Human Factors Requests for Additional Information for Review of the International Isotopes Fluorine Products Application

Title 10 of the *Code of Federal Regulations* 70.61(e) requires a safety program to ensure that each item relied on for safety (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. Integrated Safety Analysis (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 (HSI) involved in the accident sequences that include human actions, such that the impact on the IROFS can be evaluated.
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.

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 HSI for personnel activities. The 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.

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).

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

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 that 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.

The staff has not found a discussion of the structured approach to HFE. Although, Quality Assurance, Section A.3.1.3.3 describes 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.
b. Per NUREG-1520, Appendix E, Criterion E: Explain the process used to incorporated HFE into the design of the 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.

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 International Isotopes Inc. (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.
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.
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.

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).

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.
b. Clarify that the design verification process includes task support verification. If it does not, provide justification.
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.
d. Clarify whether HFE issues are also addressed by the corrective action program. If not, provide justification.
e. Provide a description of the methods to be used in the Human Factors V&V process.
f. Describe how issues identified in the V&V process are included and resolved.
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.