Human Factors

10 CFR 70.61(e) requires a safety program to ensure that each IROFS will be available and reliable to perform its intended function when needed. Many of these administrative IROFS and supporting management measures rely on personnel activities to support the safety function (e.g., maintenance). Staff guidance contained in NUREG-1513, "Integrated Safety Analysis Guidance Document," identifies that for administrative controls (e.g., certain human actions), "... the man-machine interface for that individual should be carefully designed." Given that the International Isotopes application contains many IROFS that rely on human action, the human system interfaces and control systems associated with these IROFS must be designed to adequately support operator task performance.

HF-1. Criterion A, Appendix E of NUREG-1520 states that the applicant should appropriately identify the personnel activities that are considered IROFS such that a reviewer can understand the actions, human-system interfaces involved, and the consequences. ISA Table 4-3 contains the Accident Sequence Summary and Risk Index for a number of potential events, many of which are either labeled "operator error" or which appear to involve human action. However, the human-system interfaces involved are not identified.

a. Identify the human-system interfaces involved in the accident sequences that include human actions, such that the impact on the IROFS can be evaluated.

RESPONSE: A "what if" method was used for the accident and consequence analysis of the International Isotopes Fluorine Products (IIFP) Process Hazard Analysis (PHA) and relied upon the considerable engineering and operations experience of the ISA team. This approach generally leads to a conservative evaluation with reference to safety significance as the participants consider "worst case" scenarios in the "what if" PHA method.

Human factors and human-system interface were considered as part of the accident analysis process. However, these considerations of human factor aspects were not done at the level of detail and structure required in the current NUREG 1520, Appendix E because the accident analysis and PHA information was completed prior to the revisions to NUREG-1520, Revision 1 Appendix E.

The IIFP Licenses Application (LA) will be revised as shown below to include the IIFP commitment to incorporate acceptable human factors engineering standards and applicable requirements into the safety and design program.

License Documentation Impact: Section 3.2.5.8 of the IIFP LA and Section 6.1 of the IIFP ISA Summary will be amended as follows.

Because the human factors and human-system interface design supporting the IIFI safety analysis is not at the detail design stage, information relative to human tasks, configuration of alarms, controls, displays and valve alignment configurations are not yet available for evaluation. IIFP is committed to incorporate acceptable human factors engineering standards, guidance and practices into the safety and design program.

Where IROFS involve human actions, human factors shall be considered, and human-system interfaces will be designed in accordance with applicable guidance provided in NUREG-0700, "Human-System Interface Design Review Guidelines," Rev. 2, May 2002, NUREG-0711, "Human Factors Engineering Program and Review Model," Rev. 2, February 2004, and NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," Rev. 1, Appendix E, "Human Factors Engineering for Personnel Activities", May 2010.

HF-1

b. Clarify to what extent human factors considerations (e.g., task analysis, functional analysis, operational experience reviews, and human reliability analysis) were incorporated into the accident analysis and development of IROFs

RESPONSE: Personnel involved with evaluating accident scenarios used extensive plant operating experience in those evaluations. The ISA team conducted the PHA accident analysis by organizing each of the processes into system and unit operation nodes based on conceptual design of the IIFP Facility. Each node was reviewed by a team with safety analysis and actual operating experience of like, related or similar processes to those being analyzed. Human tasks, potential for human errors, and functions of operating and maintenance personnel were considered during the review discussions (for example, valve alignment errors, drop of lifts by human actions during maintenance and response times to alarm actions). However, the team did not use a formal structured or separate stand-alone documented task analysis, functional analysis or human reliability analysis (See response to RAI HF-1a).

IIFP is committed to incorporate the human factors engineering standards, guidance and practices into the design and safety program as shown in the License Documentation Impact of RAI HF-1a response and described more specifically in following RAI HF responses.

License Documentation Impact: Refer to RAI HF-1(a) response.

Human Factors

HF-2. NUREG-1520, Appendix E, part B(ii) states that the human factors engineering (HFE) Design Review Plan should be implemented by an HFE Team with the appropriate composition, experience, and organizational authority to ensure that HFE is considered in the design of human systems interfaces (HSI) for personnel activities. Staff has reviewed the team composition presented in Section 5.1 of the ISA. Human Factors expertise is not included in the expertise listed.

Describe the HFE experience/expertise of the ISA team, and clarify whether the HFE responsibilities reside in an individual, a team, or the entire group.

RESPONSE: An Engineer with experience in human factors engineering is being added to the ISA and project team through the Design and Build Contractor. This arrangement and approach provide for the 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 of the HFE Design Review Plan and program that applies a structured approach to HFE. The Engineer will work with the ISA team and the design team to ensure that HFE and human-system interface (HSI) requirements are being met.

