International Isotopes Inc.

Note: INIS resubmitted the Radiation Protection document as public. Matt Bartlett NMSS/FCSS

January 04, 2011

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

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

To Whom it May Concern,

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

(1) Radiation Protection	Official Use Only - Security Related Information
(2) Emergency Management	Official Use Only - Security Related Information
(3) Radiation Protection	Public version

Note that there is not a Public Version of the responses to the Emergency Management RAIs.

Please contact me by phone at (208) 524-5300 or by email at jjmiller@intisoid.com if you have questions regarding these responses.

Sincerely,

John J. Miller, CHP
Radiation Safety Officer

JJM-2011-02

Enclosures (3) as stated

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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).*

RESPONSE: Training requirements and qualifications for other radiation protection staff is clarified below.

License Documentation Impact: A new second and third paragraph will be added to Section 4.5.3 of the IIFP License Application, Revision A. The Section will be amended; as follows to clarify the training requirements for radiation protection staff.

The radiation protection staff shall be trained in the following radiation protection areas:

- Radiological Fundamentals
- Biological Effects
- Radiation Limits
- ALARA Program
- Personnel Monitoring Programs
- Radiological Access and Control Postings
- Radiological Emergencies
- Practical Factors (e.g., RWPs, Dosimeters, Contamination Control, Emergency Response, Protective Clothing)

In addition, radiation protection staff will be trained on all applicable RPP procedures and policies and receive appropriate on-the-job training (OJT) based on their job requirements. Training materials as well as those qualified to provide the training will be approved by the RPM.

License Documentation Impact: Section 4.3 of the License Application, will be revised to include the following RP staff personnel qualifications as new paragraphs 5 and 6 of the Section.

Staff Health Physicists shall have as a minimum a bachelor's degree in engineering or a scientific field and experience commensurate with Health Physics and Radiation Protection duties.

Staff Radiation Control Technicians shall have a high school diploma and experience commensurate with Radiation Control duties.

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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).*

RESPONSE: Evaluation for effectiveness of training program curriculum is clarified below.

License Documentation Impact: Section 4.5.4 of the IIFP License Application, Revision A will be revised to add as a new second paragraph the following statement.

As described in Chapter 11, Section 11.3.8, the Radiation Protection Safety Training Program is systematically evaluated to measure the program's effectiveness in producing competent employees. The RPM will review the evaluation information and implement changes in the training program as necessary.

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).*

RESPONSE: Section 4.7.10 of the application is revised below to provide additional clarification regarding tracking and trending of personnel contamination events and when causes of contamination will be investigated and rectified.

License Documentation Impact: The LA, Section 4.7.10 will be revised to address further corrective actions regarding personnel contamination events by adding the following as a new second paragraph of the subject section.

Personnel contamination events that exceed a facility Administrative Control Level will be recorded, tracked, and managed through the Corrective Action Process described in the IIFP License Application Chapter 11, Section 6 "Incident Investigations and Corrective Action Process." The Corrective Action Process will require investigation of the contamination event and implementation of corrective actions to rectify any deficiencies. Contamination events that are managed through the Corrective Action Process will be reported to the ALARA Committee and reviewed as described in Section 4.2.3 "ALARA Committee." Tracking and trending will be performed in accordance with the ALARA program as stated in Section 4.2.2 "ALARA Goals."

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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.*

RESPONSE: Specific criteria suitable for volumetric clearance of a product stream or waste stream and appropriate justification for the criteria are provided.

License Documentation Impact: Section 4.7.13 "Policies for Removal of Equipment and Materials from Radiological Controlled Areas (RCAs)" will be revised, by modifying paragraph one and inserting three additional paragraphs. Section 4.7.13 will read as follows:

When removing equipment and materials from RCAs, with the exception of hazardous chemicals produced from licensed operations, the guidance contained 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 (NRC, 1993b) will be ~~and ANSI/HPS N13.12-1999, "Surface and Volume Radioactivity Standards for Clearance" (ANSI, 1999) are~~followed.~~Per approved written procedure(s), the radiation protection staff has to approve release of equipment and/or materials from RCAs.~~ Volumetrically contaminated materials will be released if the uranium concentration of the material does not exceed 30 pCi/g or the dose to a member of the public, taking into consideration the subsequent use of the material, does not exceed 1 mrem per year. The radiation protection staff must approve the release of equipment and/or materials from RCAs. The equipment and material screening and evaluation process will be governed by approved written procedures.

