August 10, 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 REVIEW FOR THE INTERNATIONAL ISOTOPES, INC.'S, 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 review on May 3, 2011 (Agencywide Documents Access and Management System [ADAMS] Accession Number ML11130A128). The NRC staff has reviewed your responses and requires additional information to complete our review. This additional information is needed for the staff to determine regulatory compliance.

Please provide the additional information requested in the enclosed RAIs within 30 days of the date of this letter.

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 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/

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 Review

Mr. John J. Miller, CHP
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Follow-up Request for Additional Information for the Human Factors Review

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Follow-up Request for Additional Information for the Human Factors Review

Introduction

In a letter dated May 3, 2011, International Isotopes, Inc., (IIFP) responded to Request for Additional Information (RAI) HF-1 by providing a 14-page Human Factors Engineering and Implementation Plan (HFE IP). The Plan addressed the nine elements defined by NUREG-1520, Rev. 1, Appendix E. The U.S. Nuclear Regulatory Commission's (NRC's) staff has reviewed the responses in this letter and the HFE IP and require further information in the following RAIs:

The NRC staff acknowledges the commitment to provide the information required by the review guidance contained in NUREG-0711, "*Human Factors Engineering Program Review Model"* and NUREG-1520, Rev. 1, Appendix E, "*Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility,"* Appendix E, "Human Factors Engineering for Personnel Activities." NUREG-0711 and NUREG-1520 contain the guidance the NRC staff uses to review license applications (LA). However, the HFE IP provided by IIFP in many places restates the guidance described in NUREG-0711 and NUREG-1520, Rev. 1, Appendix E, without further providing information on how this guidance will be achieved (implementation level detail).

The staff wishes to clarify that NUREG-0711 and NUREG-1520, Rev. 1, Appendix E do not provide a process for the design of interfaces, controls, alarms, displays or process facilities. Rather, these NUREGs provide the criteria that NRC staff uses to assess LAs. The method to achieve the criteria and the industry-accepted standards for a given element and process should be described in the IP.

Given that IIFP has not yet completed their detailed design, which would demonstrate how Human Factors (HF) design standards would be met, the staff must review the process that IIFP will use to ensure that these design standards are included in the design process. Therefore, the staff requests that IIFP provide an IP to specify the design process, which may include the standards applied, for each element of the NUREG-1520, Appendix E, that will be followed; and identify to which criteria in each section any identified standards apply. (Standards that are relevant to nuclear facilities that may be considered include—but are not limited to—NUREG-6633, NUREG-6634, NUREG-6635, and IEEE STD 1023-2004.)

Requests for Additional Information

HF-F2-1. Issue:

The HFE Plan which IIFP submitted in response to the first round of RAIs contains a number of commitments which address regulatory compliance for some of the HF requirements. Since the Integrated Safety Analysis summary is **not** part or the LA, any commitments in the HFE-Plan will not demonstrate regulatory compliance unless the Plan is incorporated into the LA.

Request:

Consistent with the requirements in 70.61(e) and 70.64(d)(2) and as described in the acceptance criteria listed in NUREG-1520 Rev. 1, Appendix E, please explain how you intend to incorporate these commitments into the LA. Note: some descriptions in the HFE IP need to be reworded as commitments (see specific items described below).

HF-F2-2. Issue:
Section 4.6.2.3 states that an HFE "expert" will be added to the Project team. Currently, the ISA team does not include an HFE "expert." Section 4.6.2.3 states:

> *This arrangement and approach provide for the HFE designated Engineer to become involved in reviews and updates of accident analyses and to ensure continuity of HFE considerations by the design team as the project progresses. This Engineer will be involved in the development and refinement of the HFE Implementation Plan (IP) that applies a structured approach to HFE.*

The staff understands that INIS had not yet added an HFE to their project team.

Request:
Demonstrate that you will have adequate HF expertise in the development and application of the HFE IP.
Since detailed design information on the HFE-Plan is not currently available, the NRC staff place additional importance on INIS's commitments to have an HFE-expert involved in overseeing the design and implementation of the HFE-Plan. Consider the following commitments, among others, to help address the above request.

- Chapter 2 contains a description of the minimum qualification for key personnel for the IIFP facility. Consider adding a description of the minimum qualification for an HFE-expert/staff in Chapter 2 of the LA or indicate which existing position will have those responsibilities and qualifications. (Note: ISA Summary Table 5-1 describes the qualifications of a specific individual for the HFE/ISA team, but a minimum qualification for the HFE-position should also be provided.)
- Provide commitments that the HFE-expert/staff will ensure (through oversight or review) that HFE is incorporated appropriately into the following areas: Procedures (4.6.7), Training (4.6.8), Design Verification (4.6.9.3 and 4.6.9.4), and Issue Resolution Verification (4.6.9.7 and 4.6.9.8).

