Requests for Additional Information (Public)
Review of the International Isotopes Fluorine Extraction and Depleted Uranium Facility

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Regulatory Compliance

Title 10 of the *Code of Federal Regulations* (CFR) Parts 20, 40, 51 and 70 contain requirements which apply to a source material applicant for a deconversion facility. The acceptance criteria for these requirements are further described in applicable portions of NUREG-1520 of the Standard Review Plan for the Review of a LA for a Fuel Cycle Facility (SRP). Although NUREG-1520 applies to special nuclear material facilities licensed under Part 70, many of the requirements for Part 40 are similar to those for Part 70, excluding criticality among other things. The SRP has been used to guide the development and review of the regulatory compliance for International Isotopes Fluorine Production, Inc.

General Information

Minor Items to Address

GI-1 Comparison between the topographical features in License Application (LA) Figures 1-3 and 1-4 gives the impression that the 640-acre plot would extend beyond the county sections represented in Figure 1-4. Consistent with NUREG-1520, Section 1.1.4.3(2), trace out the 640-acre property on LA Figure 1-4, similar to LA Figure 1-3, to clarify how county Sections 26, 27, 34 and 35 overlap with the 640-acre property.

GI-2 Consistent with the acceptance requirements presented in NUREG 1.2.4.3(4), provide a specific request for a license period such as 10 to 40 years.

GI-3 Ensure that the page numbering in the electronic version of the Environmental Report (ER) matches the hard copy submitted to the U.S. Nuclear Regulatory Commission (NRC).

GI-4 Integrated Safety Analysis (ISA) Summary Table 4-3 references release scenario evaluation number DUF-00. This term does not appear to be defined in the ISA Summary. Provide a definition for DUF-00 in ISA Summary Table 4-2 or some other appropriate location.

GI-5 Verify that the LA section break 1.6.3.4 is placed in the proper location or whether it should be moved up one paragraph, next to Hydrology.

Major Items to Address

GI-6 The application should provide a clear understanding of the site operations. Consistent with NUREG-1520, Section 1.1.4.3, provide the following information:

A. The application refers to Phase 1 and 2 of the facility in LA Section 1.2.2, LA Table 7-3, LA Chapter 9, LA Chapter 10, and multiple locations in the ER and other documents. The words “Phase 1” and “Phase 2” gives the impression that the license application covers both Phases. From a licensing review perspective, the only operation under consideration is “Phase 1.” “Phase 2” will be evaluated under a completely separate licensing action. This is further obscured by the use of the terms “design/build phase” and “operations phase,” both of which are included in the review of the current application. Consistent with NUREG-1520 , Section 1.1.4.3(1), provide the following information: Consider modifying the phrases “Phase 1” and “Phase 2” to refer to separate licensing actions. Make a clear distinction between current application activities and future application activities. Provide an explanation early in Chapter 1 which clearly explains the difference between the current application activities and future application activities. Ensure that this explanation clearly distinguishes between current requested activities and future, non-requested activities.

B. LA Sections 1.1.2.1 and 1.1.2.2 and Table 1-2 provide a description of each of the major buildings at the facility. However, buildings which process uranium (listed in Table 1-2 in bold text) are grouped and described in general terms, while other major

buildings, e.g., decontamination building, fire pump house, etc. are described individually, building by building. Consistent with the requirements in NUREG-1520, Section 1.1.4.3 (2), provide a description of the processes conducted in the processing of uranium, building by building, similar to the other major buildings listed in Section 1.1.2.2. Ensure that the description is presented in a manner that facilitates an understanding of the flow of material through the process.

C. LA Section 1.1.3.2, Page 1-13, third full paragraph contains a description of the exothermic reaction of Depleted Uranium Hexafluoride (DUF_6) to Depleted Uranium Tetrafluoride (DUF_4) and Anhydrous Hydrogen Fluoride (AHF). Consistent with NUREG-1520, Section 1.1.4.3 (3), specify what reacts exothermically with the DUF_6. Specify where this reaction takes place, e.g., in the DUF_4 building, and specify which building listed in LA Table 1-2 contains the reaction vessel for this process.

GI-7 LA Pages 1-1 and 1-2 list the estimated average inventories for the major chemicals onsite and the limits for the agreement with the state of New Mexico. In addition, LA Section 1.3 contains Table 1-4 which indicates the maximum quantity of licensed material requested in the application. However, additional information is needed regarding the quantity of materials and their chemical and physical forms. Consistent with the acceptance requirements presented in NUREG 1.2.4.3(3), provide the following information:

A. LA Table 1-1 lists the projected average for various chemicals used in the process. Each chemical is represented by a range of values. Clarify if the range of values is the minimum and maximum quantity. If not, describe how these range of values are calculated and how they represent an average. Add a description of the physical form (gas, powder, liquid) of licensed material listed in Table 1-1.

B. Section 2.4.1 of the ISA, first paragraph, indicates that the DUF_6 is vaporized via steam. State whether the DUF6 will be sublimed or passed through a liquid phase, and indicate the location and maximum quantity of liquid DUF_6 that will be produced throughout the facility.

C. Each 48Y cylinder can contain as much as 22 kg (IAEA-TECDOC-750 “Interim guidance for the safe transport of reprocessed uranium,” pg 55) of heal. Address whether Technetium-99 and transuranics will be present in the cylinder tails from previous operations.

D. Table 1-4 lists uranyl fluoride (UO_2F_2) as a chemical form for the process. In response to the RAI provide a description of where this chemical form occurs in the process and whether or not it is described in Chapter 1. Provide a description in the LA of the quantity and conditions which result in production of UO2F2 in the licensed operation. (Note: UO_2F_2 is mentioned as occurring in air effluents, but not as a part of the process.) Clarify whether UO2F2 is actually part of the process or incidental due to reaction with moisture in the air. Since UO_2F_2 is soluble, indicate the quantity of UO_2F_2 produced, the possible exposure to staff, and precautions implemented to prevent inadvertent exposure.

