~plant~~ facility and process systems is complete, the equipment and systems undergo acceptance testing as in accordance with the QA Program and approved written procedures. Following successful completion of ~~acceptance~~ integrated equipment and systems testing and acceptance, the responsibilities for managing the facility equipment and systems are transferred from the Design and Construction ~~DB~~O~~o~~rganization to the Plant Operation Organization as shown in Figure 2-2 ~~operating organization~~ by means of a transition plan. The COO~~/CFPD~~ and ~~the Startup~~ Plant Manager ensure the development of a transition plan and an orderly, safe and thorough turnover to the IIFP ~~COO/PM, Plant Engineering/Maintenance Manager and Operation/Technical Manager functions~~ Plant Operation Organization. The turnover includes the physical systems, corresponding design information, records of the facility, and as-built drawings. Following turnover, the P~~p~~lant Operation O~~o~~rganization is responsible for facility safe operations, ~~system~~ maintenance, configuration management (CM) and facility safety reviews of modifications affecting the as-built plant.

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OA-4. State whether the Quality Assurance (QA) Director mentioned in LA Section 2.1.2 is a member of the IIFP organization or the International Isotopes Inc. (INIS) organization or both.

RESPONSE: Section 2.1.2 discusses the design and construction organization and Figure 2-1 shows the design and construction organizational structure for that organization. Figure 2-1 has been revised to eliminate the matrix organization, particularly for the QA and ESH functions, to show both a Corporate ESH Manager and a Corporate QA Manager in the INIS parent corporate organization and also an IIFP ESH Manager and an IIFP QA Manager. When the IIFP positions of IIFP ESH and QA Managers are filled, any of the IIFP Facility ESH and QA responsibilities, duties and authorities that were temporarily being performed by INIS Corporate staff will transfer to the IIFP ESH and QA Managers. (identified in Revision A of the LA as the QA Coordinator) for the IIFP Facility. Also see RAI OA-7A.

License Documentation Impact: Remove Chapter 2 of the IIFP License Application, Revision A and insert the Revision B of Chapter 2 in its entirety. Figure 2-1 of the License Application is shown in the License Documentation Impact for response to RAI OA-7A and on the attached rewrite (Revision B) of Chapter 2, "Organization and Administration." The supporting text for Section 2.1.2 (new 7th paragraph) will be rewritten as follows:

As shown in Figure 2-1, the COO~~/CFPD~~ is responsible, with delegated commensurate authority from the IIFP President, for managing the administration, ESH, QA, ~~design,~~ engineering, and training. The COO is also responsible for overseeing the supporting contractor functions during the licensing, design and construction~~, initial startup, and procurement activities~~ of the IIFP Facility. Once the IIFP Engineering Manager is hired, the COO will delegate authority to the Engineering Manager for providing day-to-day oversight of the Design and Build Contractor and ensuring professional and/or contractor support is in place to perform any required Integrated Safety Analysis and licensing documentation during the design and construction of the IIFP Facility. Until the Engineering Manager position is filled, the COO (or the IIFP President if the COO position is not yet filled) carries out these Engineering Manager responsibilities. ~~The IIFP QA Coordinator and ESH Manager report to and support the COO/CFPD.~~ The INIS parent company will provide the QA and ESH Management support to the IIFP COO during the licensing and design phases of the project. Prior to start of construction activities IIFP will establish full time IIFP Quality Assurance and ESH managers for the facility When the IIFP positions of IIFP ESH and QA Managers are filled, any of the IIFP Facility ESH and QA responsibilities, duties and authorities that were temporarily being performed by INIS Corporate staff will transfer to the IIFP ESH and QA Managers.~~The QA Coordinator also has a matrix reporting relationship to the corporate Regulatory Affairs/QA Director. During the DB phase, the ESH Manager has a matrix reporting relationship to the President/ CEO. These dual reporting relationships for the QA and ESH functions facilitate objective audit, review, advisory and control activities.~~

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OA-5. The last sentence of the second full paragraph of LA Section 2.1.3 states, "During the design and construction and the transition periods, both the ESH Manager and QA Coordinator have the responsibility and authority to elevate and report any ESH or QA unresolved concern to the corporate Regulatory Affairs/QA Director or directly to the INIS/IIFP President/Chief Executive Officer (CEO)." Add an additional commitment that all ESH and QA issues will be followed through to resolution and documented.

RESPONSE: The stated commitment will be added to the second paragraph of Section 2.1.3 of the License Application

License Documentation Impact: Remove Chapter 2 of the IIFP License Application, Revision A and insert the Revision B of Chapter 2 in its entirety. The second paragraph of Section 2.1.3 of the License Application described the organizational relationship for ESH and QA functions during the transition from the design and construction phase to the operations phase of the IIFP Facility (See also RAI OA-6A). The 2nd paragraph of Section 2.1.3 on the attached rewrite (Revision B) has been rewritten as follows:

During this transition, the IIFP plant ESH and QA Managers ~~continues to~~ report to the COO/~~CFPD~~ for ESH and QA matters related to design and construction. ~~As the COO/CFPD role changes to the COO/PM, the ESH Manager transitions to directly reporting to the IIFP COO/PM on ESH matters for the startup operations. The ESH Manager who has been reporting in a matrix role to the President/CEO now changes to reporting in the matrix role to the Regulatory Affairs/Quality Director (RAQD). The IIFP QA Coordinator likewise reports to the COO/CFPD during the design and construction stage, then transitions to reporting to the IIFP COO/PM. During the design and construction and the transition periods,~~ B~~b~~oth the ESH ~~Manager~~ and QA ~~Coordinator~~ Managers have the~~responsibility and~~ authority to elevate and report any ESH or QA unresolved concern to the IIFP President. ~~and to corporate Regulatory Affairs/QA Director, respectively, or directly to the INIS/IIFP President/CEO~~ The IIFP President is ultimately responsible for ESH, QA, and other safety-related issues. All ESH and QA concerns will be followed through to resolution and documented.

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OA-6. The management structure within the IIFP should be a standalone organization so that the reporting structure is within the IIFP. Consistent with NUREG-1520, Section 2.4.3(1) & (2), provide the following information:

A. The third paragraph on LA Page 2-6 indicates that the ESH and QA have authority and responsibility to contact the INIS President/CEO (rather than the IIFP President/CEO) directly, under certain circumstances. The INIS President/CEO position appears to be outside the organizational structure of the IIFP. Consistent with NUREG-1520, 2.4.3(1) and (2), revise the reporting requirements so that the ESH and QA report to an individual within the corporate structure.

Section 2.1.4 indicates that the Chief Operations Officer (COO)/PM (Plant Manager) reports to the INIS President/CEO. This individual appears to be outside the IIFP corporate structure. Consistent with NUREG-1520, Section 2.4.3(2), revise the text in 2.1.4 to indicate that the COO/Plant Manager reports to the IIFP President/CEO.

RESPONSE: The organization is structured as a stand-alone organization with the IIFP President responsible for the entire organization and reporting to the parent corporation INIS Present/CEO shown as Figure 2-2. See RAI OA-7A for revised figure.

The fifth paragraph of Section 2.1.4 of the License Application has been removed and the reporting requirements. Eliminating the matrix reporting relationship for the QA and ESH functions has been addressed in paragraph two of the IIFP LA Section 2.1.3. Both QA and ESH Managers report directly to the IIFP COO. See license documentation impact in RAI OA-5.

Paragraph two of Section 2.1.4 has been modified to clarify and that the COO reports directly to the IIFP President. Additionally, a Plant Manager is established reporting to the COO. The organizational charts are shown in the License Documentation Impact for RAI OA-7A.

License Documentation Impact: Remove Chapter 2 of the IIFP License Application, Revision A and insert the Revision B of Chapter 2 in its entirety. The organizational chart for the IIFP Plant Operation Organization has been revised as shown in the License Documentation Impact for RAI OA-7A. Paragraph 5 of Section 2.1.4 has been removed in the attached rewrite (Revision B) of Chapter 2 and paragraph 2, Section 2.1.3 of the LA is revised as shown in the License Documentation Impact shown in response to RAI OA-5.

License Documentation Impact: The attached rewrite (Revision B) of Chapter 2 of the License Application explains the responsibilities of the parent corporate INIS and those of the subsidiary entity IIFP with respect to the IIFP Facility. The subject paragraph of Section 2.1.4 (2nd paragraph) has been rewritten to define that the COO reports to the IIFP President as follows:

The Chief Operations Officer~~/Plant Manager~~ (COO~~/PM~~) reports directly to the IIFP President who, in turn reports to the INIS President/ CEO. The COO ~~and~~ is responsible with delegated authority from the IIFP President for the overall operation, maintenance, administration and regulatory compliance of the IIFP FEP/DUP Facility~~commercial facility~~. In the discharge of these responsibilities, the COO~~/PM~~ leads the activities of the plant, including the following functions:

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- Quality Assurance,
- Plant Management (Operations/Technical),
- ~~Plant~~ Engineering~~/~~ and Maintenance,
- Administration~~/Human Resources~~,
- Training,
- Environmental, Safety and Health, and the
- Facility Safety Review Committee (FSRC)/ALARA Committee

OA-6

B. The President/CEO is sometimes referred to as a member of the INIS and sometimes a member of IIFP. The application indicates he is a member of both. Since this application is for IIFP, ensure references to the President/CEO are consistent, e.g., a member of IIFP or IIFP/INIS.

RESPONSE: The organization chart has been revised to show both an INIS President and an IIFP President for the Plant Operation Organization of the IIFP. The new position of the IIFP President is described in Section 2.2.3, in a rewrite of Chapter 2 of the License Application (Revision B). The key management position of the INIS President is still described in Section 2.2.1.