Hazardous chemicals produced from licensed materials, as defined in 10 CFR 70.4, will be considered "separated from licensed materials" by meeting the exemptions described in 10 CFR 40.13(a) for "unimportant quantities of source material." The term "Unimportant quantities of source material" is defined as "… source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than one-twentieth of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy."

Environmental health and safety controls and regulations associated with the storage, handling, transportation, and disposal of these hazardous chemicals result in more restrictive controls than those necessary to protect the worker, public, and environment from the radiological hazard associated with source material at a concentration of one-twentieth of 1 percent (0.05 percent or 500 ppm) in the hazardous chemical. For example, uranium at a concentration of 500 ppm in anhydrous hydrogen fluoride (AHF) would result in a dose of 0.09 mrem to an individual exposed to AHF at the ACGIH TLV-STEL of 2 ppm for 15 minutes. In the more extreme case, the lowest lethal concentration of HF, considered to range between 50 and 250 ppm for 5 minutes, would result in a dose between 0.75 and 3.8 mrem, respectively.

The analytical methods applied to determine the concentration of source material in hazardous chemicals will be governed by approved written procedures. Generally at IIFP, the hazardous chemicals produced from licensed materials and separated from licensed materials are products that are sold. The customers of these products will typically require routine sampling and analysis of the products to meet any required specifications. IIFP will establish a statistically confident sampling and analysis procedure including approved analytical methods to demonstrate that customer product purity and impurity limit requirements are met. IIFP will also include a statistically confident sampling and analysis procedure for source material (uranium) determination in the materials being considered as “separated from licensed materials” as an assurance that exemptions described in 10 CFR 40.13(a) remain applicable for the subject materials.

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).*

RESPONSE: Clarification to leak-test requirements is provided.

License Documentation Impact: Section 4.7.14, "Sealed Sources" of the License Application, will be revised to add the following as paragraphs two and three of the subject section.

4.7.14 Sealed Sources

When not in use, sources shall be stored in a closed container adequately designed and constructed to contain radioactive material that may otherwise be released during storage. The sources shall be tested for leakage using the Dry Wipe test method described in ~~accordance with~~ ISO 9978:1992, ~~2919:1999,~~"Radiation Protection – Sealed Radioactive Sources – ~~General Requirements and Classifications~~Leakage Test Methods" (ISO, ~~1999~~1992).

Sealed sources will be leak checked at six (6) month intervals not to exceed that specified on the sealed source and device registration certificate using a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Becquerel (Bq) (0.005 microcuries) of radioactivity.

Leak tests will not be required if:

- Sources contain only H-3;
- Sources contain only licensed material with a half-life of less than 30 days;
- Sources contain only a radioactive gas;
- Sources contain 3.7 MBq (100 microcuries) or less of beta-emitting or gamma-emitting material or 370 kBq (10 microcuries) or less of alpha-emitting material; or
- Sources are stored and are not being used (must be leak tested before use or transfer).

Sources that exhibit removable contamination in excess of 185 Bq (0.005 microcuries) will be removed from service and disposed of in accordance with regulations.

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.*

RESPONSE: Regulatory Guide 4.21 is included as a guidance document for the Facility's ALARA Committee.

License Documentation Impact: Section 4.2.3, paragraph one, of the IIFP License Application will be revised as follows:

The IIFP ALARA Committee is a part of the overall Facility Safety Review Committee (FSRC). The ALARA Committee consists of key members of ~~plant~~ facility management, supervision, and the workforce and will meet periodically on a frequency established in the RPP ALARA Program. The ALARA Committee uses the guidance provided in Regulatory Guides ~~8.10~~4.21, "Minimization of Contamination and Radioactive Waste Generation: Life-Cycle Planning" (NRC, ~~1977~~2008), 8.10 (NRC, 1977), and 8.37 (NRC, 1993) ~~for~~ to ~~formulating~~ formulate ~~plant~~ facility operating philosophy in reducing exposures. Membership of the ALARA Committee includes:

- The ~~COO/Plant Manger~~Chief Operations Officer,
- The Radiation Protection Manager,
- Selected department managers,
- The ESH Manager, and
- Selected supervisors and hourly personnel.