GI-8 Sections 1.1.1 and 1.1.2 contain site maps and a description of the site layout. The application distinguishes between a 40-acre plot and a 640-acre plot, but does not make a clear distinction between the site boundary, controlled area, and restricted

area. Consistent with the requirements in 20.1003, 70.61(f) and the acceptance criterion in NUREG-1520, Section 1.3.4.3(1), provide the following information:

In the LA and other licensing documents, define what part of the International Isotopes Fluorine Products (IIFP) will be the controlled area, e.g., 40-acre plot, in accordance with the definitions in 20.1003 "Controlled area." Clarify in the application whether the 640-acres, excluding the 40-acre plot, represent a buffer zone between the site boundary and the controlled area. Add a paragraph to the LA and other licensing documents, as appropriate, describing in general terms the controlled area and access controls. The ISA Summary in particular should contain information on the controlled area and boundary definitions [70.61(f)], including information on whether the 640-acres will be fenced and marked and information on whether the controlled area entrance will have access controls such as gates or security checkpoints.

GI-9 Sections 1.6.2.1-1.6.2.3 provide information on the local demographics. Consistent with the acceptance criteria in NUREG 1.3.4.3 (2), provide the following information:

A. LA Section 1.6.2.1 provides the population of Gaines and Andrews Counties. However, the population of Lea County is not provided. Provide the latest census numbers for the population of Lea County.

B. Section 1.6.2.1 provides the population density per kilometer for Andrews County. For consistency, provide the population density for Gaines and Lea Counties also.

C. LA Section 1.6.2.3 contains information on schools. This information appears to have discrepancies with the data in the ER in the first full paragraph above Table 3-52. Correct any discrepancies and provide the location and capacity of the nearest hospitals. Provide a sentence indicating where the nearest pre-schools, day cares, and nursing homes are located. (Note: Some of this information exists in the ER. This information may be referenced rather than repeated in the LA, if desired.)

D. Emergency Plan, Section 3.0 lists four facilities within a five-mile radius. The LA Section 1.6.2.4 only lists one of these facilities. Add the other three facilities listed in Emergency Plan to the LA. In the LA, provide the average number of employees who work at these facilities (for separate facilities and combined), and indicate how this number changes with each shift.

GI-10 LA Section 1.6.3, ER Section 3.6, and ISA Summary Section 1.3 contain information on the meteorology for the site. Some of this information contains minor typos or requires clarification. Consistent with the requirements in NUREG-1520, Section 1.3.4.3(3), provide the following information:

A. Some of the temperatures in Table 1-6 of the LA, Table 3-17 of ER, and Table 1-2 of ISA Summary are reported as positive when they should be negative. In addition, some of the temperatures in Table 3-14 of the ER should have negatives. Review all the temperatures in all the tables throughout the submittals and verify that they have the correct sign.

B. The design basis precipitation is stated at 3.5-4 inches for the 100-year timeframe in LA Section 1.1.5.3 and ISA Summary Section 1.3.2.8. The design basis precipitation

appears to be based on the data in ER Table 3-21. Incorporate or reference this table in the LA and ISA Summary. In addition, ER Sections 3.4.11.3 and 3.4.11.4, and LA Section 1.6.3.3, and ISA Summary Section 1.3.2.8 indicate that the IIFP is not within the 500-year flood plain. In response to this RAI, provide the basis for this determination. Also, if possible, consistent with the 100-year data in ER Table 3-21, provide similar precipitation data for the 500-year flood.

C. The basis quoted in ER Figure 3-27 for IIFP being outside the 100-year flood plain is based on data provided by the Economic Development Corporation (EDC) of Lea County, NM. In response to this RAI, provide a basis for the credibility of the information. Indicate if the EDC is qualified to develop these reports, or specify that the EDC compiled the information from nationally recognized sources. In addition, in the LA, ISA Summary, and ER, provide a basis for the statement that the IIFP is outside the 500-year flood plain.

D. For the design basis wind strength in the ISA Summary, provide a return year period and maximum wind speed for both intermediated term (100-500 years) and long term (>1000 years). Specify the basis for both the maximum wind speed and return year period for the information, e.g., a site-specific study, national weather service, etc. In addition, Table 3-22 in the ER has a very limited timeframe (82-97). Justify that this limited timeframe is adequate for the design basis wind. Demonstrate that the wind assessments were from a recognized source and the method used for analyzing high-wind hazard is a commonly used and accepted method.

E. Regarding the design basis threat for a tornado, provide the source of the information that 9 tornados occur annually in New Mexico, e.g., National Oceanic and Atmospheric Administration. Provide the source of the information which indicates that two tornados occurred in Lea County. Specify the probability frequency of a tornado hitting an IIFP building and provide the basis for this information. Indicated if this frequency information or some other reason is used as a basis for not assigning Items Relied on for Safety (IROFS) for tornados in the ISA.

F. In response to this RAI, provide information from the Process Hazards Assessment (PHA) which demonstrates that the Accident Analysis 101.9 from ISA Table 4-3 has a correct value of 10-4. Indicate whether this number is based on the probability of a tornado striking the facility. Add information to the description in the ISA Summary Section 1.3.2.6 which indicates the source of information for determining the tornado data.

G. Considering the population density in Lea County, the record of only 2 damaging lightning strikes since 1950 does not provide adequate evidence of limited risk. Consistent with 70.64(a)(2), add a statement to the LA and ISA Summary that demonstrates the proposed IIFP and the associated power systems are designed and built with heavy grounding or lightning protection to handle lightning strikes. Also, in response to the RAI, provide information from the PHA which demonstrates that the accident analysis for a lightning strike at the IIFP is low consequence, taking into account the average yearly thunderstorms.

GI-11 LA Sections 1.6.3.4-1.6.3.8 contain information on ground water. Consistent with the acceptance criteria in NUREG-1520, Section 1.3.4.3(4), provide the following information:

A. The third full paragraph in LA Section 1.6.3.4 indicates runoff from the site will not travel to a river. For completeness, in this same paragraph, specify the distance to the nearest river. Also, modify this commitment to be consistent with the statement in ER Section 3.4.11.5 that "IIFP plant has no direct outfall to a surface water body." Clarify the meaning of direct outfall.

B. The ER Section 4.4.7 refers to a Stormwater Pollution Prevention Plan (SWPPP). This plan does not appear to be a commitment addressed in the LA. Since the ER is not part of the license application, incorporate the commitment to maintain the SWPPP into the LA. Add a commitment similar to ER Sections 3.4.11.4 and 3.4.11.5 to the LA.