The Engineer being added to the IIFP project has more than 20 years of experience in engineering, design, and specification of instrumentation and control systems and equipment including instrumentation of process systems, the preparation of specifications, logic and loop diagrams, instrument lists, and system descriptions. The Engineer's expertise includes using good Human Factors Engineering (HFE) practices. The Engineer's experience includes development of instruments and control criteria including HFE criteria and HFE references used in Nuclear Power Plants (NPP) control room designs such as EPRI NP-3659, NUREG-0700 and NUREG-0711 as well as ANS/IEEE Standard 1023.

License Documentation Impact: Section 5.1 of the IIFP ISA Summary will be revised as follows:

- Facility and chemical process safety,
- Health physics and radiation protection,
- Chemical, mechanical, and electrical engineering,
- Plant operations and maintenance,
- Process hazards analysis,
- Safety analysis and risk assessment,
- UF_6 and chemical/nuclear processing,
- Fire safety,
- Human Factors.

License Documentation Impact: Table 5.1 of the IIFP ISA Summary will be revised as follows to include HFE experience:

Human Factors

Note : Add to bottom of Table 5.1:

Design Engineer with HFE experience	More than 20 years of experience in engineering, design, and specification of instrumentation and control systems and equipment including instrumentation of process systems, the preparation of specifications, logic and loop diagrams, instrument lists, and system descriptions. Experience in Human Factors Engineering practices and development of HFE criteria, control room designs and HFE Design Review Plan and programs including guidance provided in NUREG-0700 and NUREG-0711.

License Documentation Impact: Table 5.2 of the IIFP ISA Summary will be revised to include a column for Human Factors Engineering and will include a Human Factors Engineer as a team member of the ISA team.

License Documentation Impact: Section 3.2.7 of the IIFP LA will be updated as follows to include HFE :

- Nuclear facility safety,
- Radiological safety,
    - Process hazards analysis,
    - Safety analysis and risk assessment,
- Fire safety,
- Chemical process safety,
- Operations and maintenance,
- ISA Methods,
- Human Factors.

Human Factors

HF-3. NUREG-1520, criterion E describes the HSI design, inventory and characterization:

ISA Section 2.1.4.1 contains multiple references to alarms, displays or controls to be contained in one or more Control Rooms in the facility. The descriptions provided are very high level. It is unclear whether human factors has been or will be considered in their design. There is not a description of these Control Rooms with respect to functions controlled, alarms, communications requirements, displays or staffing, nor is there a description of the HFE/HSI analysis that will determine the requirements for these systems or a commitment to implement a program to incorporate HFE into the design of the control room(s). Per the guidance provided in NUREG-1520, Criterion E:

a. Clarify whether there is a single control room for each process building or another arrangement (e.g., multiple Control Rooms in a single building for different aspects of the process).

Note: Reference to ISA Section 2.1.4.1 in the question above appears to be incorrect.

RESPONSE: The fifth paragraph of Section 2.4 of the ISA provides a general description of the Control Rooms. The licensed material process Control Rooms will be located in the following areas:

- DUF_4 Process Building – This building has a central Control Room shared for the DUF_4 process and the related Autoclave Building operations,
- Fluorine Extraction Process (FEP) Building - This building has a central Control Room shared for the SiF_4 and BF_3 FEP processes,

The process Control Rooms will all have the appropriate monitoring, recording, alarm notification and control instrumentation to provide the latest relevant information to the operators that allow for control of the processes.

In addition, a control area will be provided in the Utilities Building for monitoring and controlling the steam boiler system, air compressors and other utility supply equipment. In the conceptual design, other supporting utilities will be controlled by local instrumentation and control panels as appropriate that are usually provided as part of packaged systems. These include utilities or supporting processes in the following buildings:

- Decontamination Building,
- Fire Pump House,
- Water Treatment Building,
- Main Switchgear Building,
- Environmental Protection Process Building
- The AHF Staging Containment Building and Fluoride Products Trailer Loading Facility share a Control Room.

The details of the process Control Rooms have not yet been developed. These Control Rooms and controls will be subject to the HFE Design Review Plan and program where applicable.

License Documentation Impact: See License Documentation Impact in HF-1a.

HF-3

b. State the minimum list of alarms, displays, and HSIs that will be provided for each of the Control Rooms. Provide the basis for this minimum inventory (e.g., derivation from task analysis, etc.)