HF-F2-3. Issue:
Section 4.6.3 states that "…IIFP ISA/HFE team and the Design and Build Contractor will identify safety-related HFE events or potential events in past and existing facilities that are similar to the IIFP Facility." As written, this is a restatement of the criteria that the NRC staff uses to assess license applications and does not provide implementation information that can be reviewed to provide reasonable assurance of safety. Section 4.6.4.2 states that the review will focus "primarily on reviews of operations and experience at facilities involving UF_6, UF_4 and uranium oxides."

Request:
Demonstrate that your plan for Operating Experience Review (OER) will cover the scope of your items relied on for safety (IROFS). Describe the search criteria to be used and how facilities will be determined to be relevant.

HF-F2-4. Issue:
Section 4.6.3.2 states that the review of HFE events will be focused on both personnel actions and Human System Interface (HSI) technology "employed at these facilities…" As written, this statement is not clear.

Request:

Clarify whether 'these facilities' refer to the IIFP facilities described in the LA or to the facilities to be named in HF-5. Explain how the search criteria for personnel actions and Human System Interface (HSI) technology will be determined.

HF-F2-5. Issue:

Section 4.6.3.3 states:

> *Discussions will be held with personnel possessing a broad base of experience in uranium processing and other manufacturing applications. Examples of this experience include using autoclaves to feed UF6, reacting UF6 to produce other products (de-conversion), producing and handling UF4 and uranium oxides, packaging fluorine products, using refrigeration systems and cold traps, handling HF, and transporting UF6, HF, fluorine products, and radiological wastes. Potential sources for such reviews include, but are not limited to, the DOE DUF6 de-conversion facilities in Paducah, Kentucky and Portsmouth, Ohio, the Areva EREF and Urenco USA centrifuge enrichment facilities, and the Sequoyah Fuels Corporation depleted UF4 former plant personnel. Other valuable resources which may be used include uranium conversion facilities (UF6 manufacturing), other uranium processing plants, and gas manufacturing and packaging facilities*.

Request:

Explain how you will ensure that an adequate minimum set of sources will be obtained, considering that any individual source may not be available.

HF-F2-6. Issue:

NUREG-1520, Rev. 1, Appendix E states that the functional allocation analysis (FAA) should be based on the OER. Section 4.6.4.2 states that the OER will be used to "functionally allocate" personnel activities. As written, this is a restatement of the review guidance and does not provide implementation information that can be reviewed.

Request:

Explain, in the HFE IP, the type of information derived from the OER that will be used for the IROFS and how it will be used to inform the FAA (determination of whether an action or event is to be performed by the human operator or by automation), including staffing requirements (per Section 4.6.6).

HF-F2-7. Issue:

Section 4.6.4.1 states that IIFP will use "Functional Allocation Analysis to take advantage of human strengths and to avoid placing demands on personnel who are not compatible with human capabilities…" This is a restatement of the guidance and does not provide any implementation information that can be used to determine reasonable assurance of safety.

Request:
Provide the standard that will be followed to perform FAA, and indicate the criteria in NUREG-1520, Appendix E, it addresses; or describe how FAA is incorporated into the development of the IROFS and any associated management measures (with respect to the criteria in NUREG-1520, Appendix E, for use of information derived from OER and human physical and cognitive capabilities. That is, show that prior root causes identified in the OER were addressed and ensure that human physical and cognitive capabilities are not exceeded. Describe in the HFE IP the information that will be developed from the FAA and Task Analysis (TA) for IROFS, including staffing requirements (per Section 4.6.6).

HF-F2-8. Issue:
Section 4.6.4.2 states:

> *Task analysis will include the scope, identification, and analysis of critical tasks focusing on personnel demands in the performance of these tasks. The task analysis process will be used to evaluate normal operations and also startup, shutdown, and emergency operations. Task analysis results will be used to support the functional allocation and are a primary consideration in HSI design as ways to best perform these tasks. Also, job design issues are considered.*

This is a restatement of the guidance provided in NUREG-1520, Rev. 1, Appendix E. It does not provide implementation information that would explain how the TA is to be performed. In addition, section 4.6.4.3 and 4.6.4.4 contain very limited description of the TA.