Organization and Administration

Minor Items to Address:

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.

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.

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."

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.

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 <u>elevate and report</u> 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.

Major Items to Address:

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)/Plant Manager (PM) 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/PM reports to the IIFP President/CEO.

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.

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/PM, Quality Assurance Coordinator (QAC), and ESH.

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.

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)."

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/PM (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/PM 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.

D. During the DB phase, LA Section 2.2.4 indicates that the COO/CFPD is ultimately responsible for all activities, including QA. Sections 2.2.1–2.2.3 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.

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.

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/PM). 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.

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.

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.)

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.

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."

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.

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.

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.

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.

Integrated Safety Analysis and Summary

[Closed]

Radiation Protection

RP-1 (1) NUREG-1520, Section 4.4.3.3, Bullet 5 states that an application is acceptable if it "describes the minimum training requirements and qualifications for the radiation protection staff." Sections 2.3.3 and 4.3 contain commitments pertinent to this requirement, but these sections do not appear to adequately address the minimum training and qualification for radiation protection staff other than the RPM and ESHM. Revise Section 4.3 of the application to clarify the training requirements and qualifications for other radiation protection staff. This is needed to assure compliance with 10 CFR 40.32(b).

RP-2 (2) NUREG-1520, Section 4.4.5.3, Bullet 6 states that an application is acceptable if it commits to "evaluate the effectiveness and adequacy of the training program curriculum and instructors." The application indicates that the training program curriculum is reviewed bi-annually and tests are given to verify the effectiveness and adequacy of training; however, it is unclear how the applicant verifies the effectiveness and adequacy of the instructors. Clarify in Section 4.5, or a subsection, whether the evaluation for effectiveness is addressed in Section 11.3.8 of the application or if another process is utilized. This is needed to assure compliance with 10 CFR 40.32(b).

RP-3 (3) NUREG-1520, Section 4.4.7.3, Bullet 9 states that an application is acceptable if it commits to "implement the facility's corrective action program when the results of personnel monitoring or contamination surveys exceed the applicant's administrative personnel contamination levels." Although the application addresses corrective actions in the event of personnel contamination (Section 4.7.10), it does not appear to adequately discuss documentation of such events, determination and rectification of causes, and tracking and trending of occurrences. Revise Section 4.7.10 of the application to provide additional clarification regarding tracking and trending of personnel contamination events and when causes of contamination will be investigated and rectified. This is needed to assure compliance with 10 CFR 40.32(c).

RP-4 (4) NUREG-1520, Section 4.4.7.3, Bullet 12 states that an application is acceptable if it commits to "establish policies to ensure equipment and materials removed from restricted areas to unrestricted areas are not contaminated above the specified release levels in NRC Branch Technical Position, "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material, April 1993." The required reference is present in Section 4.7.13 of the application but so is reference to the use of ANSI/HPS N13.12. ANSI/HPS N13.12 is not sufficient to demonstrate regulatory compliance for generic clearance of materials. Provide the specific criteria suitable for volumetric clearance of a product stream or waste stream along with possible uses and/or excluded uses of the material. The justification for the criteria should include sufficient detail to determine that clearance determinations are suitable for the intended final use of the material. This is needed to assure compliance with 10 CFR 40.32(d) and 10 CFR 20.1302.

RP-5 (5) NUREG-1520, Section 4.4.7.3, Bullet 13 states that an application is acceptable if it commits to "Leak-test all sealed sources in accordance with the following NRC Branch Technical Positions: (1) "License Condition for Leak-Testing Sealed Byproduct Material Sources," April 1993, (2) "License Condition for Leak-Testing Sealed Plutonium

Sources," April 1993, (3) "License Condition for Plutonium Alpha Sources," April 1993, (4) "License Condition for Leak-Testing Sealed Source Which Contains Alpha and/or Beta-Gamma Emitters," April 1993, and (5) "License Condition for Leak-Testing Sealed Uranium Sources," April 1993." The applicant proposes to perform leak tests consistent with guidance in International Organization for Standardization (ISO) 2919:1999 as per Section 4.7.14 of the application. In addition to compliance with the ISO guidance, provide administrative limits, the required actions if the administrative limits are exceeded, and the frequency of leak tests. These commitments should be consistent with the branch technical positions (BTPs) cited in NUREG-1520. Please revise Section 4.7.14 of the application to address this topic. This is needed to assure compliance with 10 CFR 31.5 and 10 CFR 20.1501(a)(2).

RP-6 (7) In Section 4.2.3 of the license application, the applicant references several Regulatory Guides as the basis upon which the facility's as low as is reasonably achievable (ALARA) Committee formulates its goals. This list notably excludes Regulatory Guide 4.21, "Minimization of Contamination and Radioactive Waste Generation: Life-Cycle Planning." Revise this section to incorporate Regulatory Guide 4.21 as a guidance document for the facility's ALARA Committee or else provide additional descriptions that demonstrate how the facility design and procedures for operations will minimize contamination and the generation of radioactive waste. This is needed to assure compliance with 10 CFR 20.1406.

RP-7 (8) In Section 4.4.1 of the license application, the applicant states that "routine work involving licensed materials will be administered by the use of approved written practices and procedures as described in Chapter 11, Management Measures." Please provide the specific citation in Chapter 11 so that this statement can be verified. This is needed to assure compliance with 40.32(c).

RP-8 (9) In Section 4.6.1 and applicable subsections of the license application, the applicant discusses the ventilation design and effluent treatment systems. Notably absent in this discussion is any commitment to design the ventilation system so that air flow will be from areas of low contamination potential towards areas of higher contamination potential (although it is present in Section 4.7.8 "Minimization of Contamination"). Also, the application states that general ventilation systems for areas where U is processed or handled consists of a series of fresh air intakes and a series of roof exhaust fans. Revise this section to include discussion on how the ventilation design will contribute to contamination control and how the applicant plans to monitor for effluents such as the general ventilation roof exhaust for radioactive materials (e.g., consistent with Regulatory Guide 4.16). This is necessary to assure compliance with 10 CFR 20.1101(d) and 10 CFR 20.1406.