License Documentation Impact: Remove Chapter 2 of the IIFP License Application, Revision A and insert the Revision B of Chapter 2 in its entirety. The organizational chart for the IIFP Plant Operation Organization has been revised as shown in Figure 2-2 in the attached rewrite (Revision B) of Chapter 2 of the License Application. The chart is also shown in the License Documentation Impact for RAI OA-7A. Section 2.2.1 describes the INIS President/CEO position and Section 2.2.3 describes the IIFP President position as follows:

2.2.1 INIS/~~IIFP~~ President and Chief Executive Officer

The INIS President and Chief Executive Officer (CEO) reports to, and receives policy direction from, the INIS Board of Directors. The President/CEO is responsible for establishing policies and providing overall direction and management of ~~IIFP~~ all corporate activities. The President/CEO also ensures that policies for the ESH and QA Programs are maintained and transmitted to all levels of management and implemented appropriately through approved written procedures. The President/CEO ~~of INIS/IIFP~~ shall have a bachelor's degree in a scientific field or business. At least eight years of work experience is required with the proven ability in management of a commercial chemical, radiological, or nuclear related facility, overall leadership qualities and the commitment to safety, quality and regulatory compliance.

2.2.3 IIFP President

The IIFP President reports directly to the INIS President/CEO and is responsible for the establishing policies and providing overall direction and management of all IIFP activities. The President also ensures that policies for the ESH and QA Programs are maintained and transmitted to all levels of IIFP management and implemented appropriately through approved written procedures. The IIFP President shall have as a minimum a bachelor's degree in a scientific field or business. At least five years of work experience is required with demonstrated proficiency in management of a commercial chemical, radiological, or nuclear related facility, overall leadership qualities, and a commitment to safety, quality, and regulatory compliance.

License Documentation Impact: The second full paragraph of Chapter 2, introductory section of the License Application will be revised to add a clarifying statement to show who is ultimately responsible for IIFP actions and will read of follows:

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~~Once the facility (plant) construction is completed,~~ T~~t~~he IIFP Chief Operations Officer/~~Plant Manager~~ (COO/~~PM~~) is delegated the authority by the IIFP President with the approval of the INIS President/CEO ~~has overall~~for the responsibilities~~y~~ ~~for~~ the IIFP Facility design, construction, startup and operations~~,~~ of the facility as well as safety and regulatory compliance~~ of the New Mexico plant site~~. The IIFP policy is to ensure and maintain a safe work place for its employees, to protect the public relative to the operation of its plant, and to assure operational compliance with the terms and conditions of the NRC license and applicable federal, state and local regulations. The COO/~~PM~~ reports directly to the President of IIFP who in turn reports directly to the President/CEO~~ and Chief Executive Officer (CEO)~~ of International Isotopes, Inc. (INIS). The INIS President/CEO reports to the Board of Directors of INIS, and ensures corporate policies are established, and that policy direction is communicated. Even though the IIFP COO has overall the overall responsibility for safety and regulatory compliance, the IIFP President is ultimately responsible for safety, security and protection of the environment.

OA-6

C. *LA Section 2.2.3 states that the Regulatory Affairs and Quality Assurance Director (RAQD) is appointed by the INIS President/CEO. This appears to indicate that the RAQD is an INIS employee and not an IIFP employee. The section also states that the RAQD is responsible for the ESH and QA policies. Consistent with NUREG-1520, Section 2.4.3(3), state in the LA that the RAQD is an IIFP employee. Clarify the reporting relationship and management structure between RAQD, COO/Plant Manager, Quality Assurance Coordinator (QAC), and ESH.*

RESPONSE: The organizational chart for the Plant Operation Organization of the IIFP (Figure 2-2) has been revised to replace the position of the RAQD with both a Corporate QA Manager and a Corporate ESH Manager reporting to the INIS President and CEO. The responsibilities for these corporate positions are provided in Section 2.2.2.of the attached rewrite (Revision B) of the IIFP LA Chapter 2.

The IIFP President reports to the INIS President/CEO. The IIFP COO reports to the IIFP President. The IIFP Facility QA Manager (formerly QA Coordinator) and the ESH Manager each reports to the IIFP COO. The responsibilities of these positions are described in the License Application Revision B, Chapter 2 as shown below. Additionally, a Plant Manager reporting to the COO has been added to the revised Figure 2-2. See the revised Figure 2-2 in the attached rewrite of Chapter 2, Revision B of the License Application or in the License Documentation Impact for RAI OA-7A.

License Documentation Impact: Remove Chapter 2 of the IIFP License Application, Revision A and insert the Revision B of Chapter 2 in its entirety. Figure 2-2 has been revised as shown in the License Documentation Impact for RAI OA-7A or in attached rewrite of Chapter 2 of the License Application (Revision B). Section 2.2.2 has been revised in the rewrite to describe the INIS corporate ESH and QA functions. Sections 2.2.7 and 2.2.8 have been revised to describe the IIFP QA and ESH Managers positions respectively. Section 2.2.9 has been revised in the Chapter 2 rewrite (Revision B) to describe the position of Plant Manager. Sections 2.2.2, 2.2.7, 2.2.8, and 2.2.9 have been rewritten read as follows:

~~2.2.3~~ 2.2.2 ~~INIS/IIFP Regulatory Affairs and Quality Assurance Director~~INIS Corporate ESH and QA Managers

~~The Regulatory Affairs and Quality Assurance Director (RAQD) is appointed by the INIS President/CEO and is responsible for ensuring development and communication of ESH and QA policies that will ensure safe operation and meet the licenses and permit requirements. The Director is responsible for establishing an IIFP system that will identify and evaluate potential or new regulatory requirements to determine applicability to the IIFP FEP/DUP Facility. The RAQD is also responsible for ensuring that effective audit, feedback, investigative and corrective action programs are in place both at the IIFP corporate and plant levels that will provide prompt response in preventing and correcting ESH related incidents. The RAQD provides advice, oversight and regulatory consultation in assisting the IIFP COO/PM, ESH Manager and the QA Coordinator in matters of regulatory compliance and ESH and QA programs objectives. The Regulatory Affairs and Quality Assurance Director shall have, as a minimum, a bachelor degree in an engineering or scientific field and five years of related experience in chemical, radiological or nuclear facilities.~~

The INIS Corporate ESH and QA Managers are appointed by the INIS President/CEO and are responsible for ensuring development and communication of the parent corporate ESH and QA policies that will ensure safe operation and meet the licenses, permit, and product requirements.

During the early stages of the IIFP project, the INIS Corporate ESH and QA Managers temporarily have duties that will later be fulfilled by the IIFP ESH and QA Managers, respectively. When the positions of IIFP ESH and QA Managers are filled, any of the IIFP Facility ESH and QA responsibilities, duties and authorities that were temporarily being performed by INIS Corporate staff will transfer to the IIFP ESH and QA Managers.

The Corporate ESH Manager is responsible for initially establishing an IIFP system that will identify and evaluate potential or new regulatory requirements applicable to the IIFP FEP/DUP Facility. During the design and construction stages, the ESH Manager ensures that environmental technical and licensing support, as requested by the COO or IIFP President, is provided. The Corporate ESH Manager also provides technical support for the federal, State and local environmental related permit application. A primary responsibility of the ESH Manager during the design/construction stage of the project is to prepare responses and interact with the NRC for Requests for Additional Information relative to the licensing review of the IIFP Environmental Report.

The Corporate ESH Manager also provides support for ensuring that effective audit, feedback, investigative and corrective action programs are in place across the parent and subsidiary corporate organizations that will provide prompt response in preventing and correcting ESH related incidents.

The Corporate QA Manager is responsible for the overall development and implementation of all aspects of the corporate Quality Assurance Program. The Corporate QA Manager also provides support for ensuring the QA policies, effective audit, investigative and corrective action programs are in place across the parent and subsidiary corporate organizations that will provide prompt response in preventing and correcting Quality Assurance issues and events.

The Corporate ESH and QA Managers provide advice, oversight and consultation in assisting the IIFP COO by providing support to the IIFP QA and ESH Managers in matters of regulatory compliance and ESH and QA programs objectives.

The Corporate ESH and QA Managers shall have as a minimum a bachelor's degree in an engineering or scientific field and five years of related experience in chemical, radiological or nuclear facilities.

~~2.2.11~~2.2.7 IIFP Quality Assurance (QA) ~~Coordinator~~Manager

The IIFP Quality Assurance ~~Coordinator~~ Manager~~at the facility is appointed by~~ reports to the COO~~/PM with concurrence of the INIS RAQD. The QA Coordinator reports to the COO/PM,~~ but also has an ~~reporting and~~ interacting relationship with the ~~RAQD~~Engineering, Training, and Plant Manager,~~and~~ other IIFP facility managers, and INIS QA corporate staff, on matters of QA policies, new QA requirements, and overall QA performance. The QA ~~Coordinator~~ Manager is responsible for establishing and maintaining the IIFP QA Program. Line management and their

staff are responsible for ensuring implementation of the QA Program and compliance with the Program. The QA ~~Coordinator~~ Manager position is independent from operational and safety organizations. The ~~Coordinator~~ QA Manager has the~~responsibility and~~ authority to elevate and report any ~~ESH~~ QA unresolved ~~related~~ concerns to the IIFP President. The IIFP President is ultimately responsible for QA. The IIFP QA Manager is responsible to ensure that such QA concerns will be followed through to resolution and documentation. ~~corporate management including the INIS President/CEO~~.

The IIFP QA ~~Coordinator~~ Manager ~~also~~ ensures ~~and oversees the implementation and maintenance of the plant performance assessment and action tracking program relative to ESH and QA.~~compliance with the program elements identified in Chapter 11 of the License Application and the Quality Assurance Program Description, Appendix A of the License Application. Those elements include the QA program; qualification and certification of personnel; work control; design control; procurement document control; instructions, procedures, and drawings; document control; control of purchased items and services; identification and control of materials, parts, and components; control of special processes; test control; inspection; control of measuring and test equipment; inspection, test, and operating status; control of non-conforming items; corrective actions; and audits/assessments.