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).*

RESPONSE: Section 4.4.1 will be revised as below.

License Documentation Impact: Revise paragraph one of the License Application, Revision A, Section 4.4.1 to read as follows:

Routine work involving licensed materials is administered by the use of approved written practices and procedures ~~as described in Chapter 11, Management Measures~~. IIFP uses a structured procedure development, review and control systems approach to ensure safety and health requirements are appropriately incorporated into working procedures, for example, use of cross-discipline reviews in the development or change of procedures. The IIFP process for developing and controlling procedures is described in the IIFP License Application Chapter 11, Sections 11.4.2, 11.4.3, 11.4.4 and 11.4.5. Non-routine activities, particularly those performed by non-IIFP employees generally not covered by approved written procedures, are administered by the Radiation Work Permit (RWP) system. The RWP provides a description of the work to be performed defining the authorized activities. The RWP specifies the necessary radiation safety controls, as appropriate, to include personnel monitoring devices, attendance of radiation protection staff, protective clothing, respiratory protective equipment, special air sampling, and additional precautionary measures to be taken. The RWP also contains a description of the radiological conditions in the immediate work area covered by the RWP. The RWP requires approval by the Radiation Protection Manager or designee. The designee must meet the qualification requirements of Radiation Protection Manager. RWPs have a predetermined period of validity with a specified expiration or termination time. Standing RWPs may be issued for routinely performed activities, such as tours of the ~~plant~~Facility.

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.*

RESPONSE: Ventilation design requirements and the effluent monitoring description are clarified by the changes below.

License Documentation Impact: Paragraph 10 of the IIFP License Application, Revision A, Section 4.6.1.1 will be revised as follows:

Building v~~V~~entilation systems ~~for the various buildings~~ control the temperature and the humidity of the indoor air ~~inside the building~~. ~~The~~ G~~g~~eneral ventilation systems used in areas where uranium is processed or handled consist~~s~~ of ~~a series of~~ fresh-air intakes and ~~a series of~~ roof exhaust fans. Roof exhaust fans, and other gaseous effluent emission sources, in buildings where uranium is processed or handled, will be equipped with exhaust monitoring. The effluent monitoring program is described in the IIFP Environmental Report (ER) Chapter 6, Section 6.1.1; more specifically in Section 6.1.1.1 and Table 6-1, "Gaseous Effluent Sampling Program."

License Documentation Impact: The last paragraph of the License Application, Revision A, Section 4.6.1.3 will be revised as follows:

Design of building ventilation systems in process areas and control rooms are sized with adequate flows and pressure differentials for comfort and to ensure potential airborne concentrations of radioactivity do not exceed the derived air concentration (DAC) values specified by the International Commission on Radiological Protection (ICRP)-68 (ICRP, 1995). The ventilation system is designed so that air flow will be from areas of low contamination potential towards areas of higher contamination potential to minimize the spread of contamination.

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.*

RESPONSE: Chapter 4 of the LA will be revised to address monitoring of plant processes for non-uranium radioactive material concentration.

License Documentation Impact: Paragraph one of LA, Section 4.7.1 will be revised to read as follows:

In accordance with 10 CFR 20.1501(a) and (b) (CFR, 2008f), IIFP conducts radiation surveys and radiation area monitoring with instrumentation or area dosimetry that (1) ~~are necessary to comply with the~~satisfy applicable regulations, (2) ~~and~~ are ~~reasonable~~ adequate to evaluate the magnitude and extent of radiation levels, concentrations, or quantities of radioactive material and (3) can identify ~~the~~ potential radiological hazards or the accumulation of radioactivity. Section 4.7.6, "Air Sampling Program," discusses air sampling, and Section 4.7.8, "Minimization of Contamination," discusses the Contamination Survey Program.