RP-9 (10) While the commitments in Chapter 4 of the license application generally address the radiological concerns for uranium, there is no discussion of evaluations of plant processes which may concentrate uranium daughter products and other radiological contaminants. Describe how IIFP plans to evaluate these situations so that the proper administrative controls and methods for monitoring are in place should non-uranium radioactive materials become a concern (e.g., thorium and radium isotopes)? Revise the appropriate sections of the license application to address this topic. This is necessary to assure compliance with 10 CFR 20.1204.

RP-10 (11) In Section 4.7.4.1 of the application, it is not specified whether the applicant will be running the bioassay laboratory or if the samples will be sent to a qualified contract laboratory. Revise this section to state how bioassay samples will be processed and what performance standards the bioassay laboratory will be held to (e.g., ANSI/HPS N13.22, ANSI/HPS N13.30, etc.). This is necessary to assure compliance with 10 CFR 20.1204.

RP-11 (12) In Section 4.7.4.2 of the application, it is not specified whether the applicant will be running the *in-vivo* lung counting equipment or if a qualified contractor will be performing this work. Revise this section to state how *in-vivo* lung counting will be performed and what performance standards the process will be held to (e.g., ANSI/HPS N13.35 or similar). This is necessary to assure compliance with 10 CFR 20.1204.

RP-12 Please provide information regarding ventilation rates, return air fractions, room volumes, and licensed material inventories by room/area sufficient to estimate the impact of releases of licensed materials inside the facility to workers. This is needed to verify accident analyses performed to support the ISA and confirm compliance with 10 CFR 70.61.

RP-13 (6) Section 4.6.1.3 of the application (last sentence) indicates that ventilation design criteria that are intended to assure that airborne concentrations do not exceed derived air concentration (DAC) values in International Commission on Radiological Protection (ICRP)-68. This appears to be the only reference to the use of ICRP-68 DAC and ALIs in the license application. The use of ICRP-68 instead of the values in 10 CFR 20, Appendix B requires granting an exemption to the regulations. Consistent with NUREG-1520 Revision 1, Section 1.2.3 “Areas of Review” and Section 1.2.4.3.5 “Special Exemptions or Special Authorizations,” describe the exemptions that will be requested. In addition, clarify whether INIS does not intend to request exemption from the labeling requirements in 10 CFR 20.1904.

RP-14 Section 3 of the application (last paragraph of the introductory material), states that “hazardous chemicals will be [considered] separated from licensed materials if the source material...is less than 0.05 percent of the total weight of the chemical mixture.” This Part 40 criterion appears to have been based on national security interests and, by itself, may not be an acceptable release criterion for public health and safety. As such, it should not be used as a release criterion for materials separated from licensed material. However, LA Section 4.7.13, references ANSI/HPS N13.12 (presumably 30 pCi/g U) as an alternate release criterion. Define a consistent release criterion throughout the application and provide a justification for the criterion based on public health and safety. This is needed to assure compliance with 10 CFR 70.62, 10 CFR 20.1101, and consistency with guidance established in NUREG-1520, Section 4.4.7.3 bullet 12 and Regulatory Guide 8.24.

Chemical Process Safety

[CLOSED]

Fire Safety

FS-1 [CLOSED]

FS-2 [CLOSED]

FS-3 [CLOSED]

FS-4 [CLOSED]

FS-5 [CLOSED]

FS-6 [CLOSED]

FS-7 [CLOSED]

FS-8 [CLOSED]

Chapter 7.0 Fire Safety

FS-9 Table 7-1, p. 7-1

Provide reference to the individual edition for each of the various NFPA Standards that INIS is committed to following. Although there is reference to the “most current versions” of NFPA standards, this implies that the editions committed to would change over time ,which would present an unnecessary burden to both the NRC and INIS.

The regulation 10 CFR 40.32(c) requires the applicant to provide equipment, facilities, and procedures which are adequate to protect health and minimize danger to life and property.

Emergency Management

These RAIs are based on a review of the IIFP FEP/DUP Emergency Plan (ML100130106) dated December 26, 2010. The following information is needed to demonstrate compliance with 40.31(j) and the acceptance criteria in NUREG-1520 Revision 1, Section 8.

EM-1 (EM-1) Consistent with the acceptance criteria in Section 8.4.3.1.9, provide the following information: Based on the close proximity of the Cunningham Station (0.6 miles), are there plans and/or methods available to notify the Cunningham Station personnel in the event of an emergency classification and/or possible release of chemicals/radioactive materials?

EM-2 [CLOSED]

EM-3 [CLOSED]

EM-4 [CLOSED]

Environmental Protection

General Overview:

Section 9 of the LA generally follows the acceptance criteria found in the SRP, (NUREG-1520). However, Section 9 of the applicant's LA, together with the numerous references to other sections of the LA and the ER do not provide a sufficient standalone description of the environmental protection program. To be sufficient, references to chapters of the ER and other sections of the LA must focus on specific subchapters of the ER and subsections of the LA—rather than on whole topic areas—which, in some cases, are over 100 pages. For example, references must point to specific tables and figures, as appropriate, particularly when citing numeric values or equipment locations (e.g., monitoring locations). Modifications based on the following RAIs will provide greater transparency and traceability of technical presentations, facilitate a timely document review process, assure that Section 9 of the LA is complete and accurate, and allow the lay reader to follow the discussion better.

EP-1. Section 9.2.1, Radiation Safety. Please specifically identify each of the various subsections of the LA and ER that contain supplemental information related to the four acceptance criteria for Radiation Safety referenced in LA Section 9.2.1. Since the supplemental information is referenced in the individual subjects identified within LA Section 9 (e.g., under the individual headings in Sections 9.2.1.1 and 9.2.1.2), add a new last sentence to Section 9.2.1 similar to the following: "Specific references to the supplemental information are provided below, as appropriate."

Section 9.4.3.2.1 of the SRP, NUREG-1520, addresses Radiation Safety Program in accordance with 10 CFR 20.1101.

EP-2. Section 9, Environmental Protection - Section 9 of the applicant's LA relies heavily on references to the ER. Since the ER is not part of the LA, ensure that references to the ER are only used to provide additional information and do not contain commitments.

10 CFR 40.32(c) requires the application to contain adequate commitments to protect health and minimize danger to life and property.