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

The QA ~~Coordinator~~ Manager shall have~~,~~ as a minimum~~,~~ a bachelor's degree in engineering, science or related field and five years of ~~quality~~ experience in the implementation of a QA Program at a chemical, radiological or nuclear facility.

2.2.~~10~~8 IIFP Environmental, Safety and Health Manager

The IIFP Environmental, Safety and Health (ESH) Manager ~~at the facility is appointed by the COO/PM with concurrence of the INIS RAQD. The ESH manager~~ reports to the IIFP COO~~/PM~~, but also has an ~~reporting and~~ interacting relationship with ~~the RAQD~~all managers on matters of ESH policies, regulatory requirements, plant safety and environmental compliance. In addition, the ESH Manager has the authority~~and responsibility~~ to elevate and report any ESH unresolved concern~~s~~ to the IIFP President. The IIFP President is ultimately responsible for ESH and other safety-related issues. The IIFP ESH Manager is responsible to ensure that such ESH concerns will be followed through to resolution and documentation. ~~to up through IIFP management, and if not resolved to continue up through parent corporate management and including the INIS President/CEO.~~

The IIFP ESH Manager has the responsibility to establish and oversee the Radiation Protection (RP), ~~Licensing, ISA,~~Industrial Hygiene and Safety, Environmental Protection, Fire Protection, and Emergency Preparedness/Security programs to ensure compliance with applicable federal, state, and local regulations and ~~laws~~requirements. Those programs are designed to ensure the health and safety of employees and the public, as well as the protection of the environment. The ESH Manager has plant shutdown authority in matters relative to ESH, and ensures through the

~~Shift Superintendent~~Plant Manager and COO that such shutdowns are implemented in a safe and orderly manner. The ESH Manager, or designee, must approve the restart of any operation shutdown by reasons of ESH matters or by the ESH function.

The ESH Manager shall have~~,~~ as a minimum~~,~~ a bachelor's degree in engineering, science or related field and five years of responsible assignments of ESH activities at chemical, radiological or nuclear facilities.

2.2.9 ~~IIFP Chief Operations Officer/~~Plant Manager

~~The IIFP Chief Operations Officer/Plant Manager (COO/PM) is appointed by the INIS President/CEO, and is the individual with the overall responsibility for safety and operational activities at the New Mexico Facility. The COO/PM reports directly to the President/CEO. The responsibilities of the COO/PM are defined by IIFP policies, procedures, and instructions. The COO/PM is ultimately responsible for safety, control of operations, and protection of employees, the environment, emergency preparedness and response, and the public and any other accident consequences as related to the plant site and operations. The COO/PM also has responsibility for regulatory compliance with the facility NRC licenses and other federal, state and local permits or licenses.~~

~~The COO/PM ensures proper selection of staff for the key positions including positions of the Facility Safety and Review Committee and ALARA and approval of positions of the ALARA radiation protection committee. The COO/PM appropriately delegates specific responsibilities for implementing ESH and QA related programs to qualified line management and area managers.~~

~~The COO/PM shall be cognizant of the safety program as applied to the overall safety of the facility and shall have the authority to enforce the shutdown of any process or building. The COO/PM will also delegate facility shutdown authority to appropriate organizations and line managers. The COO/PM must approve restart of an operation that was shut down due to safety and/or regulatory concerns.~~

The Plant Manager (PM) reports directly to the COO. The PM is responsible for implementing safe practices, procedures and activities related to the operation of the production processes, utilities, environmental protection and waste treatment systems, fire system, laboratory, and warehouses. The PM is responsible for the safe conduct and control of operations and protection of employees. The PM also has responsibility for day to day regulatory and procedural compliance associated with the facility operations. The PM is responsible for hiring and training of qualified staff and operating personnel in the Plant Management organization.

During initial startup of the facility the Plant Manager is responsible for coordinating with the Training Manager for developing safe and effective operating procedures and training program plans. The PM is responsible for staffing of the operations organization, and for ensuring operational readiness and acceptance testing plans, schedules, and documentation during startup.

The PM shall be responsible for application of the safety program to facility operations and shall have the authority to enforce the shutdown of any process or building. The PM will also delegate

facility shutdown authority to appropriate organizations and line managers. The PM must approve restart of an operation that was shut down due to safety and/or regulatory concerns.

The ~~COO~~/PM shall have~~,~~ as a minimum~~,~~ a bachelor's degree and ~~seven~~ five years of experience in chemical, radiological, or nuclear related operations. The experience shall include senior responsible assignments involving engineering or facility operations management. The ~~COO~~/PM shall be cognizant of the IIFP licensing documentation and the overall ESH requirements of the IIFP Facility.

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OA-7. The organizational structures displayed in LA Figures 2-1 and 2-2 have a complex interconnectivity ("matrix structure") which is not well defined in LA Sections 2.1.2 and 2.1.4 Consistent with NUREG-1520, Sections 2.4.3(1) and 2.4.3(2), provide the following information:

A. To demonstrate a clear, unambiguous set of management controls and communications among organizational units, reduce the complexity of LA Figures 2-1 and 2-2 or expand the explanations in 2.1.2 and 2.1.4, or both. This may involve reducing the level of detail in the figures, focusing the explanation in the text to explain the groups responsible for the "design, construction, and operation of the facility [NUREG-1520, 2.4.3(1)]," removing or explaining dual reporting relationships, making the Figures layouts easier to read, etc. Any dual reporting listed in the Figures should be explained in the text.

RESPONSE: The matrix structure has been omitted from organizational charts (Figures 2-1 and 2-2) with the corresponding dual reporting text deleted in the LA Chapter 2 Revision B rewrite of Sections 2.1.2 and 2.1.4.

License Documentation Impact: Remove Chapter 2 of the IIFP License Application, Revision A and insert the Revision B of Chapter 2 in its entirety. Sections 2.1.2 and 2.1.4 have been rewritten to address the revised organizational charts eliminating the matrix structure and the text to reflect the revised organizations. Sections 2.1.2 and 2.1.4 on the attached rewrite (Revision B) have been rewritten as shown below:

2.1.2. IIFP Design and Construction Organizational Structure

~~As the owner and operator of the plant,~~ IIFP management is responsible with delegated authority from the INIS President/CEO for the design, engineering, construction, startup, operation, maintenance, modification, testing and final facility decommissioning.

In the early stages of the project concept, INIS hired a contractor to help develop the IIFP FEP/DUP Project. The contractor has experience in uranium and fluorine technologies and related commercial operations including the environmental, safety and health (ESH) aspects. The contractor's scope of work included developing and managing early project activities and preparing a conceptual design of the plant. The contractor was also hired to prepare the NRC License Application and the Environmental Report for ~~INIS/IIFP approval and submittal~~ the project.

The facility site evaluation and selection was conducted by INIS and its experienced contractors. The selected site at Hobbs, New Mexico is described in the IIFP LA, Chapter 1.

A design and build (DB) contractor ~~is~~will be~~ing~~ contracted to perform detailed design and construction of the IIFP F~~f~~acility.

The design and build (DB) terminology is used synonymously with design and construction work as shown in Figure 2-1, "IIFP Project Design and Construction Organization."

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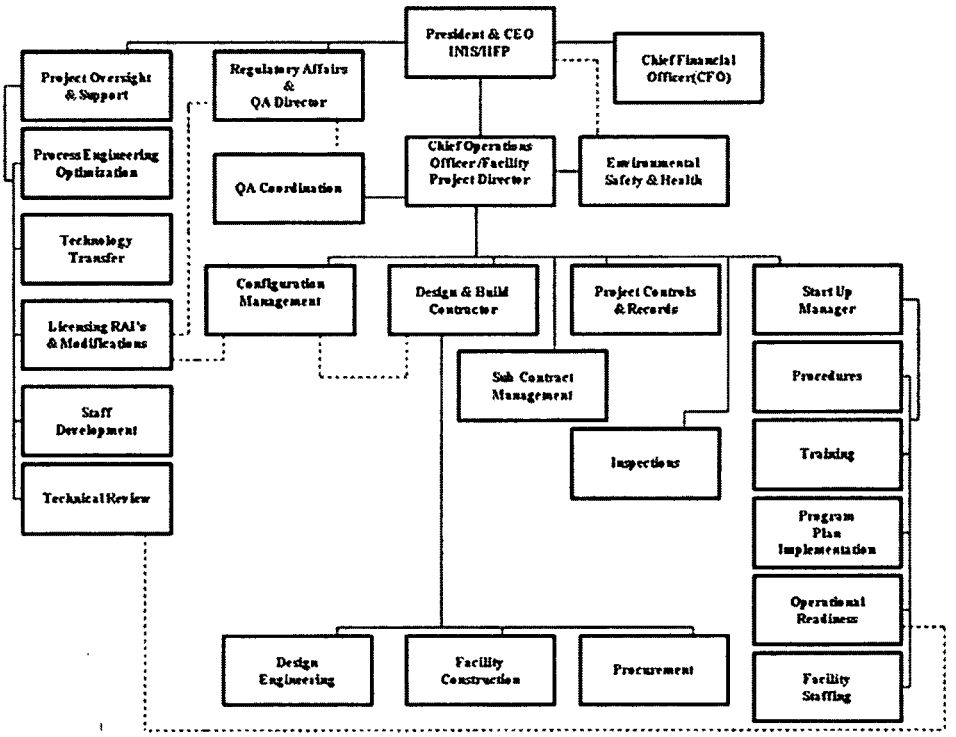
~~As the project moves from its development and licensing phase, IIFP will hire a Chief Operations Officer who will take responsibility as the Chief Operations Officer/Commercial Facility Project Director (COO/CFPD) during the DB phase of the Project. Plans are to have the COO/CFPD transition into the COO/Plant Manager role upon startup of the FEP/DUP Facility operations. Figure 2-1 presents the Project organization and lines of communications during the DB phase.~~

While the project is in licensing, design, and construction phases the President of INIS will continue to also act as the President of IIFP. One of the first positions that will be filled in the IIFP organization will be the Chief Operations Officer who will take direct responsibility and will be delegated the commensurate authority by the IIFP President for all aspects of the project including selecting additional IIFP management staff. As the project moves into construction, startup, and finally operations the COO will add appropriate management positions in order that they gain knowledge of the plant at the appropriate stages and in order to put additional staff and programs in place to support the safe operation of the facility. Figure 2-1 presents the planned project organization during the project design and construction phases of the project.

