July 19, 2010

MEMORANDUM TO: Thomas G. Hiltz, Chief
Advanced Fuel Cycle, Enrichment,
and Uranium Conversion Branch
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

FROM: Matthew A. Bartlett, Project Manager **/RA/**
Advanced Fuel Cycle, Enrichment,
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Division of Fuel Cycle Safety
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Office of Nuclear Material Safety
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SUBJECT: JUNE 22, 2010 CONTINUED JUNE 24, 2010, CALL SUMMARY REGARDING DISCUSSION OF DRAFT REQUESTS FOR ADDITIONAL INFORMATION WITH INTERNATIONAL ISOTOPES INC. (TAC NO. L32739)

The U.S. Nuclear Regulatory Commission (NRC) held a conference call with International Isotopes Inc. (INIS) and their contractor on June 22, 2010, and continued on June 24, 2010. The calls were to discuss draft requests for additional information (RAIs) regarding the safety review of the INIS application. The NRC provided draft RAIs to the applicant prior to the call in order to facilitate the discussions. The calls were designed to ensure the applicant understands the RAIs and incorporate any needed clarifications into the formal RAIs. The calls addressed the following areas of review: General Information, Organization and Administration, Financial Assurance (FA), Material Control and Accounting (MC&A), and Quality Assurance (QA).

Several major issues were addressed during the call. INIS indicated they intend to fund their FA incrementally. The NRC reviewer indicated that this would require an exemption to Title 10 of the *Code of Federal Regulations* 40.36(d). Similar exemptions have been granted on a case-by-case basis in the past. The MC&A reviewer clarified that most of the depleted uranium processed by INIS is foreign obligated. As such, it must be tracked in the Nuclear Materials Management and Safeguards System. The QA reviewer indicated that the QA Program Description was being reviewed separately from chapter 11 of the license application. Several RAIs from that review would be provided to the applicant at a later date. These issues and other minor revisions will be incorporated into the formal RAIs.

CONTACT: Matt Bartlett, NMSS/FCSS
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Once INIS receives the formal RAIs, they have 30 days to provide a written response and updated application documents. The NRC indicated the updates should be provided using some form of track changes, e.g. Word track changes. INIS and the NRC agreed that any updates to the application should be submitted in sections, by chapters.

INIS reviewed this summary for factual correctness.

Docket No.: 40-9086

Enclosures: List of Participants
Draft Requests for Additional Information

cc w/enclosures:
John J. Miller, CHP
4137 Commerce Circle
Idaho Falls, ID 83401

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LIST OF PARTICIPANTS FOR TELEPHONE CONFERENCE TO DISCUSS REQUESTS FOR ADDITIONAL INFORMATION REGARDING INTERNATIONAL ISOTOPES, INC.'S PROPOSED DECONVERSION FACILITY JUNE 22 AND 24, 2010

NAME	AFFILIATION
Matt Bartlett	U.S. Nuclear Regulatory Commission (NRC)/Office of Nuclear Material Safety and Safeguards (NMSS)
Damaris Arroyo	NRC/NMSS
Roman Przygodzki	NRC/Office of Federal and State Materials and Environmental Management Programs
Tom Pham	NRC/NMSS
Steve Laflin	International Isotopes, Inc. (INIS)
John Miller	INIS
Jim Thomas	INIS/Contractor
et al.	INIS/Contractor

DRAFT REQUESTS FOR ADDITIONAL INFORMATION
FOR REVIEW OF THE INTERNATIONAL ISOTOPES FLUORINE EXTRACTION
AND DEPLETED URANIUM FACILITY

Regulatory Compliance

Title 10 of the *Code of Federal Regulations* (10 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 (SRP) for the Review of a License Application (LA) for a Fuel Cycle Facility. 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 (IIFP).

General Information

Minor Items to Address:

GI-1 Comparison between the topographical features in LA Figure 1-3 and 1-4 give 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 acres property on LA Figure 1-4, similar to LA Figure 1-3, to clarify how county section 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 The page numbering in the Environmental Report (ER) is not correct. Ensure proper page numbering.