EP-3. Section 9.2.1.1, Radiological (ALARA) Goals for Effluent Control – This subsection states that ALARA Goals are typically 10-20 percent of the 10 CFR 20 Appendix B values. Please provide the specific ALARA Goals for air and liquid effluents and provide a more specific reference to LA Section 4; provide a more detailed discussion regarding how compliance with ALARA goals is demonstrated by discussing how each of the listed items (monitoring, analysis, and evaluations) contributes to compliance; and as part of that discussion, include greater detail addressing each of the three numbered items in LA Section 9.2.2.1 that are to be evaluated in order to assess trends.

Section 9.4.3.2.1(1) of the SRP, NUREG-1520, provides that ALARA goals are to be set at a modest fraction (from 10-20%) of the 10 CFR 20, Appendix B values.

EP-4. Section 9.2.1.2, Effluent Controls to Maintain Public Doses ALARA – Please provide more specific references to subchapters within ER Chapters 2 and 6, and provide relevant tables or figures, if any (e.g., facility diagram of referenced equipment or buildings). Section 9.4.3.2.1(2) of the SRP, NUREG-1520, provides that the applicant

describe and commit to the use of effluent controls to maintain public doses ALARA in accordance with 10 CFR 20.1101.

EP-5. Section 9.2.1.3, ALARA Reviews and Reports to Management – Section 9.4.3.2.1(3) of the SRP, NUREG-1520, provides, among other things, that the applicant commit to report the results of the annual review of the ALARA effluent control program to senior management. Please identify the senior management to whom the results of the ALARA review are reported. Also, provide a more specific reference to subsections within LA Section 4.

EP-6. Section 9.2.1.4, Waste Minimization – Please identify and, if appropriate, provide a specific description of waste-minimization systems and operational procedures regarding conservation and recycling important compounds. Also, please identify the waste minimization practices that are consistent with Regulatory Guide 4.21.

Section 9.4.3.2.1(4) of the SRP, NUREG-1520, identifies, among other things, the elements of an acceptable waste minimization program under 10 CFR 20.1406.

EP-7. Section 9.2.2, Effluent and Environmental Controls and Monitoring – Please identify or provide specific cross references to the subchapters of the ER and subsections of the LA that identify the effluent and environmental controls that are at and around the facility. Also, please provide a specific description of the portions of the Radiation Protection Plan (RPP) that address environmental protection.

Section 9.4.3.2.2(1) of the SRP, NUREG-1520, identifies, among other things, the criteria of an acceptable effluent monitoring program.

EP-8. Section 9.2.2.1, Expected Concentrations – Please identify the concentrations, calculations, and modeling of airborne and solid radioactive materials listed in this section. If available, provide specific references to the ER and LA subsections (including specific tables or Figures) which contain the information. Also, please identify or reference the conservative assumptions used in calculations and modeling of those concentrations.

Section 9.4.3.2.2(1)(a) of the SRP, NUREG-1520, identifies Expected Concentrations for effluent monitoring that are to be below limits specified in 10 CFR 20, Appendix B.

EP-9. Section 9.2.2.1, Calculations of Total Effective Dose Equivalent – It appears that compliance with dose limits for individual members of the public is demonstrated by calculation of the Total Effective Dose Equivalent (TEDE) as opposed to calculation of annual average concentrations of radioactive material released. Please provide more detailed discussions of the calculation of the TEDE by pathway analyses to demonstrate that the appropriate models, codes, and assumptions accurately represent the facility, site, the surrounding area, and the pathways considered. Also, please provide citations to any relevant tables and discussion within the ER, e.g., Subsection ER-4.12.

Section 9.4.3.2.2(1)(b) of the SRP, NUREG-1520, identifies Calculations of Expected Dose for effluent monitoring within limits in 10 CFR 20.1301 through calibrations identified in 10 CFR 20.1302.

EP-10. Section 9.2.2.1, Effluent Discharge Locations – Please identify the locations of airborne effluent discharges and monitoring. Also identify contributing sources, if any, for discharge points.

Section 9.4.3.2.2(1)(c) of the SRP, NUREG-1520, addresses Effluent Discharge Locations for effluent monitoring.

EP-11. Section 9.2.2.1, Continuous Sampling Airborne Effluents – Briefly summarize relevant portions of ER Chapter 6 that are referenced. Please define (quantify) what is meant by "significant" regarding increases in radiation levels that would trigger additional analyses. Also, please summarize (briefly) the purpose of the Effluent Monitoring Program (EMP), and provide a more specific reference to subchapters within ER Chapter 6 where the EMP is discussed.

Section 9.4.3.2.2(1)(d) of the SRP, NUREG-1520, addresses Continuous Sampling Airborne Effluents for effluent monitoring under the Radiation Protection Program under 10 CFR 20. 1101.

EP-12. Section 9.2.2.1, Sample Collection and Analysis – Please clarify what is meant by the term "appropriate" sample collection and analysis methods and frequencies for the effluent medium and indicate the radionuclides sampled. Provide a brief summary of the EMP that addresses sample collection and analysis and frequencies.

Section 9.4.3.2.2(1)(e) of the SRP, NUREG-1520, addresses Sample Collection and Analysis for effluent monitoring.

EP-13. Section 9.2.2.1, Radionuclide-Specific Analysis – Specify that plant preventive maintenance procedures will be maintained onsite and implemented. Specify where monitoring reports are discussed. Alternatively, briefly summarize what is meant by the term, summary reports. Also, in the second paragraph, clarify what is meant by "a significant increase" in gross radioactivity. Briefly summarize relevant portions of ER Chapter 6.1.1.

Section 9.4.3.2.2(1)(f) of the SRP, NUREG-1520, addresses Radionuclide-Specific Analysis for effluent monitoring.

EP-14. Section 9.2.2.1, Minimum Detectable Concentrations – Please provide a more specific reference to subchapters within ER Chapter 6. Provide a summary of relevant portions of Chapter 6 that are referenced.

Section 9.4.3.2.2(1)(g) of the SRP, NUREG-1520, addresses Minimum Detectable Concentrations for effluent monitoring for concentrations in 10 CFR 20, Appendix B.

EP-15. Section 9.2.2.1, Action Levels – Please identify the specific action levels. Also, identify any steps involving effluent monitoring that would be taken before shutdown.

