

October 11, 2011

Mr. John J. Miller, CHP
International Isotopes, Inc.
4137 Commerce Circle
Idaho Falls, ID 83401

SUBJECT: FOLLOW-UP REQUEST FOR ADDITIONAL INFORMATION TO SUPPORT THE HUMAN FACTORS, SEISMIC AND STRUCTURAL, INTEGRATED SAFETY ANALYSIS AND FINANCIAL ASSURANCE REVIEW FOR THE INTERNATIONAL ISOTOPES, INC., APPLICATION (TAC 32739)

Dear Mr. Miller:

The U.S. Nuclear Regulatory Commission's (NRC's) staff received your responses to our Requests for Additional Information (RAI) regarding the Human Factors, Seismic and Structural, Integrated Safety Analysis (ISA) and Financial Assurance letters dated May 3, 2011, May 6, 2011, April 1, 2011, and April 29, 2011, respectively. The NRC staff reviewed your responses and requires additional information to complete our review. This additional information is needed for the staff to determine regulatory compliance.

In accordance with Title 10 of the *Code of Federal Regulations* 2.390 of the NRC's "Rules of Practice," a copy of this letter and enclosure will be available electronically from the NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

If you have any questions regarding this letter, please contact Matthew Bartlett at 301-492-3119, or via E-mail to Matthew.Bartlett@nrc.gov. You may also contact Maria Guardiola at 301-492-3566, or via E-mail to Maria.Guardiola@nrc.gov.

Sincerely,

/RA/ M. Guardiola for

Matthew Bartlett, Project Manager
Conversion, Deconversion
and Enrichment Branch
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

Docket No. 40-9086

Enclosure:
Follow-up Request for Additional Information
for the Human Factors, Seismic and
Structural, ISA and Financial Assurance Review

Mr. John J. Miller, CHP
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OFFICE	NMSS/CDEB	NMSS/CDEB	NMSS/CDEB	NMSS/CDEB
NAME	MGuardiola	MBartlett	LAllen	THiltz
DATE	10/03/2011	10/03/2011	10/06/2011	10/11/2011

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FINAL REQUESTS FOR ADDITIONAL INFORMATION FOR INTERNATIONAL ISOTOPES FLUORINE PRODUCTS

Human Factors

In order to demonstrate compliance with the acceptance criteria in NUREG-1520 Revision 1, Appendix E to Chapter 3, please provide the following information:

FRAI-1. The License Application (LA) Sections 3.1.4.4 and 3.1.4.5 of the Human Factors Engineering (HFE) Implementation Plan (IP) provide a number of references to human factors standards—including NUREG/CR-3331, MIL-STD-1478, MIL-HDBK-46855A, and IEEE-1023, which are to be referenced for the Task Analysis, Functional Requirements, and Human System Interface Design elements, respectively, of the HFE IP. The references to these standards in the application use the phrases “similar to” and “or equivalent guidance.” The U.S. Nuclear Regulatory Commission (NRC) staff understands that significant portions of the guidance documents listed above do not apply to a Part 40 Deconversion facility (e.g., International Isotopes Fluorine Products [IIFP]), which is not a nuclear power plant. Therefore, a commitment to the entire standard is not appropriate. The NRC staff needs adequate assurance that all appropriate portions of the guidance will be implemented. Therefore, for each of the three standards listed above, replace the phrase “similar to” with a commitment to implement portions of the guidance used to meet the acceptance criteria listed in NUREG-1520 Appendix E. Also, remove the reference to equivalent guidance.

Example: HFE IP Section 3.1.4.4 (last paragraph): “IIFP intends to use applicable standards as guidance for the functional allocation analysis process. The FAA will utilize description analysis methods drawn from NUREG/CR-3331- ~~similar to that described in~~ consistent with the sections needed to demonstrate compliance with the acceptance criteria in NUREG-1520 Appendix E of NUREG/CR-3331 ~~or equivalent guidance~~”

FRAI-2. The original HFE RAI-1(a) response (Revision A) contained the following two sentences:

“Human factors and human-system interface were considered as part of the accident analysis review and discussion process. However, these considerations of human factor aspects were not done at the level and structure of the current NUREG- 1520, Appendix E because the accident analysis and PHA information used in developing the IIFP License Application was conducted and completed prior to the revisions to NUREG-1520, Revision I Appendix E, criterion E.”

This text was not included in the second HFE RAI response (Revision B). Please incorporate a similar statement into LA Section 3.1.4, or other location as appropriate. This information is needed to clarify that the HSI was evaluated as part of the accident analysis.

FRAI-3. LA Section 11.1.3, titled “Configuration Management Controls on the Design Requirements” contains a commitment to conduct design verification. Provide a cross-reference in the HFE IP which refers to LA Section 11.1.3 and states that this design verification will also be applied to human factors. This information is needed to clarify that the design verification will be applied to human factors.

FRAI-4. RAI HF-F2-1 License Documentation Impact 4 through 8 indicate the HFE Expert will be incorporated into the Integrated Safety Analysis Team (ISA). For clarity, add a statement or cross-reference in HFE IP Section 3.1.4.2 which indicates the HFE Expert will be part of the ISA team. This information is needed to ensure consistency between LA Section 3.1.4.2 and the ISA Summary Table 5-2.