License Documentation Impact: The first sentence of paragraph one of the License Application, Revision A, Section 4.7.9 will be revised to read as follows:

Routine surveys are performed in areas that are most likely to be contaminated or where contamination from licensed processes, licensed material decay products or other radionuclide contaminates may concentrate. The radiation protection staff determines survey frequencies, compares the survey results to action guide values as specified in approved written procedures, and ensures the appropriate responses are taken. If the results exceed the action guide values, the Radiation Protection Manager (or designee) is informed, and he/she determines if an investigation and/or corrective actions are necessary.

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.*

RESPONSE: Bioassay sample processing is clarified as discussed in License Application document revisions below.

License Documentation Impact: Paragraph one of LA, Section 4.7.4 will be revised as follows:

The Personnel Monitoring Program is designed and implemented for internal occupational radiation exposures based on the requirements of 10 CFR 20.1201 (CFR, 2008h), 10 CFR 20.1204, "Determination of Internal Exposure" (CFR, 2008t) 10 CFR 20.1502(b) (CFR, 2008g), and 10 CFR 20.1704(i), "Further Restrictions on the Use of Respiratory Protection Equipment" (CFR, 2008u). Intakes are assigned to individuals based upon one or more types of measurements as follows: air sampling, in vitro bioassay (i.e. urinalysis or fecal) and/or in vivo bioassay (i.e. lung counting). The type and frequency of measurement~~(s)~~ for an individual ~~is~~ are determined by their job function and properties of the licensed material associated with a known or suspected intake. The measurements are commensurate with the amount of time an individual spends working with or near radioactive material. Intakes are converted to committed dose equivalent (CDE) and committed effective dose equivalent (CEDE) for the purposes of limiting and recording occupational doses. Action levels are established in approved written procedures to prevent an individual from exceeding the occupational exposure limits specified in 10 CFR 20.1201 (CFR, 2008h). Work activity restrictions are imposed when an individual's exposure exceeds 80 percent of the 10 CFR 20.1201 (CFR, 2008h) limit. Control actions include temporarily restricting the individual from working in an area containing airborne radioactivity, and actions are taken as necessary to prevent recurrence.

License Documentation Impact: Section 4.7.4.1 of the IIFP License Application, Revision A, will be revised (including heading title) to read as follows:

4.7.4.1 ~~Urinalysis Program~~In Vitro Bioassay Program

The In Vitro (urinalysis and/or fecal) Bioassay~~Urinalysis~~ Program is conducted primarily to evaluate the intake of soluble uranium to assure the 10 CFR 20.1201(e) (CFR, 2008h) intake limit of 10 milligram (mg) per week is not exceeded. Personnel assigned to work in areas where soluble airborne uranium compounds are present in concentrations likely to result in intakes in excess of 10 percent of the applicable limits in 10 CFR 20.1201 (CFR, 2008h) are monitored by urinalysis and/or fecal bioassay methods. The minimum sampling frequency for these individuals is specified in approved written procedures. ~~Urinalysis~~ In vitro monitoring may also be used to monitor individuals involved in non-routine operations, perturbations, or incidents.

~~Urine~~ In vitro sampling frequencies and action levels are established in approved written procedures based on the appropriate bio-kinetic models for the ~~present~~ uranium compounds present. Results above the applicable action level are investigated. Work activity restrictions are imposed when an individual's exposure (TEDE) exceeds 80 percent of the occupational dose limit in 10 CFR 20.1201(a) (CFR, 2008h). Exceeding an action level~~s~~ will result in a temporary work restriction for the individual to prevent additional exposure and allow a more accurate assessment of the intake.

License Documentation Impact: A third paragraph will be added to LA, Section 4.7.4.1 that states:

An off-site laboratory that meets the performance standards specified in ANSI/HPS N13.22 and ANSI/HPS N13.30 will be utilized to process and analyze in vitro bioassay samples.

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.*

RESPONSE: In-vivo lung counting description is clarified below.