Revision A figure below is deleted and replaced with Figure 2-1 on following page



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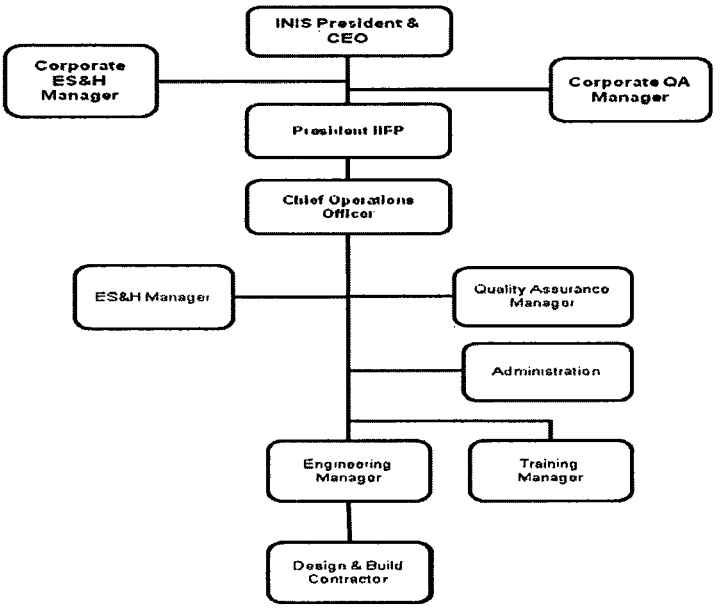


Figure 2-1 IIFP Project Design and Construction Organization

As shown in Figure 2-1, the COO~~/CFPD~~ is responsible, with delegated commensurate authority from the IIFP President, for managing the administration, ESH, QA, ~~design,~~engineering, and training. The COO is also responsible for overseeing the supporting contractor functions during the licensing, design and construction, ~~initial startup, and procurement activities~~ of the IIFP Facility. Once an IIFP Engineering Manager is hired, the COO will delegate authority to the Engineering Manager for providing the day-to-day oversight of the Design and Build Contractor and ensuring professional and contractor support is in place to perform any required Integrated Safety Analysis and licensing documentation during the design and construction of the IIFP Facility. Until the Engineering Manager position is filled, the COO (or the IIFP President if the COO position is not yet filled) carries out these Engineering Manager responsibilities. ~~The IIFP QA Coordinator and ESH Managers report to and support the COO/CFPD.~~The INIS parent company will provide the QA and ESH Management support to the IIFP COO during the licensing and design phases of the project. Prior to start of construction activities IIFP will establish full time Quality Assurance and ESH managers for the facility. When the positions of IIFP ESH and QA Managers are filled, any of the IIFP Facility ESH and QA responsibilities, duties and authorities that were temporarily being performed by INIS Corporate staff will transfer to the IIFP ESH and QA Managers.~~The QA Coordinator also has a matrix reporting relationship to the corporate Regulatory Affairs/QA Director. During the DB phase, the ESH Manager has a matrix reporting relationship to the President/ CEO. These dual reporting relationships for the QA and ESH functions facilitate objective audit, review, advisory and control activities.~~

~~During the DB phase, the engineering and construction and related documentation are completed utilizing qualified contractors. The IIFP QA function reviews the DB contractor qualified QA programs in accordance with the IIFP QA (QAP). Approval of vendor, DB contractor and sub-contractor QAPs, where required by the IIFP QA Program Plan (QAPP) (IIFP, 2009a), shall be obtained prior to commencing with the DB and procurement work activities.~~

Procurement for the commercial plant project is generally performed by the DB Ceontractor, but in some cases may be performed by IIFP or ~~its~~ subcontractors. The IIFP QA function ensures that evaluation and pre-approval of vendor qualification is performed where the procurement involves IROFS as identified in the IIFP ISA Summary. This review and pre-approval is to ensure the vendor quality assurance programs are in accordance with the requirements of the IIFP QA Program. Likewise, the ~~INIS~~ QA function ensures reviews of vendor performance in accordance with the IIFP QA Program, where the procurement involves QA Levels 1 and 2 systems, structures and components as defined by the IIFP QA Program documentation.

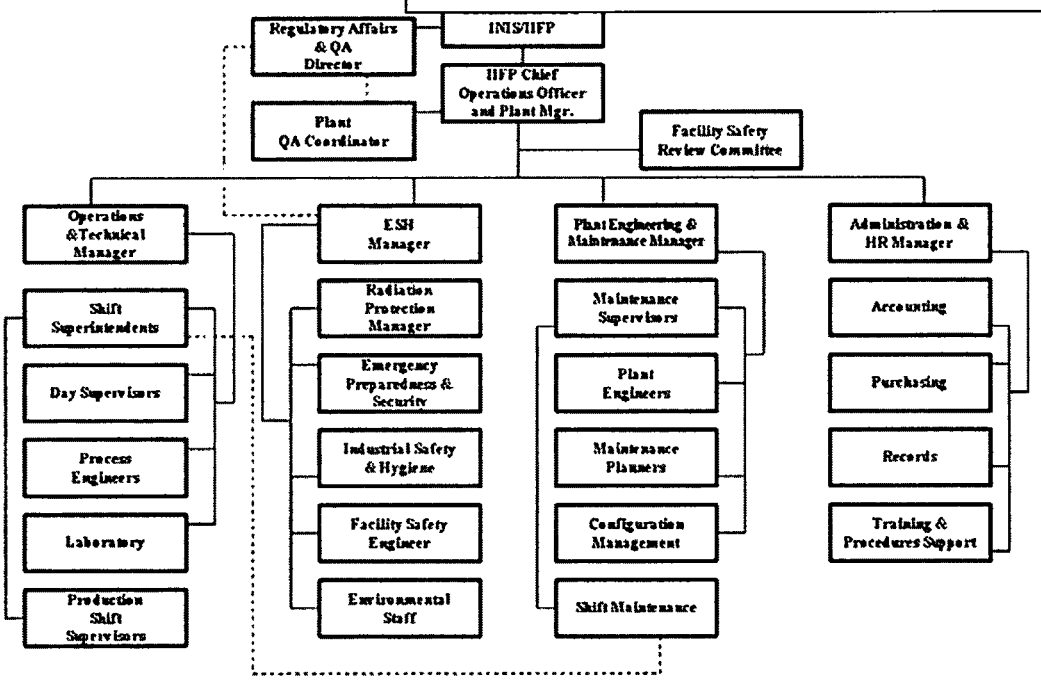
Configuration management (CM) and design modification safety reviews are discussed in Section 2.3.1.

Position descriptions of key management personnel in the design and construction organization will be accessible to affected personnel and the NRC.

2.1.4. IIFP Operations Organizational Structure

The IIFP plant operations organizational structure and lines of communication are shown in Figure 2-2. IIFP has responsibility for pre-operational testing, startup, operation, and maintenance of the FEP/DUP commercial plant

Revision A figure below is deleted and replaced with Figure 2-2 on next page



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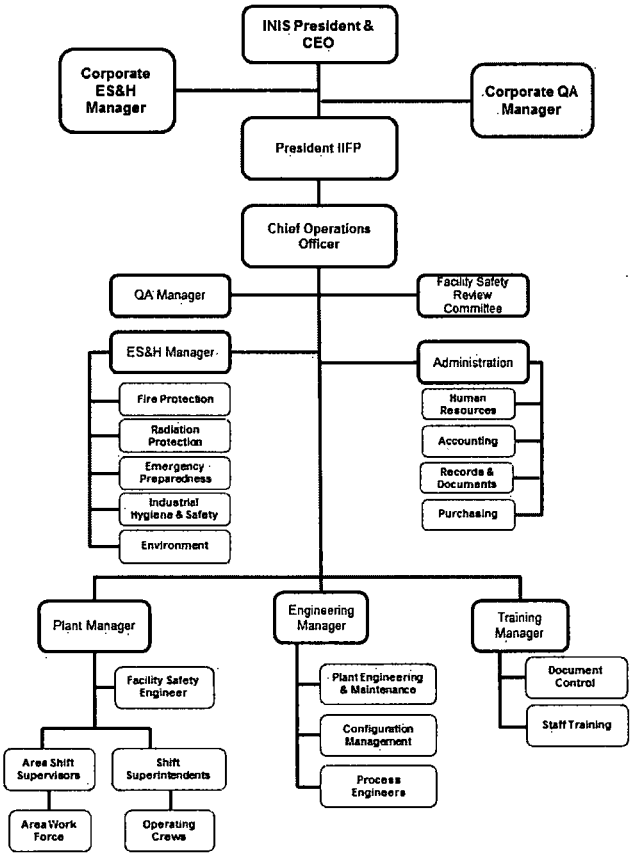

Figure 2-2 Plant Operation Organization

The Chief Operations Officer (COO/PM) reports directly to the IIFP President who, in turn reports to the INIS President/ CEO. The COO is responsible with delegated authority from the IIFP President for the overall operation, maintenance, administration and regulatory compliance of the IIFP FEP/DUP ~~commercial~~ Ffacility. In the discharge of these responsibilities, the COO/~~PM~~ leads the activities of the project including the following functions:

- Quality Assurance,
- Plant Management (Operations/Technical),
- ~~Plant~~ Engineering/ and Maintenance,
- Administration/~~Human Resources~~,
- Training,
- Environmental, Safety and Health, ~~Training,~~ and the
- Facility Safety Review Committee (FSRC)/ALARA Committee

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The responsibilities, authorities, and lines of communication of key management positions within the plant organization are discussed in Section 2.2, "Key Management Positions, Responsibilities, and Qualifications."