Section 9.4.3.2.2(1)(i) of the SRP, NUREG-1520, addresses Action Levels for effluent monitoring.

EP-16. Section 9.2.2.1, Federal and State Standards for Discharges – Please define the term, "air-contaminant source." Also, provide a specific reference to the ER subchapter that provides the status of all Federal, State, and local requirements.

Section 9.4.3.2.2(1)(j) of the SRP, NUREG-1520, addresses Federal and State Standards for Discharges for effluent monitoring.

EP-17. Section 9.2.2.1, Waste Management Procedures – If possible, specify the Low Level Waste disposal site that may be used. Please provide a reference, include any figures, to the plant description in the LA or ER that contains the waste management facilities, as discussed in paragraph 2 of this section.

Section 9.4.3.2.2(1)(n) of the SRP, NUREG-1520, addresses Waste Management Procedures for effluent monitoring.

EP-18. Section 9.2.2.2, Environmental Monitoring - Environmental Monitoring is mislabeled as merely being one of several topics under Section 9.2.2.1, Effluent Monitoring. Instead, Environmental Monitoring should be identified separately as the second subsection under Section 9.2.2, Effluent and Environmental Controls and Monitoring. Because Environmental Monitoring is the second part of Section 9.2.2, it should be numbered separately as Subsection 9.2.2.2.

Section 9.4.3.2.2(2)of the SRP, NUREG-1520, addresses Environmental Monitoring.

EP-19. Section 9.2.2.2, Environmental Monitoring – As noted above, Section 9.2.2.2 should have been the location within the LA to describe Environmental Monitoring. LA Section 9.2.2.1, Effluent Monitoring, identifies 14 topics related to the effluent monitoring acceptance criteria. The acceptance criteria closely track the topic headings identified in Section 9.4.3.2.2(1) of the SRP, (NUREG-1520). However, Environmental Monitoring, which should have been numbered as LA Section 9.2.2.2, did not identify the 9 SRP topics related to the environmental monitoring acceptance criteria. LA Section 9.2.2.2 only identified two SRP topics in a very brief and conclusory manner. These two topics only touch lightly on a few of the remaining (missing) topics. Provide additional discussion to address all of the nine SRP topics and provide additional specific cross-referencing.

Environmental Monitoring acceptance criteria in Section 9.4.3.2.2(2) of the SRP (NUREG-1520), which are labeled as being (a) through (i), address the specific information needed in the Effluent Monitoring section of the LA, as discussed above. Provide a brief summary for each of these, as well as a cross-reference to the appropriate LA or ER subsections or subchapters that provide the needed additional detail. Note that it appears that some criteria are not addressed at all (e.g., (d) analytical methods and instrumentation, maintenance and calibration program, (e) action levels and actions to be taken, (f) identify MDCs for Environmental Monitoring that are at least as low as those for Effluent Monitoring for air and water (g) data analysis methods and criteria, and (i) adequacy of environmental data to assess impacts from any releases identified in the ISA). Please provide this missing information.

Section 9.4.3.2.2(2) of the SRP, NUREG-1520, addresses Environmental Monitoring under 10 CFR 20.

EP-20. Section 9.2.3, Integrated Safety Analysis (ISA) – Clarify whether the IROFS also address the consequences of accidental releases on the environment outside the site boundary. Briefly summarize accidents that could impact the members of the public located outside the facility boundary and any associated IROFS; provide appropriate specific references to the ISA.

Section 9.4.3.2.3 of the SRP (NUREG-1520) addresses environmental protection in the ISA.

Decommissioning

The following information is necessary for INIS to demonstrate compliance with 10 CFR 40.36(a), (c)(1), and (d).

D-1. In Section 10.1.3.8 of the application, INIS states that evaluation of the final radiation survey is based in part on an initial radiation survey performed prior to operations. The initial survey determines the natural background radiation of the area; therefore, it provides a baseline datum for measurements which determine any increase in levels of radioactivity. This initial radiation survey is not described in the application. Since uranium-238 and its decay products are likely to be present in the background, perform a baseline environmental survey of the site that is adequate to stand as a valid background survey for eventual decommissioning.

D-2. In the Environmental Report, Section 6.1.2, "Radiological Environmental Monitoring Program" (REMP), INIS describes the REMP and proposes to initiate it at least 12 months prior to plant operations. However, the REMP includes only five soil samples and does not identify the isotopes for which the samples will be analyzed. NUREG-1757 (see reference below) includes guidance for determining background radiation. Consistent with the guidance in NUREG-1757, demonstrate a more rigorous initial survey than that described in the application and ER. Provide the sampling locations inside the footprint of the buildings and along the perimeter. Also identify the isotopes for which the soils will be analyzed.

The following NRC references contain NRC guidance for determining background radiation and selecting background reference areas:

- NUREG-1757, Consolidated Decommissioning Guidance, Volume 2 Characterization, Survey, and Determination of Radiological Criteria, Volume 2, Revision 1, September 2006;
- NUREG-1505, A Nonparametric Statistical Methodology for the Design and Analysis of Final Status Decommissioning Surveys, Revision 1, June 1998, Section 2.2.5; and
- NUREG-1575, Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM), Revision 1, August 2000, Section 4.5.

D-3. Section 10.1.3.8, Final Radiation Survey, of the LA describes the initial survey and a final survey that will systematically measure radioactivity over the entire site. Tables 10-10, 10-11, and 10-12 of the LA do not specifically include a final survey of site soils. Notes 1 and 2 to these tables state that there is a low likelihood of contaminating the facility grounds at levels that would require excavation or restoration, and small spills will be cleaned immediately.

Specify that the final status survey will be designed to detect any unreported spills and any generalized contamination that might accumulate over the period of operation of the facility. Identify the parameters or isotopes for which the grid samples will be analyzed, and describe how these results will be compared to the initial survey results to demonstrate that the site is suitable for unrestricted release. Revise the Decommissioning Cost Estimate (DCE) to include costs for designing and performing a final survey of the site.