License Documentation Impact: Paragraph one of the License Application, Revision A, Section 4.7.4.2 will be revised with the new text shown below:

In vivo lung counting will be conducted as necessary to supplement or verify in vitro bioassay results. ~~In vivo lung counting frequencies are established for personnel who regularly work in areas where insoluble uranium compounds are processed or handled. Baseline and termination counts are typically performed. Lung counting frequencies are based on individual airborne exposure assignments and prior counting results. The minimum count frequency for individuals with an assigned intake greater than 10 percent of the annual limit intake (ALI) is annually.~~

License Documentation Impact: Add a new paragraph three to the License Application, Revision A, Section 4.7.4.2 to read as follows:

In vivo lung counting will be performed by qualified contractors in accordance with ANSI/HPS N13.35 performance standards.

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.

RESPONSE: To determine worker exposure for indoor releases, the entire Source Term is assumed to be evenly distributed throughout the building volume. No building ventilation rates or return air exchanges are assumed. Building volumes as dictated by the current design are cited in Table 2-1 of the ISA Summary, and source terms are determined from process flow rates or hazardous material inventory data cited in NSA-TR-10-11, "Accident Consequence Evaluation" (ACE). Upon completion of the final design, the accident consequence calculations will be reviewed and updated as necessary to reflect changes in room volumes, ventilation rates, return air fractions, and licensed material inventories which may impact accident analyses.

License Documentation Impact: No changes are required to be made in the license documentation.

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.*

RESPONSE: IIFP will not request exemption from the labeling requirements in 20.1904. Exemption requests will be added as necessary and the IIFP License Application, Revision A, Chapter 1 will be amended as follows.

License Documentation Impact: A new Section 1.5 will be added to the IIFP License Application (LA) Chapter 1, as "Special Exemptions or Special Authorizations". The original Section 1.5 of LA, Revision A, Chapter 1, "Security of Classified Information" will be changed to Section 1.6 and subsequent sections and subsections will be renumbered in sequence, accordingly. The new Section 1.5, "Special Exemptions or Special Authorizations" will read as follows:

1.5 Special Exemptions or Special Authorizations

In lieu of the values in 10 CFR 20, Appendix B, IIFP will use the International Commission on Radiation Protection (ICRP)-68 derived air concentration (DAC) and annual limit intake (ALI) values in determination of dose due to radioactive effluents. An official letter requesting authorization to utilize the ICRP-68 DAC and ALI values will be submitted separate from this license application.

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.

RESPONSE: The proposed IIFP operations are unique in that they will provide services to the uranium enrichment industry for converting (de-conversion) depleted uranium hexafluoride (DUF_6) into uranium oxide for long-term stable disposal at the same time recovering the fluorine in order to produce commercial quantities of specialty fluoride gas products for sale. The front end of the process involves the handling of depleted uranium compounds and is best described as a radiological operation. Once the fluorine has been extracted from the source material the IIFP operations are consistent with that of a chemical manufacturing facility. It is the dual aspect of the IIFP operations that we believe warrants two distinct release criteria.

As mentioned in Section 4.7.13 of the license application; developing site specific procedures incorporating the methodology cited in ANSI/HPS N13.12 and Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material, issued April 1993 to govern the removal of equipment and materials from radiological controlled areas is a fairly standard and accepted practice utilized at radiological facilities. It is the one that IIFP intends to implement during licensed operations. As stated in Section 4.7.13, the process of releasing equipment and materials will be controlled through the use of approved written procedures. The purpose of using approved written procedures is to ensure that the methodology and instrumentation utilized to release equipment and materials from radiological areas takes into account the physical variations one would anticipate between the types of equipment and materials.

It is the chemical operations associated with the proposed IIFP facility that the 10 CFR 40.13(a) criterion is most applicable. In addition to being valuable products, the high-purity silicon tetrafluoride (SiF_4) and boron trifluoride (BF_3) manufactured utilizing the fluorine derived from the de-conversion of DUF_6 as well as the anhydrous hydrogen fluoride (AHF) produced during the de-conversion are all hazardous chemicals produced from licensed material that will subsequently be sold and transferred to customers. A majority of these customers will not have an NRC or Agreement State license to possess source material. For these fluorine products, IIFP believes it is more appropriate and justifiable to apply the 0.05% by weight exemption provided in 10 CFR 40.13(a) in lieu of the 30 pCi/g U clearance level ANSI/HPS N13.12. The justification and applicability of the 10 CFR 40.13 criterion is two-fold.