RESPONSE: A draft listing of anticipated displays has been developed during the conceptual stage of the design. The basis for the inventory is from team members past experiences with similar process plants. This listing will be used as a preliminary starting point of the design for the remainder of the systems and subsystems. Each display and supporting instrumentation and controls will be developed, designed, and implemented using a structured approach as detailed in the HFE Design Review Plan and program. The HSI design will incorporate the functional allocation analysis and task analysis process into the detailed design of safety-significant HSI components (e.g., alarms, displays, controls, and operator aids) through the systematic application of HFE. The display and alarm design work is conceptual and it is too early at this stage of design to provide.

License Documentation Impact: None

HF-3

c. Describe how human factors will be considered in the layout of the Control Rooms and considerations for ergonomics for the development of the Control Rooms. The design should provide the overall work environment including lighting, noise control, control panel and console design, etc. Describe the commitment to apply human factors to the HSI.

RESPONSE: A structured systematic HFE approach will be applied to the layout for the process Control Rooms as well as local control stations or panels. This involves performing the following for each:

- Task definition,
- Function allocation (human and computer; personnel organization),
- Layout of process Control Rooms, local control stations,
- Functional requirements analysis and functional allocation,
- Staffing and qualification.

The HSI will be based on similar process plants but modernized considering ergonomic and technologies such as Visual Display Units (VDU) integrated into work stations, large panel displays, adequate work surfaces, etc. with the layouts being determined by the tasks of the operators. The number, location, spatial arrangements, sizes, and relative positions of control consoles will be established using proven HFE principles, guidelines, and experience gained from similar facilities. The design process will follow the program steps as described in the HFE Design Review Plan and program.

Determination of environmental conditions (lighting, noise, ambient working temperatures, radiation, air quality, and humidity) in the process Control Rooms, and at local control stations will employ well-accepted standards from the fields of industrial and human engineering (e.g. MIL-STD-1472, etc.) and relevant guidance from prior studies.

License Documentation Impact: None

HF-3

d. Describe how the design process excludes the development of extraneous controls and displays.

RESPONSE: Extraneous control and displays will be identified during the task support verification process. Unnecessary HSI components will be identified. Unnecessary HSIs can introduce clutter and distract personnel for the selection of appropriate HSIs. Appropriate HSI components may not appear to be associated with personnel tasks. (See RAI HF-7b response).

License Documentation Impact: None

HF-4. NUREG-1520, Appendix E, criterion B(iii) states that a structured approach to HFE should be included in the HFE Design Review. It also states the HFE Design Review should identify appropriate goals and scope to ensure that HFE practices and guidelines are implemented during design, construction and operation of the facility

Staff has not found a discussion of the structured approach to HFE. Although, quality assurance section A.3.1.3.3 does describe the factors required for the design analyses of documents. , the scope and goals of the HFE process do not appear to be defined in the application.

a. Consistent with NUREG-1520, Appendix E, criterion B (iii) provide the goals and scope of the HFE Design Review and program.

RESPONSE: An HFE Design Review Plan and program will be developed that addresses the review elements of NUREG-1520 Rev. 1, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility", Appendix E, "Human Factors Engineering for Personnel Activities". The HFE Design Review Plan and program will provide design goals to ensure:

- Critical personnel tasks are defined and accomplished within applicable time and performance criteria,
- The anthropomorphic standards for the relevant population are defined and applied,
- HSIs, procedures, staffing/qualifications, training, management, and organizational variables support a high degree of operating crew situational awareness,
- Allocation of functions accommodates human capabilities and limitations,
- Operator vigilance is maintained and distractions are minimized,
- Acceptable operator workload is met,
- Operator interfaces contribute to an error free environment,
- Error detection and recovery capabilities are provided,
- Control areas minimize stressors and fatigue while assuring adequate communication.

The HFE Design Review Plan and program will be developed in accordance with the nine elements of the HFE design process described in NUREG-1520, Rev.1 Appendix E and encompass all of the following elements and their sub-elements.

Element 1(E1) -Identification of Personnel Activities
Element 2(E2) -HFE Design Review Planning
Element 3(E3) -Operating Experience Review
Element 4(E4) -Functional Allocation Analysis and Task Analysis
Element 5(E5) -HSI Design, Inventory, and Characterization
Element 6(E6) -Staffing
Element 7(E7) -Procedure Development
Element 8(E8) -Training Program Development
Element 9(E9) -Verification and Validation

The scope of the HFE Design Review Plan and program includes the applicable process Control Rooms and local panels, supporting procedures, training, applicable operations, accident management, emergency response management, maintenance, test, inspection and surveillance interfaces (including procedures), facility management, and facility personnel. The HFE design process implementing the above elements will follow the NUREG 0711, 1.2.1(4) guidance and requirements.