Request:
Define what standards will be followed to perform the TA process, for example: U.S. Department of Defense Handbook, MIL-HDBK-46855A, "Human Engineering Program Process and Procedures" (DOD, 2010). Or include the following in the HFE IP:

a. Demonstrate that the TA covers the scope of the IROFS,
b. Define how human actions in IROFS will be identified and analyzed,
c. Define how the TA will inform staffing requirements (per Section 4.6.6).

Also, clarify what general categories of tasks will be analyzed (scope of the analysis) and whether the analysis will be iterative. Describe whether the HFE-expert/staff will play a role in overseeing and approving the task analysis.

HF-F2-9. Issue:
NUREG-1520, Rev. 1, Appendix E states that HSI designs should incorporate FAA and TA via the systematic application of HFE. Sections 4.6.5 and 4.6.5.1 of the HFE IP state that a structured methodology will be used to identify and select the HSI approach, define the detailed design and perform Verification and Validation (V&V) testing; and that this structured methodology and its results will be documented in accordance with the requirements of the IIFP Quality Assurance Program Description. As written, the HFE IP is a restatement of the guidance. No implementation information is provided. Stating that there will be a systematic approach is not sufficient, as it does not provide reasonable assurance that HF will be incorporated into the design; nor does it provide a commitment to a process that can be examined to determine if it provides a reasonable assurance of safety. The process itself must be reviewed. The NRC staff must review the process that will be

followed and the standards that will provide the technical basis for the development of the HSI.

Request:

a. Define the process (which could be defined by use of a standard) to be used that will incorporate FAA and TA into the design of the HSI.
b. Explain in the HFE IP how unnecessary controls and displays will be identified and eliminated during Task Support Verification.
c. Define the technical basis for the Design Review Criteria and Style Guidance to be used in HSI development (discussed in Section 4.6.5.1). Ensure that it is consistent with accepted standards for HSI design (such as NUREG-0700).
d. Indicate in the HFE IP standards to be used to inform the systematic processes used to design the HSI and to perform V&V.

HF-F2-10. Issue:

NUREG-1520, Rev. 1, Appendix E states that the HFE IP should indicate how the training program development is coordinated with other activities in the HFE design process, and how it will be implemented in an effective manner consistent with HF principles and practices.

Request:

Explain in the HFE IP how HF's principles and practices will be used to support development of the training plan. Explain in the HFE IP the inputs to the training program from the other aspects of the HFE design process and the outputs of the training process to other aspects of the HFE design process.

HF-F2-11. Issue:

NUREG-1520, Rev. 1, Appendix E states that the V&V should confirm that the design incorporates HFE to HSI in a manner to enable successful completion of personnel activities.

Requests:

a. The methodology provided in the HFE IP states that the criteria for HSI requirements will come from personnel tasks defined for 'selected operational conditions.' Commit that HSI and personnel tasks will be assessed in V&V under all reasonable conditions; define "reasonable conditions."
b. Section 4.6.9.2 (i) indicates that the task support verification will compare the characteristics of the HSI to personnel requirements identified in the TA. Explain how personnel task requirements will be compared to HSI characteristics.
c. NUREG-1520, Rev. 1, Appendix E, states that the V&V should be applied to both personnel activities and HSI design. However, the HFE IP only discusses the review of HSI. Clarify in the HFE IP that personnel tasks associated with IROFS will also be reviewed to provide reasonable assurance they can be completed successfully.
d. Section 4.6.9.4 is a condensation and restatement of the guidance contained in NUREG-1520, Rev. 1, Appendix E, I (ii). As such, it does not provide reasonable assurance that design verification will be implemented in accordance with HFE practices. Describe in the HFE IP how deviations from accepted HFE principles and guidelines will be identified and then justified and documented for resolution.
e. Section 4.6.9.6 states that the part-task simulator will have a 'high degree' of fidelity. Define 'high degree' or state to what standard it will be designed. State what standard or process will be followed in the performance of the Integrated

System Validation (ISV). Ensure that ISV will be performed with HF expertise supported by operations expertise. NUREG-1520 Rev. 1, Appendix E, Section I (iii), states that the applicant should conduct a performance-based evaluation of the integrated design to ensure that the HFE/HSI supports the safe operation of the plant. Define in the HFE IP the metrics that will be used to ensure that human performance on the IROFS is adequate. (In other words, define how you will know that your operator performance is good enough.) Clarify for what aspects of V&V the part-task simulator will be used.