First the 0.05% (500 ppm) provides a definitive parameter that is missing from the definition of *hazardous chemicals produced from licensed materials*. As defined in 10 CFR 70.4 "Hazardous chemicals produced from licensed materials" means substances having licensed material as precursor compound(s) or substances that physically or chemically interact with licensed materials; and that are toxic, explosive, flammable, corrosive, or reactive to the extent that they can endanger life or health if not adequately controlled. These include substances commingled

with licensed material, and include substances such as hydrogen fluoride that is produced by the reaction of uranium hexafluoride and water, but do not include substances prior to process addition to licensed material or after process separation from licensed material. There is however no criteria provided in Title 10 Code of Federal Regulations Part 70 that defines what "or after process separation" means. And there is no discussion in the Federal Registers 64 FR 41338 or 65 FR 56211 nor is there guidance in NUREG 1520 that establishes such criteria. It is necessary to define this "process separation" in order to determine which regulatory authority, NRC or OSHA, has jurisdiction over certain processes and facilities associated with the IIFP operations. The importance of identifying jurisdictional boundaries allows IIFP to determine whether an Integrated Safety Analysis as prescribed by Title 10 CFR 70.62 or a Process Hazard Analysis prescribed by Title 29 CFR 1910.119 applies to specific operations or processes. Identifying jurisdictional boundaries is also consistent with the intent of the 1988 NRC-OSHA Memorandum of Understanding.

A second and equally important aspect associated with the 10 CFR 40.13(a) criterion is that it is an exemption currently provided by regulation that supports the portion of the IIFP business model of supplying fluorine compounds produced from source material to persons that are not otherwise licensed by the NRC, an Agreement State or, in the case of foreign customers, an equivalent regulatory agency.

While the reviewer's comment, "This Part 40 criterion appears to have been based on national security interests…" is consistent with the narrative found in Section 3.2 of NUREG 1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Materials," an evaluation conducted by the NRC of the 10 CFR 40.13(a) exemption did not result in a recommendation to revise or remove the exemption. The second half of the reviewer's sentence, "…and, by itself, may not be an acceptable release criterion for public health and safety" has not been overlooked or disregarded by IIFP. IIFP has taken into account that the chemical hazards associated with the fluorine compounds produced by the IIFP processes require health and safety controls that are far more stringent than those associated with the products evaluated in NUREG 1717 Section 3.2 or any other materials that may contain source material at concentrations up to 0.05% by weight. To illustrate this point consider uranium at a concentration of 500 ppm in AHF. An individual exposed to the ACGIH TLV-STEL of 2 ppm for 15 minutes would receive a dose of 0.09 mrem. In the more extreme case the lowest lethal concentration of HF, considered to range between 50 and 250 ppm for 5 minutes, would result in a dose between 0.75 and 3.8 mrem, respectively. Controls implemented to mitigate chemical exposures are more than adequate to protect chemical workers as well as members of the public.

We do believe additional clarification is required to the license application to justify the use of two distinct release criteria. These clarifications are described in the changes below.

Further explanation is provided in response to RAI RP-4 and the License Documentation Impact information given in RAI RP-4.

License Documentation Impact: Section 4.7.13 of the IIFP License Application, Revision A will be revised, by modifying paragraph one and inserting three additional paragraphs to read as follows. See RAI RP-4 for the revised Section 4.7.13.

License Documentation Impact: Revise the last paragraph of the License Application, Revision A, Section 3, "Integrated Safety Analysis" to read as follows:

For the purposes of the ~~this~~ ISA and subsequent licensed operations, hazardous chemicals will be considered "separated from licensed materials" if the source material in any chemical mixture, compound or solution is less than one-twentieth of 1 percent (0.05 percent) of the total weight of the chemical mixture, compound or solution, consistent with the criteria specified in ~~§~~10 CFR 40.13 "Unimportant quantities of source material." The environmental health and safety controls and regulations associated with the storage, handling, transportation and disposal of the hazardous chemicals associated with the IIFP licensed operations is more restrictive than those controls that would be necessary to protect the worker, public and environment from the radiological hazard associated with source material at a concentration of 500 ppm and provides additional justification to utilize the 10 CFR 40.13(a) criteria.