~~In the plant line organization, related to routine operations of the facility, the IIFP plant ESH Manager and the plant QA Coordinator both report to the COO/PM. In a matrix role, the ESH Manager and the QA Coordinator report to the corporate RAQD. As part of the matrix role, those managers interact with other ESH and QA activities and functions in the corporate structure and receive ESH and QA policy and technical standards guidance from the corporate RAQD.~~

~~Additionally, the plant ESH and QA managers have the authority and responsibility to directly contact the INIS President/CEO with any ESH or QA concerns, respectively. These reporting relationships are part of the independence assurance provided by IIFP that concerns or issues in ESH or quality can be directly reported and resolved in alignment with the corporate ESH and QA commitment.~~

Position descriptions for key management personnel in the operating organization will be accessible to affected personnel and to the NRC.

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B. LA Sections 2.1.2 and 2.1.4 refer to a "matrix role" for reporting between organizational structures. This phrase does not appear to be defined in the application and its implications are unclear. Consistent with NUREG-1520, Section 2.4.3(2), define the phrase "matrix role." In the application, add a complete description of how the "matrix role" impacts the organizational structure, such as reporting requirements, oversight, and reporting structure. Define the key organizational positions within the matrix, and clearly indicate a subordinate management structure. Provide a sufficient description of LA Figures 2-1 and 2-2, the "matrix role," to demonstrate that it provides "clear, unambiguous management controls and communications [...] among organizations (NUREG-1520, Section 2.4.3(2)."

RESPONSE: The matrix role for reporting between organization structures has been deleted from the organizational charts and from the text as explained in the License Documentation Impact below:

License Documentation Impact: Remove Chapter 2 of the IIFP License Application, Revision A and insert the rewritten Revision B of Chapter 2 in its entirety. Sections 2.1.2 and 2.1.4 have been rewritten to revise the organizational charts eliminating the matrix structure, and the text has been revised to reflect the revised organization. See License Documentation Impact for RAI OA 7.A for the revised text and organization charts or see the revised Sections 2.1.2 and 2.1.4 in the rewrite (redline version) of Chapter 2 of the License Application Revision B attached.

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C. *The application indicates that the COO has responsibility for the design, engineering, construction, startup, operation, maintenance, etc. However, the COO/Commercial Facility Project Director (CFPD) (Design/Build (DB) phase) is not at the top of the Figure 2-1; nor is the COO/Plant Manager (operations phase) at the top of Figure 2-2. In addition, several other groups are parallel or above the COO for both phases. Consistent with NUREG-1520 2.4.3(1), clearly indicate which individuals listed in LA Figures 2-1 and 2-2 are ultimately responsible for overseeing the design, construction and operation of the facility.*

If the COO/CFPD and COO/Plant Manager are in fact responsible for the design, engineering, construction, startup, operation, maintenance, etc., provide a clear description in the text to explain the relationship between the COO and other parallel and higher management individuals represented in Figures 2-1 and 2-2. Describe what role these other groups play in overseeing the design, construction and operation of the facility and how their authority interrelates with parallel organizations.

RESPONSE:

Figure 2-1 has been revised with the IIFP President at the top of the IIFP organization and the highest authority within IIFP. The IIFP President reports to the parent corporation INIS President/Chief Executive Officer. The other management individuals in the parent corporation that interrelate with the IIFP President are the Corporate ESH Manager and the Corporate QA Manager. These parent corporate staff managers interrelate with the IIFP President by assisting the IIFP COO and providing support to the IIFP ESH and QA management (See Section 2.2.2 of the IIFP LA Chapter 2 Revision B attached). The COO reports directly to the IIFP President and as such is delegated the line organization authority for the responsibility of managing the administration, ESH, QA, engineering, training and supporting contractor functions during the licensing, design and construction of the IIFP Facility. Once the IIFP Engineering Manager is hired the COO will assign responsibilities and delegate authority to the Engineering Manager, who reports to the COO, for providing design authority and direct oversight of the Design and Build Contractor and for ensuring professional and contractor support is in place to perform any required Integrated Safety Analysis and licensing documentation.

Section 2.1.2 of the IIFP LA Chapter 2, "IIFP Design and Construction Organization Structure" addresses the organization structure during the DB phase of the IIFP Project. Figure 2-1 addresses that organizational structure. The roles and responsibilities of individual positions in managing the design, construction and operation of the facility are discussed in response to RAI OA-7A above.

The revised Figure 2-2 shows the same organizational structure during the plant operations phase. A position of Plant Manager reporting to the COO was added to the Plant Operation Organization chart. The responsibilities for the Engineering Manager, the COO, the Plant Manager, and the IIFP President are delineated in Section 2.2, "Key Management Positions, Responsibilities, and Qualifications."

License Documentation Impact: Remove Chapter 2 of the IIFP License Application, Revision A and insert Revision B of Chapter 2 in its entirety. Section 2.1.2 has been revised and is shown in RAI OA-7A. Figure 2-1 has been revised in Section 2.1.2 as shown in License Documentation

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Impact for RAI OA-7A. Figure 2-2 has also been revised in Section 2.1.4 as shown in License Documentation Impact for RAI OA-7A. The responsibilities for the IIFP President, the COO, Engineering Manager, and the Plant Manager are delineated in Section 2.2.3, 2.2.4, 2.2.5. 2.2.9, respectively, can be viewed in the attached rewrite for Chapter 2 of the License Application Revision B.

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D. *During the DB phase, LA Section 2.2.4 indicates that the COO/CFPD is ultimately responsible for all activities, including QA. Sections 2.2.1–2.2. describe other management individuals who are also responsible for these activities, e.g., Regulatory Affairs/QA Director or INIS/IIFP President/CEO (LA Section 2.1.3, second full paragraph). Consistent with NUREG-1520, 2.4.3(2), clarify the management structure for the ESH and QA during the DB phase. During the Operations phase, LA Figure 2-2 shows that the ESH and QA report to two separate managers. Consistent with NUREG-1520, Section 2.4.3(1), clarify the management structure for the ESH and QA during the Operations phase. Also clarify the role of the RAQD regarding the oversight of the ESH and QA program.*

RESPONSE: Section 2.2.4 of the LA Chapter 2 Revision A described the responsibilities of the COO/CFPD. The COO/CFPD's responsibilities have been redefined in the attached rewrite of the License Application Chapter 2 Revision B for the position of the COO.

The organizational charts for the Project Design and Construction (Figure 2-1) and for the Plant Operation Organization of the IIFP (Figure 2-2) have been revised to replace the position of the Regulatory Affairs/QA Director (RAQD) with both a Corporate QA Manager and a Corporate ESH Manager reporting to the INIS President and CEO. In the revised figures, the IIFP President reports to the INIS President/CEO, and the COO reports to the IIFP President see response and license documentation impact for RAI OA-7A.

The management structure for the Corporate QA and ESH Managers and for the IIFP QA and ESH managers is explained in response to RAI OA-6C above.

License Documentation Impact: Remove Chapter 2 of the IIFP License Application, Revision A and insert Revision B of Chapter 2 in its entirety. Figure 2-1 and Figure 2-2 have been revised as shown in the License Documentation Impact for RAI OA-7A or in attached rewrite of Chapter 2 of the License Application. See also responses and license documentation Impacts for RAIs OA-6C and OA-8A view rewritten sections 2.2.1 through 2.2.8 in the attached Revision B of Chapter 2 of the License Application.

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OA-8. LA Section 2.2 describes key organizational positions. The list of key positions in LA Figures 2-1, 2-2 and Section 2.2 do not match. Consistent with NUREG-1520, Section 2.4.3(1), provide the following information:

*A. Some positions listed in LA Figures 2-1 and 2-2 are not described in LA Section 2-2. Conversely, many of the key positions described in LA Section 2.2 are not listed in LA Figure 2-1 or Figure 2-2, e.g., 2.2.5 Project Integrated Safety Analysis Lead, 2.2.6 Project Environmental Assessment Lead, 2.2.12 Production/Technical Manager, 2.2.20 Fire Protection Lead, 2.2.22 Environmental Lead, and 2.2.24 Records/Documents Lead. Although a description for each item listed in the figures is not required, there does not appear to be a logical system for determining which items are described and which are not. Consistent with NUREG-1520,Section 2.4.3(1), ensure that **key positions** listed in LA Figure 2-1 and Figure 2-2 have corresponding descriptions in LA Section 2.2. In response to this RAI, explain what logical criteria are used to determine which management functions are described and which are not.*

RESPONSE: Figure 2-1 and Figure 2-2 were revised in a rewrite to the License Application Chapter 2. Section 2.2, "Key Management Positions, Responsibilities, and Qualifications," was also revised to describe positions that have key management, supervisory or direct professional responsibilities relative to ESH, Quality Assurance and safe operation of the IIFP Facility. Positions shown in Figures 2-1 and 2-2 that are not described: 1) do not have supervisory or management responsibilities for ESH or QA, for example the Administration managers or 2) are not supervisors/managers, for example the operating crews and document control clerks.