License Documentation Impact: See response to RAI HF-1a

HF-4

b. Per NUREG-1520, Appendix E, criterion E: Explain the process used to incorporated HFE into the design of the human system interfaces (HSIs), alarms, and communications systems that support the Process Control Rooms to support the operator in controlling the facility under normal and abnormal/emergency conditions.

RESPONSE: See responses to HF-1b, HF-4a and HF-3c.

License Documentation Impact: See response to HF-1a

HF-5. NUREG-1520, Appendix E, criterion C (i, ii, and iii) states that a review of HFE related events and operational experience in existing facilities should be conducted. This review should include operator interviews, surveys, and analysis of the HSI for relevant events. While the INIS facility may be somewhat unique in application, experience should be drawn from related facilities, e.g., chemical plants and nuclear facilities.

a. Clarify what, if any, HFE related events from existing chemical and nuclear facilities were evaluated and used to inform the INIS application. Describe to what extent operator interviews/surveys on existing HSI technology were conducted and incorporated into the facility design and IROFS. Identify the types of facilities that were evaluated. Define how the information derived from operational experience reviews will be used to inform other aspects of the design.

RESPONSE: See response to HF-1a and HF-1b

License Documentation Impact: See response to RAI HF-1a

HF-5

b. *The use of task analysis which underlies the development of the IROFS involving human factors is not discussed. Section 2.3.3 of the Licensing Application (LA-IFP-001 Revision A) uses the term "Job Task Analysis". Define this term and provide a description of the methods used to perform it. Define the techniques used to perform the task analysis, the techniques to identify and analyze critical tasks, how the personnel demands in tasks were identified, and how job design analysis was conducted.*

RESPONSE: The term "Job Task Analysis" and techniques to perform the task analysis will meet the HFE Design Review Plan and program that will be developed and described in the above RAI Human Factors responses.

License Documentation Impact: See RAI HF-1a response.

HF-5

c. *The basis for the functional allocation analysis and the functional requirements analysis which underlies the development of HSIs and the definition of the tasks to be performed at the facility is not apparent. Define how operational experience was used to inform the functional requirements analysis. Define how the task analysis interacts with the functional analysis. Define how functional analysis was conducted to avoid overloading human capabilities and to take advantage of human strengths.*

RESPONSE: See response to RAI HF-1a and HF-1b

License Documentation Impact: None

HF-6. NUREG-1520, Appendix E, criterion F indicates that discussion of staffing should be included in the applicant's approach to the HFE Design Review. Further, development of management measures for IROFS as well as the potential impact of human error on administrative IROFS is a function of staffing, workload, training, skills and experience. ISA Summary Section 4.2.3 states that personnel qualifications will include minimum education, technical background, experience, etc., along with physical skills needed to perform individual tasks.

Clarify how the requisite number of staff will be identified and how the requisite qualifications of personnel for each activity will be determined (with respect to functional requirements and task analysis).

RESPONSE: Consideration will be given to staffing requirements throughout the design process and will be a formal review, where applicable, and an evaluation element of the HFE Design Review Plan and program. While primary emphasis will be placed on sufficient staffing to operate the plant safely, the need to operate the plant efficiently will also be a factor and will also be considered in the development of staffing goals. Regulatory requirements will also be considered and will definitely impact staffing requirements.

Qualifications for skilled positions will be established, where applicable, and candidates will be measured against those qualifications in the selection of the workforce. The initial estimates of staffing requirements and the acceptability of staffing goals will be evaluated throughout the design process as plant layout and required worker activities are better defined.

License Documentation Impact: None

HF-7. NUREG-1520, Appendix E, Criterion I, sub-criteria i through v, provide detailed guidance on the need for Validation and Verification (V&V). This ensures the design incorporates human factors into the HSI in a manner that enables the successful completion of personnel activities. The V&V is needed to confirm, prior to operational deployment, that the design incorporates HFE to HSI in a manner that ensures IROFS will be available and reliable.

The Quality Assurance Plan, Section A.3.1.3.4 provides discussion of the design verification program but does not discuss validation of the design with respect to human factors requirements. The inclusion of V&V of the human factors engineering in design V&V in this process is not clear.

a. Clarify whether V&V of the human factors engineering of the facility is included in the design verification plan. If it does not, please provide justification.

RESPONSE: Although not specifically identified in the Quality Assurance Plan (QAP), the HFE Design Review Plan and program will be subject to the requirements of the QAP. HFE requirements and design documents will be controlled under the design control provisions of the Configuration Management Program and subject to the same change control as safety analysis, specifications, and drawings.