GI-4 Integrated Safety Analysis (ISA) Summary Table 4-3 references release scenario evaluation number depleted uranium hexafluoride (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.

GI-6 The time frame listed for Figure 3-5 of the ER differs from the 1914-2006 date provided in the text. Explain/correct this discrepancy.

Major Items to Address:

GI-7 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 sections 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 confused 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. Modify the references to refer to 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 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, 3rd full paragraph contains a description of the exothermic reaction of Depleted Uranium Hexafluoride (DUF6) to Depleted Uranium Tetrafluoride (DUF4) and Anhydrous Hydrogen Fluoride (AHF). Consistent with NUREG-1520 section 1.1.4.3 (3), specify what reacts exothermically with the DUF6. Specify where this reaction takes place, i.e. in the DUF4 building, and specify which building listed in LA Table 1-2 contains the reaction vessel for this process.

GI-8 Requests for Additional Information: LA section 1.2.2 indicates IIFP plans to raise $75-90 million dollars through capital investors. Consistent with the acceptance criteria in NUREG-1520 1.2.4.3(2), provide a description of the financial qualifications which demonstrate the applicants current and continuing access to the financial resources necessary to conduct construction and begin operations.

GI-9 LA page 1-1 and 1-2 list the estimated average inventories for the major chemicals on site 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-1520 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 the DUF6 is vaporized via steam. State whether the DUF6 will be sublimed or pass through a liquid phase, and indicate the location and maximum quantity of liquid DUF6 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 (Tc-99) and transuranics will be present in the cylinder tails from previous operations.

D. Table 1-4 lists the uranyl fluoride (UO2F2) 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 describe 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: It is mentioned 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 UO2F2 is soluble, indicate the quantity of UO2F2 produced, the possible exposure to staff, and precautions implemented to prevent inadvertent exposure.

GI-10 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 IIFP will be the controlled area, e.g. 40 acres plot, in accordance with the definitions in 20.1003 "Controlled area." Clarify in the application whether the 640 acres, excluding the 40 acres plot, represents 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-11 Section 1.6.2.1-1.6.2.3 provides information on the local demographics. Consistent with the acceptance criteria in NUREG-1520 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 County 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, daycares,

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 which work at these facilities (for separate facilities and combined) and indicate how this number changes with shift.

GI-12 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 they have the correct sign.

B. The design basis precipitation is stated at 3.5-4in 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 the IIFP is not within the 500-year flood plain. In response to this RAI, provide the basis for this determination. Also, 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 the 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 national 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 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 tornadoes in the ISA.

F. In response to this RAI, provide information from the process hazard analysis (PHA) which demonstrates 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 two 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 accident analysis for a lightning strike at the IIFP is low consequence, taking into account the average yearly thunderstorms.

GI-13 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 section 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 third paragraph of page 2-1, first sentence.

OA-2 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-3 The acronym Environmental Safety and Health (ESH) is used on LA page 31 before it is defined on LA page 67. Ensure ESH is defined at its first use.

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

OA-5 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-6 LA Section 2.2.18 provides a description of the Industrial Safety and Hygiene function which does not provide much additional information, beyond what is already contained in the section title, i.e. in charge of industrial safety and hygiene. Consistent with NUREG-1520 section 2.4.3(1), either remove this individual from the key description list, or expand the description to demonstrate the key role of this individual in the plant organizations.

OA-7 Consistent with ANSI/ANS 3.1, in the RAI response, indicate if some amount of experience may be substituted for higher education.

OA-8 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 [RA]/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 resolved and documented prior to startup.

Major items to address:

OA-9 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 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 is outside the organizational structure of the IIFP. Consistent with NUREG-1520, 2.4.3(1) and (2), revise the reporting requirements so that ESH and QA report to an individual within the corporate structure.

Section 2.1.4 indicates the Chief Operations Officer (COO)/Plant Manager (PM) reports to the INIS President/CEO. This individual is outside the IIFP corporate structure. Consistent with NUREG-1520, section 2.4.3(2), revise the text in 2.1.4 to indicate 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), in the LA state 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-10 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 section 2.4.3(1) and 2.4.3(2), provide the following information.