License Documentation Impact: Remove Chapter 2 of the IIFP License Application, Revision A and insert Revision B of Chapter 2 in its entirety. Figure 2-1 and Figure 2-2 have been revised as shown in the License Documentation Impact for RAI OA-7A or in the attached rewrite for the License Application Chapter 2. Sections 2.2 through 2.2.11 has been revised to include descriptions of key (supervisory and management positions with ESH and QA responsibilities) positions identified in Figures 2-1 and 2-2 in the attached rewrite of License Application Revision B of Chapter 2.

Follow-up License Documentation Impact: Section 2.2.9.3 "Shift Superintendent", of Chapter 2, License Application Revision A will be revised to clarify the roles and responsibilities of the Shift Superintendent as follows:

~~Each operating shift at the IIFP is staffed with a Shift Superintendent, who is appointed by the Production/Technical Manager and approved by the IIFP COO/PM. The Shift Superintendent normally reports to the Production/Technical Manager, but during declared emergencies may act in the capacity of the IIFP COO/PM, as the Emergency Director, until relieved by the COO/PM, or designee. The role and responsibilities of the Shift Superintendent during declared emergencies are specifically stated in the IIFP FEP/DUP Emergency Plan, latest revision (IIFP, 2009b).~~

The Shift Superintendents report directly to the Plant Manager. A Shift Superintendent (SSP) is assigned and scheduled for each work shift including weekends and holidays. The SSP when scheduled on the back shift (afternoons, nights, holidays and weekends) has the role in coordinating the IIFP Facility operational and maintenance tasks and support activities. This role includes: 1) assuring coordination among work groups in the authorization of safety and radiological permits, 2) arranging any additional or replacement qualified staff, as needed, for the

work shift to support planned and emerging work activities, 3) ensuring corrective response and reporting for any abnormal events and 4) setting priorities and coordinating activities among the various shift functional groups when emerging or unexpected task requirements arise. When the SSP is scheduled to work on the day shift, he/she assists in emergency preparedness planning and related training, supports the Plant Manager on special projects and assignments and attends refresher training as needed. ~~The Shift Superintendent is responsible for directing the day-to-day operations on all shifts including the back-shift, weekend and holiday periods and for ensuring safe operations, and the identification and correction of any off-normal operating conditions.~~ The Shift Superintendent has the authority to stop work and shut down operations in a safe and orderly manner in matters related to ESH or QA. ~~Each Shift Superintendent directs assigned personnel from the production, technical, ESH, maintenance and support functions to provide a continuity of safe and compliant operations.~~

Additionally, the Shift Superintendent takes the lead role of the facility Emergency Director until the Chief Operations Officer, or designee can assume that role in the event of an emergency. Once relieved of the Emergency Director role, the SSP then fills the role of the Field Incident Commander during the emergency event. The role and responsibilities of the SSP during declared emergencies are specifically stated in the IIFP FEP/DUP Emergency Plan (EP), latest revision (IIFP, 2009b).

The Shift Superintendent shall have~~,~~ as a minimum~~,~~ a bachelor's degree in an engineering or scientific field, and a minimum of four years of responsible experience in supervising and implementing chemical, radiological or nuclear-related operations programs. Educational requirement may be substituted with relevant military and/or civilian work experience.

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B. *The individuals and positions listed in LA Section 2.2 do not appear to be listed in a logical order consistent with the LA Figures 2-1 or 2-2, e.g., contractors from the DB phase are listed after individuals who manage the operation phase (e.g., COO/Plant Manager). Consistent with NUREG-1520, Section 2.4.3 (2-3), provide a logical order to the groups listed in LA Section 2.2 so that management structure is easy to understand. In response to this RAI, provide the logic behind the ordering of groups described in Section 2.2, and indicate how the ordering correlates with Figures 2-1 and 2-2. LA Sections 2.2.1 through 2.2.25 do not distinguish between the Design phase and the Operations phase. Provide some method, e.g., in the title or by grouping, to distinguish which organizational groups are used for design and which are used for operations.*

RESPONSE: Figure 2-1 shows the organizational makeup of the IIFP during the Project Design and Construction phase. The same organization makeup is used during the Operations phase except that additional personnel are added during the transition from construction to operations. The only organization in the project design and construction organization that does not transition to the plant operations phase is the Design and Build Contractor owing to this being a temporary position for design and construction of the IIFP Facility. In the rewrite to Chapter 2 of the License Application (attached) the key management position (determined by responsibility for ESH, QA and safe operation of the facility) descriptions in Section 2.2 have been logically organized in the following order of discussion: 1) firstly, the parent corporate President/CEO and the parent corporate staff that interact with the subsidiary IIFP organization are described; then 2) the IIFP Facility organization is described beginning with the IIFP President, followed down the line organization to the IIFP COO as a direct report to the IIFP President; 3) next the direct reports to the IIFP COO are described beginning with the Engineering Manager followed by the direct reports to the Engineering Manager down the line within the Engineering organization. The DB Contractor is included in this reporting chain because of the oversight by the Engineering Manager of the DB Contractor during design and construction and also because of the DB Contractor's importance to safe design and construction of the facility; 4) then each of the other direct reports to the COO are described beginning on the left side of the Figure 2-2 chart and then following down the right side of the chart. As each position reporting to the COO is described then each function or individual reporting to that management position is described in order down the line within that respective organization.

License Documentation Impact: Remove Chapter 2 of the IIFP License Application, Revision A and insert Revision B of Chapter 2 in its entirety. Key Management Positions, Responsibilities and Qualifications have been revised in Section 2.2 of Revision B (redline version attached). These are discussed in LA Chapter 2 Revision B in the logic order described in the Response section above in relationship to the revised organizational charts shown in Sections 2.12 and 2.1.4 of Revision B.

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C. *The bulleted list in Section 2.1.4 on Pages 2-5 and 2-6 appears to match positions listed in LA Figure 2-2. Ensure that the management positions listed in Figure 2-2 match the positions contained in the bulleted list.*

RESPONSE: The subject bulleted list does not include all the positions listed in Figure 2-2. It has been revised to include the IIFP Facility functions where the IIFP COO provides leadership and responsibility.

License Documentation Impact: Remove Chapter 2 of the IIFP License Application, Revision A and insert Revision B of Chapter 2 in its entirety. See response to RAI OA-6A for revisions to Section 2.1.4 (2nd paragraph).

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OA-9. Several of the key management positions described in LA Section 2.2 need additional descriptions to understand their responsibilities. Consistent with NUREG-1520, Section 2.4.3(3) provide the following information:

A. LA Section 2.2.1 indicates the President/CEO's credentials must include proven ability in management, leadership qualities, and a commitment to safety, etc. These items are not quantifiable. Consistent with NUREG-1520, Section 2.4.3(3), provide the minimum quantifiable criteria required for the President/CEO such as: the number of years of experience in management, the years and type of demonstrated leadership, and the number of years and type of education. (Note: If there aren't specific criteria, specify in response to the RAI why this is acceptable.)

RESPONSE: The subject sentence in Section 2.2.1 has been revised to provide quantifiable criteria required for the INIS President/CEO. In addition, key positions described in Section 2.2, including new Section 2.2.3 for the IIFP President have been reviewed to ensure that the minimum quantifiable criteria required for the positions have been incorporated in the position descriptions.

License Documentation Impact: Remove Chapter 2 of the IIFP License Application, Revision A and insert Revision B of Chapter 2 in its entirety. See response to RAI OA-6B license documentation impact for rewrites of Section 2.2.1 and 2.2.3.

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B. *In LA Section 2.2.4, first paragraph, the first few sentences describe the role of the COO/CFPD. The remainder of the paragraph shifts to a focus on Configuration Management (CM). Consistent with NUREG-1520, Section 2.4.3 (1-3), modify the paragraph so that it defines the role of the COO/CFPD rather than provide a discussion of the CM and other items. If CM is an integral role of the COO/CFPD, provide additional description of the COO/CFPD's CM role. Separate the remainder of the paragraph which focuses on the QAC, ESH Manager and the President/CEO or clarify how these positions impact the responsibility of the COO/CFPD.*

RESPONSE: The CM discussion and other items have been removed from Section 2.2.4 and it has been rewritten to focus on describing the responsibility/role and qualification of the COO.

License Documentation Impact: Section 2.2.4 has been rewritten as shown below to delete the description of CM and to provide the description for the COO.

2.2.4_____Chief Operations Officer ~~and Commercial Facility Project Director~~

The Chief Operations Officer ~~who will be the Commercial Facility Project Director~~ (COO~~/CFPD) during the DB project phase~~ is selected by the ~~INIS~~/IIFP President/~~CEO~~. In the role of COO~~/CFPD~~, he/she is responsible for managing the design, detailed engineering, construction, pre-startup, procurement, configuration management (CM), quality assurance, ESH, subcontracting, project control and records. ~~Modifications resulting from design and engineering changes are controlled through CM. The change management is coordinated with the ISA and licensing support group for technical review and analysis, documentation and/or licensing amendments, where required. Where modifications involve existing or new IROFS, the ISA documentation and any licensing amendment require the review and approval, at a minimum, of the QA Coordinator, ESH Manager and COO/CFPD. In addition, any licensing amendment requires the approval of the INIS/IIFP President/CEO, or designee, prior to submitting the amendment to the NRC.~~

The COO is the individual with the overall responsibility for safety and operational activities of the FEP/DUP Facility. The responsibilities of the COO are defined by IIFP policies, procedures, and instructions. The COO is responsible for the safe conduct and control of operations, and protection of employees. The COO also has responsibility for regulatory compliance with the facility NRC licenses and other federal, state, and local permits or licenses. The COO ensures proper selection of staff for the key positions including positions for the Facility Safety Review and ALARA Committees.