Financial Assurance

The financial assurance requirements for source material licensees, among others, are located in 10 CFR 40.36, 10 CFR 40.42 and the Consolidated Decommissioning Guidance contained in NUREG 1757. The following information is needed to demonstrate compliance with the acceptance criteria in NUREG-1757 and the regulatory requirements in Part 40. Consistent with 10 CFR 40.32, 10 CFR 40.42, and NUREG-1757, please provide the following information:

FA-1 Clarify that the DCE uses the following: a) independent third-party labor costs and; b) that all third-party labor costs, including profit, are presented (NUREG-1757, Volume 3, Appendix A, Pages A-26 to A-28).

A. Neither the Major Assumptions (§ 10.2.2.2) nor Table 10-14 "Worker Unit Cost Schedule" state explicitly that all labor costs are based on a third-party contractor performing the work. Section 10.1.2.4 "Management Organization," states the following:

> IIFP intends to be the Prime Decommissioning Operations Contractor (DOC) responsible for decommissioning the FEP/DUP. In this capacity, IIFP will have direct experience with the plant operations and have control and oversight over all decommissioning activities. IIFP also plans to secure contract services to supplement its capabilities, as necessary.

NUREG-1757 states that "[e]stimated costs should be based on reasonable and documented assumptions, and provide sufficient funds to allow an independent third party to assume responsibility for and carry out the decommissioning of the facility if the licensee is unable to do so." (A-27) However, it is unclear whether the DFP submitted by IIFP is based on independent third-party costs, and the material quoted above suggests that it is not. If the DFP is based on third-party labor costs, state that fact explicitly as one of the assumptions. Otherwise, revise the cost estimate to ensure that it is based on the costs of an independent third-party contractor performing the work.

B. NUREG-1757 states that labor cost estimates include basic wages and benefits, overhead costs, and profit "sufficient to allow an independent third party to carry out the decommissioning project." (A-28) Although Table 10-14 provides amounts for "salary and fringe" for eight separate labor categories and adds a 25 percent "overhead rate," there is no indication that profit for a third-party contractor is included in the estimated labor costs. Clarify whether an estimate for third-party contractor profit is included in the "overhead rate;" and if it is not, add a reasonable estimate for profit to the estimated labor costs in the DFP.

FA-2 [CLOSED]

FA-3 [CLOSED]

FA-4 [CLOSED]

FA-5 [CLOSED]

FA-6 Provide clarification in the application that the IIFP submittal does not include Phase 2.

The first paragraph of LA Section 10.1 states, “The Decommissioning Funding Plan addresses the overall strategy for decommissioning the entire Phase 2 facility.” This sentence gives the erroneous impression that Phases 1 and 2 of the facility are both included in the current decommissioning plan. The statement in the last sentence of the first paragraph in Section 10.1 which states, “Expansion of the plant to Phase 2 will require amendments to the IIFP license,” does not provide adequate clarification that Phase 2 is not under consideration in this license application. Consistent with the requirements in 10 CFR 40.36, explain explicitly that no portion of Phase 2 is under consideration as part of the current license application, and as such does not need to be addressed as part of the current Decommissioning Plan. Remove or clarify the discussion of Phase 2, particularly the first sentence of Section 10.1, to overcome the impression that Phase 2 is part of the current submittal.

FA-7 [CLOSED]

FA-8 Provide draft text of the proposed financial instruments, including an appropriate financial assurance mechanism as detailed in 10 CFR 40.36(e), standby trust agreement (if required by the assurance mechanism selected), and certification of financial assurance.

Financial assurance for decommissioning must be provided by one or more of the methods as set forth in 10 CFR 40.36(e). In addition, 10 CFR 40.36(d) states that a Decommissioning Funding Plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate. LA Section 1.2.2 states, “IIFP presently intends to utilize a surety bond and Standby Trust Fund method to provide reasonable financial assurance of decommissioning funding….” To avoid duplication of effort and expense, provide draft text of the proposed financial instruments, including an appropriate financial assurance mechanism as detailed in 10 CFR 40.36(e), standby trust agreement (if required by the assurance mechanism selected), and certification of financial assurance.

Quality Assurance (Management Measures)

QA-1 (QA-2) In the fourth paragraph of the introduction of Section 11, "Management Measures" the application states, "The provisions contained in this QA Program Description are applicable during design and construction of the IIFP Facility for design activities taking place beginning on the date the DB contactor assumes the detailed design and engineering role and establishes the design organization and controls during design and construction phase of the IIFP Facility beginning on the date the DB contactor assumes the detailed design and engineering role and establishes the design organization and controls." Consistent with 10 CFR 70.64, "Safety program and integrated safety analysis," clarify this sentence and its intent and correct the editorial errors. In addition, clarify if the provisions in Chapter 11 or the Quality Assurance Program Description (QAPD) just applicable to design and construction? What documents will be applicable to operations?

QA-2 (QA-4) In the fifth paragraph of the introduction of Section 11, "Management Measures" the application states, "The COO/PM is responsible for implementing and maintaining the management systems for the operating facility." Consistent with the acceptance criteria in NUREG-1520 Revision 1, Section 11.4.3.1, in the first three bullets, clarify the wording management systems.

QA-3 (QA-5) In the second paragraph of Section 11.1.1, "Configuration Management Policy," the application states, "In addition, the applicant will identify design documents that provide design input, analysis and results specifically for IROFS with the appropriate QA level." Consistent with the acceptance criteria in NUREG-1520 Revision 1, Section 11.4.3.8, in the third bullet, describe the intent of this sentence and provide a description of the QA Levels.

QA-4 (QA-7) In Section 11.1.1.4, "Organizational Structure and Staffing Interfaces," the applicant states, "The various IIFP departments and contractors of IIFP perform quality-related activities." Consistent with the acceptance criteria in NUREG-1520 Revision 1, Section 11.4.3.8, clarify the meaning of this sentence and provide a description of these quality-related activities.

QA-5 (QA-8) Consistent with the acceptance criteria in NUREG-1520 Revision 1, Section 11.4.3.1 and Section 11.5.1.3, provide the following information:

a In Section 11.1.2, "Design Requirements," the application states, "The associated design documents are subject to interdisciplinary reviews and design verification. Changes to the design are evaluated to ensure consistency with the design basis." Clarify if these sentences are referring to IROFS or QL-1 or QL-2 items.

b (QA-9) In Section 11.1.2, "Design Requirements," the application states, "During the check and review, emphasis is placed on assuring conformance with applicable codes, standards and LA design commitments." Clarify the meaning of "check and review." To which documents the sentence is referring?

c (QA-10) In Section 11.1.2, “Design Requirements,” the application states, “In accordance with these procedures, the report is forwarded for appropriate review to the responsible manager….” Clarify to which report the sentence refers to.