A. In order 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 figure layout easier to read, etc. Any dual reporting listed in the figures must 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 LA 2-1 and 2-2, the "matrix role," to demonstrate the it provides "clear, unambiguous management controls and communications […] among organizations (NUREG-1520, Section 2.4.3(2)."

C. The application indicates the COO has the 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, and 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 figure 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 figure 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 parallels organizations.

D. During the DB phase, LA section 2.2.4 indicates the COO/CFPD is ultimately responsible for all activities, including QA. Section 2.2.1 – 2.2.3 describe other management individuals who are also responsible for these activities, e.g. RA/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.

E. In the application, clarify the role of the RAQD and the COO during the DB phase and operations phase regarding the oversight of the ESH and QA program.

OA-11 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 figure 2-1 and figure 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 ISA 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 <u>key positions</u> 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 aren't.

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. #15 LA sections 2.2.1 through 2.2.25 do not distinguish between design phase and 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 & 2-6 appears to match positions listed in LA figure 2-2. Ensure the management jobs listed in figure 2-2 match the positions contained in the bulleted list.

OA-12 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 to qualify to be 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.

B. LA section 2.2.4, in the first paragraph, the first few sentences describe the role of the COO/CFPD. The remainder of the paragraph shifts to a focus on CM, a term which does not appear to be defined in the paragraph. Based on the context, it appears CM stands for change management. Consistent with NUREG 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. Define the term CM.

C. The QA Coordinator 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-13 The description of the transition from DB 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 (SM). 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 SM is a standalone position or whether the role is filled by other managers for a limited time. If multiple individuals serve as the SM, 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 this 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 2.4.3 (2), clarify what happens to the CFO in the transition from design/build to organization.

C. LA section 2.1.3 in the 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 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.

Financial Assurance

The FA 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 decommissioning funding plan (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 Provide a more complete estimate of the amount of radioactive wastes that will require disposal (NUREG-1757, Volume 3, Appendix A, page A-27)

A. Tables 10-1 through 10-6 of the DFP provide volume estimates for individual components for each of the separate buildings at the facility. However, these tables do not sum these estimates to provide either a building-specific estimate or a comprehensive facility-wide total for the amount of low level radioactive waste (LLRW) that will need to be disposed as part of the decommissioning. Revise Tables

10-1 through 10-6 to provide a building-specific estimate of the total amount of LLRW and sum these to provide a comprehensive, facility-wide estimate of wastes that will need to be disposed during decommissioning;

B. Table 10-16 "Shipping and Disposal of Radioactive Wastes," provides the estimated costs of LLRW disposal for various floors of various buildings throughout the facility. Table 10-16 does not sum these estimates to provide building-specific disposal costs. In addition, the amounts of LLRW corresponding to the specified costs are not included in the table. Revise Table 10-16 to provide a building specific estimate of the total costs along with the corresponding quantity of LLRW, and sum these to provide a comprehensive, facility-wide estimate of the costs and wastes that will need to be disposed during decommissioning.

C. Furthermore, the relationship between the data in Tables 10-1 through 10-6 and the data in Table 10-16 is not easily discernable. As a result it is difficult to ascertain which data from Table(s) 10-1 through 10-6 provide a basis for the estimated LLRW volume and disposal costs listed in Table 10-16. (For instance, if Table 10-1 corresponds to the "DUF_4 Process Building 1st level" through "DUF_4 Process Building 5th level," the DFP should clearly state this.) (2)Clearly indicate which data from the supporting tables (e.g. 10-1 through 10-6), provide a basis for the estimated LLRW volume and disposal costs which will be listed in Table 10-16, once it is revised in accordance with b) above.

D. Section 10.1.3.7 of the DFP states that "[a] complete estimate of the wastes and effluent to be produced during decommissioning will be provided in the Decommissioning Plan that will be submitted prior to initiating the decommissioning of the plant" (page 10-8). However, the DFP is to represent the best estimate of the amount of wastes to be disposed at the time it is prepared, even if that estimate is later revised in the final Decommissioning Plan. As written, the above excerpt suggests that the current estimate is incomplete. Therefore, either revise the DFP so that it represents the best estimate of the amount of waste to be disposed, or if the DFP currently represents the best estimate revise the statement above to indicate that an updated estimate will be provided in the Decommissioning Plan.