The COO~~/CFPD~~ shall have the authority to enforce the shutdown of any construction or pre-start activity. The COO~~/CFPD~~ will also delegate facility shutdown authority to appropriate organizations and line managers. The COO~~/CFPD~~ must approve restart of any activity that was shut down due to safety and/or regulatory concerns.

The COO~~/CFPD~~ shall have~~,~~ as a minimum~~,~~ a bachelor's degree in a scientific field and ~~seven~~ five years of experience in chemical, radiological, or nuclear related operations. The

experience shall include ~~senior~~ responsible assignments involving engineering and either project management or facility operations management. The COO~~/CFPD~~ shall be cognizant of the IIFP licensing documentation and the overall ESH and QA requirements of the facility design and construction.

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C. *The QAC description in LA Section 2.2.11 contains the following sentence: "The IIFP QA Coordinator also ensures and oversees the implementation and maintenance of the plant performance assessment and action tracking program relative to ESH and QA." Provide a brief description of the "plant performance assessment" and "action tracking program" so individuals unfamiliar with these programs understand their purpose. In addition, the QAC description contains a sentence which states, "The QA Coordinator shall have, as a minimum, a bachelor's degree in engineering, science or related field and five years of quality experience in the implementation of a QA Program at a chemical, radiological or nuclear facility." Clarify what is meant by "quality experience."*

RESPONSE: The subject sentence referring to the plant performance assessment and action tracking program has been deleted in the rewrite to Chapter 2 of the License Application. Since these are only two of the elements for which the QA Manager has responsibility, the sentence was replaced by expanding Section 2.2.6 to explain all those elements of the QA program under the IIFP QA Manager's responsibility. Additionally, the word "quality" in "quality experience" was deleted since the experience required is in the implementation of a QA Program.

Facility performance assessment and the corrective action program are described in Sections 2.3.5 and 2.3.6 of the LA Chapter 2. These programs are further described in Sections 11.5 and 11.6 of the IIFP LA Chapter 11.

License Documentation Impact: Remove Chapter 2 of the IIFP License Application, Revision A and insert Revision B of Chapter 2 in its entirety. Section 2.2.11 (now 2.2.7) of the License Application was rewritten to rename the QA Coordinator as the IIFP Quality Assurance (QA) Manager, and to include all the quality elements for which the QA Manager is responsible, and to show the experience required for the QA Manager. The rewrite of former Section 2.2.11 (now 2.2.7) can be viewed in the license documentation impact of RAI OA-6C or in the attached rewrite of Chapter 2 of the License Application, Revision B.

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OA-10. The description of the transition from DB contractor to operations must demonstrate adequate planning and staffing. Consistent with the NUREG-1520, Section 2.4.3 (4), provide the following information:

A. LA Section 2.1.3 states that the Engineering and Maintenance Manager and the Operation and Technical Manager may serve as the Startup Manager. This appears to be inconsistent with the description in Section 2.2.8 "Startup Manager," which indicates a dedicated individual will be assigned to the position. Consistent with NUREG-1520, Section 2.4.3(4), clarify whether the Startup Manager is a standalone position or whether the role is filled by other managers for a limited time. If multiple individuals serve as the Startup Manager, explain how this transition takes place and its implication for who has authority over the startup of operations.

RESPONSE: The Startup Manager has been deleted as a key management position in Section 2.2. Section 2.1.3 of the License Application has been rewritten to delete reference to the Startup Manager. The Plant Manager will take a lead role with authorization and support from the Chief Operations Officer in the transition from the design and construction phase to the operations phase of the IIFP Facility.

License Documentation Impact: Remove Chapter 2 of the IIFP License Application, Revision A and insert Revision B of Chapter 2 in its entirety. Chapter 2 has been rewritten to eliminate the position of the Startup Manager in Section 2.2 and to clarify the roles during the transition from construction to operations in Section 2.1.3. Section 2.1.3 in the attached License Application (Revision B) will be rewritten to read as follows:

2.1.3 Transition from Design and Construction to Startup and Plant Operations

~~When~~ Prior to the end of construction ~~approaches~~, the focus of the organization will shift from design and construction to initial startup and operation. At an appropriate time during construction, IIFP will supplement and expand the initial organization structure to include a Plant Manager (PM) and other management positions and disciplines necessary to ensure readiness of the facility for safely starting and effectively transitioning from construction activities to operating activities. These additional positions will be hired well in advance of the scheduled startup of operations, and may serve in interim organizational roles during the construction phase of the project. ~~Prior to completing construction, IIFP will staff the facility operating organization to ensure readiness of the facility for safely starting and effectively transitioning from construction activities to operation activities. The persons that will take the responsibilities of Plant Engineering and Maintenance Manager and the Operation and Technical Manager are hired well in advance of the scheduled start up of operations, and may serve in DB organizational roles, such as the Startup Manager, until the transition from DB to facility operation.~~

During this transition, the IIFP plant ESH and QA Managers ~~continues to~~ report to the COO/~~CFPD~~ for ESH and QA matters related to design and construction. ~~As the COO/CFPD role changes to the COO/PM, the ESH Manager transitions to directly reporting to the IIFP COO/PM on ESH matters for the startup operations. The ESH Manager who has been reporting in a matrix role to the President/CEO now changes to reporting in the matrix role to the Regulatory Affairs/Quality Director (RAQD). The IIFP QA Coordinator likewise reports to the COO/CFPD during the design and construction stage, then transitions to reporting to the IIFP COO/PM.~~

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~~During the design and construction and the transition periods,~~ B~~b~~oth the ESH ~~Manager~~ and QA ~~Coordinator~~ Managers have the~~responsibility and~~ authority to elevate and report any ESH or QA unresolved concern to the IIFP President. ~~and to corporate Regulatory Affairs/QA Director, respectively. or directly to the INIS/IIFP President/CEO~~ The IIFP President is ultimately responsible for ESH, QA, and other safety-related issues. All ESH and QA concerns will be followed through to resolution and documented.

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

When construction of the plant and process systems is complete, the equipment and systems undergo acceptance testing as in accordance with the QA Program and approved written procedures. Following successful completion of ~~acceptance~~ integrated equipment and systems testing and acceptance, the responsibilities for managing the facility equipment and systems are transferred from the ~~DB~~ Design and Construction O~~o~~rganization to the Plant O~~o~~peration~~ing~~ O~~o~~rganization as shown in Figure 2-2 by means of a transition plan. The COO~~/CFPD~~ and ~~the Startup~~Plant Manager ensure the development of a transition plan and an orderly, safe and thorough turnover to the IIFP ~~COO/PM, Plant Engineering/Maintenance Manager and Operation/Technical Manager functions~~Plant Operation Organization. The turnover includes the physical systems, corresponding design information, records of the facility, and as-built drawings. Following turnover, the P~~p~~lant Operation O~~o~~rganization is responsible for facility safe operations, ~~system~~ maintenance, configuration management (CM) and facility safety reviews of modifications affecting the as-built plant.

The design basis for the facility is maintained during the transition from construction to operations through the CM Program described in LA Chapter 11; "Management Measures."

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B. The second full paragraph of LA Section 2.1.3 indicates that the ESH reports to a different manager after the transition from the DB phase to the Operations phase. Based on LA Figures 2-1 and 2-2, the entire management structure changes during this transition. Consistent with NUREG-1520, Section 2.4.3(4), clarify why only the ESH is called out specifically in Section 2.1.3; and describe the transitions for all key managers. Also, introduce new key organizations created for the Operations phase and provide a description of the new positions in LA Section 2.2. Provide an overview of how the positions listed in Figure 2-1 will be transitioned to the positions in Figure 2-2, similar to the description provided for the COO.

LA Section 2.2.2 describes the Chief Financial Officer (CFO). This position does not appear in LA Figure 2-2. Consistent with NUREG-1520, Section 2.4.3 (2), clarify what happens to the CFO in the transition from DB to organization.

RESPONSE: Figures 2-1 and 2-2 have been revised as a result of a rewrite to Chapter 2 of the License Application. Figure 2-1 portrays the organizational makeup of the IIFP during the Project Design and Construction phase. The same organization makeup is used during the Operations phase, except that additional personnel are added during the transition from construction to operations. All the organizations in the project design and construction organization transition to the plant operations phase except for the Design and Build Contractor. Section 2.1.3 has been rewritten to clarify the transition from construction to operations and to clarify that both ESH and QA have the authority to elevate unresolved ESH and QA concerns to the IIFP President. See License Documentation Impact for RAI OA-10A. Section 2.2 has been rewritten to include position description for the key positions. See License Documentation Impact for RAI OA-8A.

License Documentation Impact: Remove Chapter 2 of the IIFP License Application, Revision A and insert Revision B of Chapter 2 in its entirety. See License Documentation Impact for RAI OA-8A for the rewrite of key position descriptions (Section 2.2) to be viewed in the attached Chapter 2, of the License Application, Revision B. See License Documentation Impact for RAI OA-10A for the rewrite of Section 2.1.3 to clarify roles during the transition between construction and operations phases. See License Documentation Impact for RAI OA-7A for the revised organization charts (Figures 2-1 and 2-2).

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C. *LA Section 2.1.3, fourth paragraph, references two separate plans, the Quality Assurance Plan and the Transition Plan. The purpose and use of these plans is not well defined. Consistent with NUREG-1520, Section 2.4.3(4), clarify whether the plans will ensure that IROFS, equipment, procedures, etc., are in place and functioning safely, efficiently, and are tested. This paragraph also indicates acceptance testing of the system will be conducted before final operations. Summarize the things that will be tested (e.g., safety equipment, procedures, process equipment, etc.) and what criteria will be used to determine the items are ready for operations. Clarify which individuals/functions are responsible for overseeing the testing and which manager ultimately decides items are ready for operations. State whether an integrated systems test will be preformed prior to operations.*

RESPONSE: The Transition Plan will be developed following the requirements of the QA Program Description (QAPD) of the License Application and will include the same elements of the QA Program. Section 2.1.3 has been rewritten to reflect only the Transition Plan. Requirements for pre-operational testing were added to the QAPD for Test Control (See License Documentation Impact for RAI QAPD-1). The Transition Plan, which will include an integrated equipment and systems test, will follow the requirements of Test Control of the QAPD.