QA-6 (QA-14) In Section 11.2.2.4, “Functional Testing – Post-Maintenance Testing,” the application states, “This test is performed, with acceptable results, prior to returning the equipment into service.” Consistent with the acceptance criteria in NUREG-1520 Revision 1, Section 11.4.3.2, clarify the intent of this sentence. For example, what happens if the test fails or the results are not acceptable?

QA-7 (QA-21) Section 11.3.8, “Evaluation of Training Effectiveness,” includes the statement, “Unacceptable individual performance is transmitted to the appropriate line manager.” Consistent with the requirements in NUREG-1520 Revision 1, Section 11.4.3.3, clarify if this statement is misplaced in this section instead that in Section 11.3.10, “Periodic Personnel Evaluations/Needs for Retraining.”

QA-8 (QA-25) Section 11.5.3 of the application, “Conduct of Audits and Assessments,” states, “Audits are conducted on an annual basis.” Section 11.5.5, “Scheduling of Audits and Assessments,” states “The frequency of audits and assessments is based upon the status and safety importance of the activities being performed and upon work history.” Consistent with the requirements in NUREG-1520 Revision 1, Section 11.4.3.5, modify sections as necessary to make them consistent with each other.

QA-9 (QA-27) Section 11.7 of the application, “Records Management and Document Control,” states, “The principal elements of each of the records management and document control programs and a brief description of the manner in which the functions associated with each element shall be performed along with a list of the types of records that are retained for the duration of the NRC license at the site.” Consistent with the requirements in NUREG-1520 Revision 1, Section 11.4.3.7, clarify the meaning of this sentence.

QA-10 (QA-6) In Section 11.1.1.1, “Scope of Structures, Systems, and Components,” the application states, “These documents include documentation related to IROFS that is generated through functional interface with QA, maintenance, and training and qualifications of personnel. Consistent with 70.62(d), clarify why other management measures (e.g., procedures, incident investigations, audits and assessments, and records management) are not mentioned.

QA-11 (QA-11) In Section 11.1.4, “Document Control,” the application states, “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.” Consistent with Section 11.4.3.1 of NUREG-1520, “Configuration Management,” clarify that the following documents are included in this description: ISAs, all procedures that are 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.

QA-12 (QA-15) Section 11.2.2.4, “Functional Testing,” includes the requirements for functional testing, pre-operational testing and post maintenance testing. Consistent with the

acceptance criteria in NUREG-1520 Revision 1, Section 11.4.3.2, clarify if there will be periodic or special testing as part of the maintenance program.

QA-13 Section 11.2, “Maintenance,” outlines the maintenance program to be implemented in the operations phase of the facility. Consistent with Section 11.4.3.2 of NUREG-1520, “Maintenance,”

i. (QA-16) Clarify how the maintenance function uses, interfaces with, or is linked to the various management measures.

ii. (QA-17) Provide justifications for assignment of differing degrees of maintenance to individual IROFS based on the item’s contribution to the reduction of risk.

QA-14 (QA-19) Section 11.3.1, “Organization and Management of Training,” states, “Training records are maintained to support management information needs associated with personnel training, job performance, and qualification.” Consistent with Section 11.4.3.3 of NUREG-1520, “Maintenance,” clarify if programmatic and individual training records will be maintained.

QA-15 (QA-22) Section 11.4.1.2, “Administrative Procedures,” provides a list of the activities that will be covered by administrative procedures. Consistent with Section 11.4.3.4 of NUREG-1520, “Maintenance,” clarify if existing or planned procedures will direct the following activities: construction, radiation safety, and criticality safety.

QA-16 (QA-23) Section 11.4.1.3, “Maintenance Procedures,” describes the controls for the maintenance procedures. Consistent with Section 11.4.3.4 of NUREG-1520, “Maintenance,”

i. Clarify if pre-maintenance activities will involve reviews of the work to be performed, including procedure reviews for accuracy and completeness.

ii. Clarify if the maintenance procedures will include the procedure steps that will require notification of all affected parties before performance of work and on completion of maintenance of work, including the discussion of potential degradation of IROFS during planned maintenance.

QA-17 (QA-28) Section 11.7.1. “Records Management,” establish the elements and requirements of the records management program applicable to QA Level 1 and QA Level 2 Structure, System, and Components and activities; or to ESH, financial, quality, emergency response or investigation related records as required by regulations or approved procedures. In accordance with Section 11.4.3.7 of NUREG-1520, “Records Management,”

i. Please clarify if there are implementing procedures that: (1) assign responsibilities for records management; (2) specify the authority needed for records retention or disposal; (3) specify which records must have controlled access and provide the controls needed; (4) provide for the protection of records from loss, damage, tampering, and theft or during an emergency; and (5) specify procedures for ensuring that the records management system remains effective.

ii. Please clarify if records of IROFS failures will be maintained and updated in accordance with 10 CFR 70.62(a)(3).

QAPD-1 The QAPD does not address requirements for criteria such as Control of Special Processes; Test Control; and Inspection, Test, and Operating Status. Consistent with -NUREG-1520 Revision 1, Section 11.4.3.8, please clarify if the application of these measures to IROFS are appropriate.

QAPD-2 Section A.7.1.3.3 of the Quality Assurance Program Description states that "The criteria and methods shall identify the critical characteristics that are essential to ensure the item will perform its intended IROFS function." Consistent with 10 CFR Part 21, "Reporting of Defects and Noncompliance," dedication occurs after receipt when the item is designated for use as a basic component. Please clearly describe the dedication process; and, if critical characteristics will be verified, please identify those methods.

Material Control and Accounting

MCA-1 10 CFR 40.64 details the requirements for reporting to the Nuclear Materials Management and Safeguards System for Part 40 licensees. Please describe how these requirements will be met and where adherence to these requirements will be documented.

MCA-2 Also, describe how material subject to the requirements of 10 CFR 40.64 will be tracked and accounted for to provide the reports required under these regulations.

Seismic/Structural

[CLOSED]

Security Plan

[CLOSED]