Seismic

FRAI-5. Issue:

In response to “Follow-Up Clarification to RAI SS-7(5),” the applicant has stated that Load Combination 4 for “Severe Environmental Load Combinations” has not been used “since the operating basis earthquake load (earthquake load for which plant’s power production equipment is designed to remain functional without undue risk to public health and safety) is not applicable. The emergency generator and UPS system are designed to remain functional during any postulated natural phenomena hazard event.”

This combination pertains to continued operation of the items relied on for safety (IROFS) structures after earthquakes.

Request:

Expand the justification for not using the Severe Environmental Load Combinations listed in follow-up RAI response #SS-7-5 Section 3(a) #4, 3(b) #5, and 3(c) #5. To include a justification based on compliance with 70.61(e), i.e., IROFS remain available and reliable and have management measures [Note: Consider including a cross-reference to LA Section 3.1.3 (or other sections) which contain a commitment to utilize Management Measures to maintain the IROFS.]

ISA:

FRAI-6. LA Section 3.2.4.3, “New Facilities or New Processes at Existing Facilities” contains commitments to implement the Baseline Design Criteria (BDC), consistent with Title 10 of the *Code of Federal Regulations* (10 CFR) 70.64. The BDC are intended to ensure that a minimum level of good engineering practices, defense-in-depth, and safety considerations are incorporated throughout the facility. The BDC must be applied to the entire facility, including those safety features which are not designated as IROFS. The current commitments in LA Section 3.2.4.3 appear to only apply to IROFS. These commitments need to be expanded to also apply to the entire facility, including safety features which are not designated as IROFS. Consistent with the requirements in 10 CFR Part 70.62(a), expand the Subsections of the LA 3.2.4.3 including Natural Phenomena Hazards, Fire Protection, Chemical Protection, and Emergency Capability to indicate that the BDC addresses the safety systems throughout the entire facility. An example of the type of language needed is provided below.

Examples:

Section 3.2.4.3 New Facilities.... *New text in italics.*

Natural Phenomena Hazards

The IIFP Facility design has been developed with natural phenomena in mind such that if an external event should occur, the health and safety of the workforce from

licensed material or chemicals produced from licensed material are maintained.
“Structures, systems, and components. (SSC)s that are....”

Fire Protection

The IIFP Facility design provides adequate protection from credible fire and explosion accident scenarios by adherence to the requirements of the ISA and recognized codes and standards. “SSCs that are IROFS....”

Chemical Protection

Replace existing wording which is very confusing with the following: *The IIFP Facility design provides for adequate protection against chemical risks produced from licensed material. Chemical protection is addressed in Chapter 6.0 of the LA.*

Emergency Capability

The IIFP Facility design provides for emergency capability to maintain control of licensed material and hazardous chemicals produced from licensed material, evacuation of onsite personnel, and onsite emergency facilities and services. “SSCs that are required....”

Exemption Request for Financial Assurance:

FRAI-7. By letter dated August 12, 2011 (Agencywide Documents Access and Management System [ADAMS] ML112351140) INIS submitted an exemption request to 10 CFR 40.36(e) for financial assurance. Specifically the exemption requested a modified timeframe for submitting financial assurance for decommissioning which states, “provide the financial assurance instruments to the NRC 6 months prior to operations and to fund the instruments 21 days prior to operations.

In a telephone conversation held September 16, 2011, (ADAMS Accession No. ML112700375) the NRC expressed concern that INIS may receive contaminated equipment during construction as part of their purchase of equipment from the Sequoyah Fuels former uranium deconversion facility. The exemption mentions that decommissioning costs may be required for this contamination, but does not include the decommissioning cost analysis or funding mechanism required by 40.36. In subsequent phone conversions, the NRC staff has come to understand that the contamination consists of source material (UF4) and would not exceed 15 lbs. This information has not been provided formally to the NRC.

Consistent with the regulatory requirements in 40.14 and 40.36, provide additional information in the exemption request on the type, quantity, and chemical form of “contamination” which may be received onsite during construction. Specify how the material will be licensed and whether or not it needs to be addressed as part of the financial assurance exemption request. If the material is part of the exemption request (e.g., not licensed under a general license), address the decommissioning costs associated with this “contamination.” If the intent is to limit the “contamination” below a regulatory threshold during construction (e.g., a general license, 40.22 or 40.36(b)), provide a commitment in the LA which specifies the material will not exceed the threshold; and summarize the basis for not providing financial assurance during construction.

FRAI-8. The current language in the exemption request contains a number of phrases which do not provide an adequate scope to define the extent of the exemption. The original exemption request contains several different phrases including, “prior to operations,” “prior to start-up,” “prior to licensed operations,” “provide reasonable financial assurance,” etc. These phrases are not well defined.

Consistent with the requirements in 40.36(d), clarify the meaning of the phrases “operations” and “start-up” to be the receipt on site of radioactive material under the proposed license. Replace the phrase “reasonable financial assurance” with “financial assurance in the amount of the cost estimate.”