License Documentation Impact: Remove Chapter 2 of the IIFP License Application, Revision A and insert Revision B of Chapter 2 in its entirety. Section 2.1.3 has been rewritten to reflect only the Transition Plan, acceptance testing in accordance with QA program requirements, and completion of integrated equipment and systems testing. See the License Documentation Impact for RAI OA-10A for the rewrite of Section 2.1.3.

Test control requirements were added to the Quality Assurance Program Description (Appendix A to the License Application) as shown below and as in the License Documentation Impact for RAI QAPD-1:

A.11 Test Control

A.11.1 General

A system is established for design verification testing, acceptance testing, pre-operational and operational testing, and post-maintenance testing of IROFS. This system provides measures to ensure that this testing is completed satisfactorily.

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

A.11.2 Responsibilities

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

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

A.11.3 Requirements

Tests required for conformance verification of an item or computer program to specified requirements and to demonstrate satisfactory performance for service are planned and executed.

Characteristics to be tested and test methods to be employed are specified.

Test results are documented and their conformance with acceptance criteria is evaluated.

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

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

Test policies, plans, and/or procedures contain the following information, as appropriate:

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

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

Test records contain the following information:

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

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D. *The last paragraph on Page 2-4 states, "...physical systems, corresponding design information, records of the facility and as-built drawings," will be turned over to the Engineering/Maintenance Manger and Operations/Technical Manager. LA Section 2.1.3 does not specify who these responsibilities will be transferred from. Also, these responsibilities do not appear to be described in the DB Organization in LA Section 2.1.2. Consistent with NUREG 2.4.3(1), clarify if these are key organizational responsibilities in the DB phase. Ensure that key organizational responsibilities are consistently described and transitioned throughout LA Sections 2.1.2, 2.1.3, and 2.1.4.*

RESPONSE: Earlier in subject paragraph of Section 2.1.3 prior to the subject sentence, it states that the systems are transferred from the DB organization. Section 2.1.3 was rewritten to generalize this transition from the DB organization to the IIFP organization. Responsibilities for the DB organization have been added to Section 2.2.

License Documentation Impact: Remove Chapter 2 of the IIFP License Application, Revision A and insert Revision B of Chapter 2 in its entirety. See the License Documentation Impact for RAI QA 10A for the rewrite for Section 2.1.3 which shows the generalized transition from the design and build phase to the operations phase. Section 2.2 has been rewritten as shown in the License Documentation Impact for RAI QA-8A and includes the key management position of the Design and Build Contractor Section 2.2.6 as shown below:

~~2.2.7~~2.2.6 Design and Build Contractor

The Design and Build (DB) Contractor ~~(DBC)~~ is selected by the INIS~~/IIFP~~ President/CEO, and approved by the INIS Board of Directors. The DB Contractor, under a formal approved written contract with IIFP, is responsible for performing the detailed design, engineering, procurement and construction of the IIFP FEP/DUP ~~plant~~Facility. The DB~~C~~ Contractor assigned manager is the lead-official representative of the design/build contract.~~,~~ In the initial design phase the DB Contractor will ~~and~~ reports directly to the COO~~/CFPD~~. Once the Engineering Manager position is filled the DB Contractor shall report directly to the Engineering Manager. The DB Contractor coordinates ~~and~~ works ~~with~~ on the project and ~~CM,~~ controls ~~and records,~~ subcontractors, inspections, and startup functions to ensure a safe design, construction, acceptance testing and turnover to the IIFP Plant ~~Operating~~ Operation Organization.

During the detailed design, construction and startup stage of the project, the DB Contractor will also ensure, as part of the written contract, that design meets all the applicable federal, state and local codes and standards.

The approved DB Contractor shall have~~,~~ as a minimum~~,~~ a demonstrated safe record of experience in design, engineering, procurement and construction of chemical, radiological or nuclear facilities at project complexity levels equivalent with that of the IIFP Project. The DB Contractor shall also have the professional and trade craft capabilities of either performing or subcontracting (with IIFP approval) for design, engineering, procurement, construction and support of acceptance testing for the plant process equipment, systems and facility infrastructure.

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OA (No number) New Follow Up Question

The staff has confirmed that the revised application addresses all the acceptance criteria in NUREG-1520, Chapter 2, except possibly for the fifth bullet on page 2-3 (under criteria for existing facilities). For completeness, please clarify how this 5th bullet has been addressed in the application (ESH implemented via written and approved procedures)

RESPONSE: The fifth bullet of the criteria states, "The activities that are essential for effective implementation of the ESH functions are documented in formally approved, written procedures, prepared in compliance with a formal document control program." Chapter 11, "Management Measures," of the License Application and the "Quality Assurance Program Description" (Appendix A of the License Application) address this bullet as follows:

11.1.4 Document Control

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

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

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

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

Document control encompasses those documents that are relied on for safety, e.g. the ISA, all procedures that pertain to IROFS, procedures involving training, QA, maintenance, audits and assessments, emergency operating procedures, emergency response plans, system modification documents, assessment reports, and others that the applicant deems part of CM. See Section 11.1.1.1, "Scope of Structures, Systems, and Components," for a general accounting of the documents subject to configuration management during design, construction, and operations of the IIFP Facility. A more detailed listing of documents under configuration control during design is provided in Section 11.1.2,

"Design Requirement" and Section 11.1.3, "Configuration Management Controls on the Design Requirements." Documentation under CM during construction is delineated in Section 11.1.5.2 below. Similarly, Section 11.1.5.3 provides a discussion of documentation under CM during the operations phase.

11.4 Procedures Development and Implementation

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

All activities involving IROFS and QA level 1 and 2 items (See ~~Section~~ subsection 11.8.42.2) are conducted in accordance with approved procedures. As noted throughout this document, procedures are used to control IROFS activities to ensure the activities are carried out in a safe manner and in accordance with regulatory requirements.

11.4.1 Type of Procedures

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

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

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

11.4.1.2 Management Control (Administrative) Procedures

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

issues) apply to workers, visitors, contractors, and vendors. These management control procedures, includeing management measures such as the following:

- Configuration management;
- Industrial Safety, radiation safety, chemical safety, and fire safety;
- Quality Assurance;
- Design control;
- Plant personnel training and qualification;
- Audits and assessments;
- Incident investigations;
- Record keeping and document control;
- Reporting; and
- Procurement

Procedures for construction will be an integral part of the procedures of the Design and Build (DB) contractor chosen by IIFP. The DB contractor will use those procedures during the construction phases of the IIFP Facility.

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

11.4.2.5 Approval

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

11.4.4 Topics to be Covered in Procedures

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

MANAGEMENT CONTROL (ADMINISTRATIVE) PROCEDURES

1. Configuration Management

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

4. Procedures Development and Implementation
5. Audits and Assessments Procedures, Including
    - Audits
    - Certification of Audit Personnel
    - Management Assessments
6. Incident Investigations and Corrective Actions Management
7. Records Management and Document Control
8. Other Quality Assurance Elements
    - Organization
    - Quality Assurance Program
    - Design Control
    - Procurement Document Control
    - Supplier Qualification
    - Instructions, Procedures, and Drawings
    - Document Review
    - Continuous Improvement
    - Control of Purchased Items and Services
    - Identification and Control of Items
    - Inspection
    - Test Control
    - Control of Special Processes
    - Control of Nonconforming Items, Materials, and Components
    - Inspection, Test, and Operating Status
    - Quality Assurance Records
9. Environmental, Safety, and Health Procedures
    - Hazard Communication Program (HAZCOM)
    - Fire Prevention Plan
    - Energy Control (Lock/out/Tag/out)
    - Respirator Program
    - Confined Space Entry
    - Exposure Control Plan (Bloodborne Pathogens Program)
    - Fall Protection
    - Chemical Hygiene Plan (Laboratory Safety Program)
    - Hazardous Waste Operations and Emergency Response (HAZWOPER)
    - Process Safety Management
    - Radiation Protection
    - Environmental Protection
    - Spill Control Response
10. Fire Protection Procedures
11. Nonradiological/Radioactive Waste Management Procedures
12. Laboratory Analytical Procedures
13. Security Procedures

11.8.5 Instructions, Procedures, and Drawings

Activities affecting the availability or reliability of IROFS are prescribed by and accomplished in accordance with documented specifications, requirements, procedures, instructions, and drawings of a type appropriate to the circumstances. These documents include or reference appropriate acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. Standard guidelines for the format, content, review, and approval processes for documents are established. ~~(~~See Section 11.4 "Procedures Development and Implementation" and LA Appendix A.5.1, "Instructions, Procedures, and Drawings."~~)~~.

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

11.8.6 Document Control~~/Records Management~~

A document control ~~and records management~~ system is established for IROFS and related activities and services within the scope of the ~~QAP~~QA program. This system ensures that documents ~~and records~~ defining the performance of ~~quality-related activities~~management measures are controlled so only current and correct information is available at the location where the activity is performed prior to commencing the work. See Section 11.7, "Records Management and Document Control" and LA Appendix A.6, "Document Control."

The Quality Assurance Program Description (Appendix A of the License Application) addresses this bullet as follows:

A.5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

A.5. 1 General

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

A.5. 3 Requirements (2nd paragraph only)

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 are specified in procedures.

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