FA-3 Provide a basis for the reduced size volume factors in Tables 10-1 through 10-6 (NUREG-1757, Volume 3, Appendix A, page A-27);

Section 10.1.4 of the DFP describes the decontamination and size reduction process that will be followed in decommissioning the facility. Section 10.1.4.2 states that the methodology will use "conventional" size reduction techniques and Section 10.1.4.4 states that "[c]ontaminated plant components will be processed through the size reduction packaging facilities." Tables 10-1 through 10-6 each contain a column for "Reduced Size Volume (ft^3)" indicating that some facility components will be reduced in volume by various amounts. However, the DFP does not contain any indication of the basis for the size reduction factors, which in some cases result in a substantial reduction in the volume of waste, including LLRW, to be disposed. NUREG-1757 states that the decommissioning cost estimate be based on "reasonable and documented assumptions." (A-27). Provide a documented basis for the size reduction factors used in the DFP.

FA-4 Provide a basis for the estimated labor costs for packaging in Table 10-13 (NUREG-1757, Volume 3, Appendix A, page A-27)

Four of the five decommissioning activities described in Table 10-13 "Total Work Days by Labor Category (Labor Days)" are supported by a preceding table providing a labor breakdown by activity or facility component. For example, Table 10-9, "Decontamination or Dismantling of Radioactive Components," provides information about the number of hours, for each of eight labor categories, allocated to work on each of 14 separate areas of the facility. The data in Table 10-9 support summary data in Table 10-13. However, no supporting data are provided for the "Packaging" category in Table 10-13, which accounts for almost 40 percent of the total labor. Provide further support, either in the form of a table similar to Table 10-9 or in the form of narrative, for the labor estimates for packaging in Table 10-13.

FA-5 Provide sources for the estimated costs of LLRW packaging, transportation, and disposal in Table 10-16 (NUREG-1757, Volume 3, Appendix A, page A-28)

Section 10.1.2.6 of the DFP states that radioactive and hazardous wastes "will ultimately be disposed in licensed radioactive or hazardous waste disposal facilities located elsewhere." Table 10-16, "Shipping and Disposal of Radioactive Wastes," provides a breakdown of packaging, LLRW disposal, and transportation costs for wastes from 14 separate components of the plant. However, the DFP does not provide unit disposal cost factors for the packaging, LLRW disposal costs, transportation costs, or the sources and basis for these costs. Provide additional supporting information about the estimated costs for packaging, transportation, and disposal of LLRW waste, to ensure that the costs are based on reasonable and documented assumptions.

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 Phase 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 Provide the articles of incorporation, corporate organizational charts, and pro forma financial statements (10 CFR 40.38).

Provide a corporate organizational chart that indicates all the entities in the corporate lineage, including any parent companies and/or subsidiaries of IIFP. Indicate the type of entity (e.g. Corporation, LLC, et cetera), as well as the location of incorporation. Indicate which entity would have direct control of the U.S. Nuclear Regulatory Commission (NRC) license, and which entity would own the site and facility.

Provide a copy of the articles of incorporation, a list of corporate officers and their country of citizenship for the corporate entity which has direct control of the NRC license and its parent company(ies).

Provide five years of *pro-forma* cash flow statements and five years of *pro-forma* balance sheets for INIS and IIFP. Provide two years of audited historical financial statements (balance sheets, income statements, and cash flow statements) for INIS. All the above information is needed to identify the corporate entities that have direct or indirect control of the license, site and facility, and to determine if IIFP is owned, controlled or dominated by an alien, a foreign corporation or a foreign government (10 CFR 40.38); as well as to have reasonable assurance that INIS and IIFP are a going concern.

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 FA.

FA 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 FA mechanism as detailed in 10 CFR 40.36(e), standby trust agreement (if required by the assurance mechanism selected), and certification of FA.

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 in order to provide the reports required under these regulations.

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 QAPD are 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 what is "check and review" and 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. (i.e. 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 what was meant by 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, preoperational 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 any 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 will include 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 SSCs 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).