The check and review process will be performed by qualified, independent reviewers (others than those who performed the design) as specified in the QAP. The results of HFE V&V activities will be summarized in a summary report, and any discrepancies will be identified in a written report and will include resolutions of the discrepancies.

License Documentation Impact: None

HF-7

b. Clarify that the design verification process includes task support verification. If it does not, provide justification.

RESPONSE: Task support verification will be a part of the HFE V&V process. The objective of task support verification is to verify that the HSI provides alarms, information, and control capabilities and procedures required for personnel tasks. It verifies that all monitoring and operating functions are available, and that all operation controls are viable.

The criteria for task support verification come from task analyses of HSI requirements for performance of personnel tasks that are defined for selected operational conditions. An example of the criteria used will be as follows:

i. *General Methodology* - The HSIs and their characteristics (as defined in the HSI inventory and characterization) are compared to the personnel task requirements identified in the task analysis.

ii. *Task Requirements Deficiencies* – Human Engineering Discrepancies (HEDs) will be identified when:

- an HSI needed for task performance (e.g., a required control or display) is not available,
- HSI characteristics do not match the personnel task requirements, e.g., a display shows the necessary plant parameter but not the range or precision needed for the task.

iii. *Unnecessary HSI Components* - An HED will be identified for HSIs that are available in the operating area but are not needed for any task. Appropriate HSI components may not appear to be associated with personnel tasks for the following reasons:

- The HSI component is needed for a task that was not addressed by the task analysis (e.g., it was not within the scope of the design review),
- The task analysis was incomplete, and thus overlooked the need for the HSI component,
- The HSI component only partially meets the personnel task requirements that were established.

If an HSI component has no associated personnel tasks because the function and task analysis was incomplete, any shortcomings in that analysis will be identified and resolved.

License Documentation Impact: None

HF-7

c. Clarify that the design verification process includes integrated system verification with respect to human factors, as defined in NUREG-1520. If not, provide justification.

RESPONSE: The Team believes the question refers to "system validation" and not "verification" to be consistent with NUREG-1520. The HFE Design Review Plan and program will include Integrated System Validation testing. "Integrated system validation is the process by which an integrated system design (i.e., hardware, software, and personnel elements) is evaluated to determine whether it acceptably supports safe operation of the plant. It is intended to evaluate the acceptability of those aspects of the design that cannot be determined though such analytical means as HSI task-support verification and HFE design verification" (NUREG-0711).

These evaluations will be performed by knowledgeable personnel to perform task walkthroughs and validate the following (as a minimum):

- Role of plant personnel,
- Staffing assignments,
- Human ergonomic function,
- Specific personnel tasks,
- Failure tolerance of integrated system performance,
- Procedure adequacy, allocation, and fidelity.

License Documentation Impact: None

HF-7

d. Clarify whether HFE issues are also addressed by the corrective action program. If not, provide justification.

RESPONSE: A corrective action program is described in Chapter 11, Section 11.6 and in the Quality Assurance Program description, Section A.15 of the IIFP License Application. This corrective action program and the related implementation procedures include root-cause analysis of issues related to Quality Assurance and Environmental Safety and Health. Consideration of human factors is one of the basic elements and integral parts of the root-cause analysis methodology. When HFE issues arise, those will be incorporated into the corrective action program with a commitment to follow through on the corrective action to resolution.

License Documentation Impact: None

HF-7

e. Provide a description of the methods to be used in the Human Factors V&V process.

RESPONSE: The V&V portion of the HFE Design Review Plan and program is described in HF-7, parts (a) through (d), above.

License Documentation Impact: None

HF-7

f. Describe how issues identified in the V&V process are included and resolved.

RESPONSE: See response to HF-7(a) above. Issues are identified as Human Engineering Discrepancies (HED) and are documented, tracked, and resolved.

License Documentation Impact: None

Human Factors

HF-7

g. Section 11.1.5.3 of the License Application states that human factors will be considered in evaluating a modification. Describe the issues, methods, techniques or processes that will be used to consider human factors with respect to a plant modification.

RESPONSE: The following license documentation impact will be added to LA Section 11.1.5.3.

License Documentation Impact:

HFE will be included in the facility modification procedure as a review/evaluation activity for any modifications that may impact Human-System Interfaces. Modifications affecting HSI may be implemented for the following reasons:

- Obsolescence,
- Lack of spare parts,
- Lack of vendor support,
- New functionality requirements,
- Improve process performance,
- Enhance operator performance,
- Others.

If the assessment reveals that the modification affects HSI, the HFE process will be applied. This approach to assessing modifications will be included in the HFE Design Review Plan and program.