



International Isotopes Inc.

May 3, 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 document is 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.

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Please contact me by phone at 208 524-5300 or email at jjmiller@intisoid.com if you have any questions regarding this letter or require additional information.

Sincerely,

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Radiation Safety Officer

JJM-2011-31

Enclosure as Stated

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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 process of the 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 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 1 Appendix E, criterion E.

The IIFP License Application (LA) will be revised as shown below in License Documentation Impact number 1 to include the IIFP commitment to incorporate acceptable human factors engineering standards and applicable requirements into the safety and design program. Because the human factors and human-system interface (HSI) design supporting the IIFP safety analysis is not at the detail design stage, information relative to human tasks, specific human-system interfaces (HSIs) design or style guides, 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.

The basic Human Factors Engineering (HFE) Implementation Plan (referred to as the Plan) is being added to the IIFP Integrated Safety Analysis (ISA) Summary as shown below in the License Documentation Impact number 2 below. The Plan has been renamed the "HFE Implementation Plan" to replace the name "HFE Design Review Plan" that was submitted in the response to the draft Human Factors RAIs. This title change is being made to better reflect that human factors will be considered and developed beyond just the design aspects. Human factors will also be addressed during development of operating procedures, personnel training and other management measurement procedures involving Items Relied On For Safety (IROFS). The Plan being incorporated into the ISA Summary identifies the IIFP program elements, describes the basic processes by which these elements will be implemented and further assures IIFP commitments to HFE consideration in the design and operation of the IIFP Facility. The implementation process for each HFE element will be applied accordingly to ensure consideration

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of the HFE aspects for the IROFS structures, systems and components (SSCs) once those SSCs are defined and prior to actual design and design review. The Plan and its elements will be updated by the HFE/ISA team, approved by IIFP and reviewed by the affected design engineers prior to beginning detail design of the IROFS SSCs. The HFE/ISA team authorization and responsibilities are discussed in paragraph number 4 of the ISA Summary Section 4.6. Before beginning that IROFS detail design, the Plan update will be made available for NRC staff review including the identification of human-system interfaces involved in the IROFS, actions and consequences of those human-interface actions, and a design review or style guide focused toward a depleted uranium de-conversion facility.

License Documentation Impact (1): Section 3.2.5.8 of the IIFP LA will be revised by adding the following to the end of the section.

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," Revision 2, May 2002, (USNRC, 2002a) NUREG-0711, "Human Factors Engineering Program and Review Model," Revision 2, February 2004 (USNRC, 2004), and NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," Revision 1, Appendix E, "Human Factors Engineering for Personnel Activities", May 2010 (USNRC, 2010).

License Documentation Impact (2): Renumber ISA Summary Section 4.6 "References" to Section 4.7 "References." Add a new Section 4.6 "Human Factors Engineering and Implementation" to the IIFP ISA Summary to read as follow.

4.6 Human Factors Engineering and Implementation

IIFP commits to following acceptable Human Factors Engineering (HFE) guidance for personnel activities identified as safety significant (involving IROFS). The Integrated Safety Analysis (ISA) Summary will be used to identify those areas and to further determine whether an Item Relied on for Safety (IROFS) has special or unique safety significance relative to human factors. Where IROFS involve human actions, they will be evaluated further to consider potential consequences of human related errors or failures. The goal of this application of HFE to personnel activities is to ensure that the potential for human error in facility operations is addressed during the design of the facility and during operating procedure development and personnel training to minimize human error and resulting impacts and to provide means for detecting and correcting or compensating for error.

IIFP intends to comply with HFE guidance provided in NUREG-0700, "Human-System Interface Design Review Guidelines," Revision 2, May 2002, NUREG-0711, "Human Factors Engineering Program and Review Model," Revision 2, February 2004, and NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," Revision 1, Appendix E, "Human Factors Engineering for Personnel Activities, May 2010.

The Human Factors Engineering (HFE) Implementation Plan identifies the IIFP program elements, describes the basic processes by which these elements will be implemented and further assures IIFP commitments to HFE considerations in design and operation of the IIFP Facility. The implementation process for each HFE element will be applied accordingly to ensure consideration of the HFE aspects for the IROFS structures, systems and components (SSCs) once those SSCs are defined and prior to actual design and design review.

The IIFP President will approve the makeup and membership of a joint HFE/ISA team and

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delegate the authority to this team to carry out the responsibilities of: 1) identifying the human-system interfaces relative to IROFS and evaluating actions and consequences involved, 2) developing the specific information for updating the Plan prior to actual detail design of IROFS, 3) interviewing persons with technical, operational or maintenance experience in processes and controls associated with facilities handling, processing or manufacturing UF₆, UF₄ and uranium oxide and related radiological or chemical hazards and 4) coordinating and communicating with the design team, QA staff and the IIFP Facility project team to develop and implement criteria, requirements, design review (style) guidance and findings of analyses derived from the Plan implementation processes.

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

- Section 1.0 Identification of Personnel Activities (E1)
- Section 2.0 HFE Design Review Planning (E2)
- Section 3.0 Operating Experience Review (E3)
- Section 4.0 Functional Allocation Analysis and Task Analysis (E4)
- Section 5.0 HSI Design, Inventory, and Characterization (E5)
- Section 6.0 Staffing (E6)
- Section 7.0 Procedure Development (E7)
- Section 8.0 Training Program Development (E8)
- Section 9.0 Verification and Validation (E9)

Brief descriptions as to how the elements of HFE provided in Appendix E of NUREG-1520 will be implemented are provided in sections 4.6.1 through 4.6.9 of the ISA Summary.

The HFE design process to be used for the IIFP Facility is depicted in Figure 4-1.

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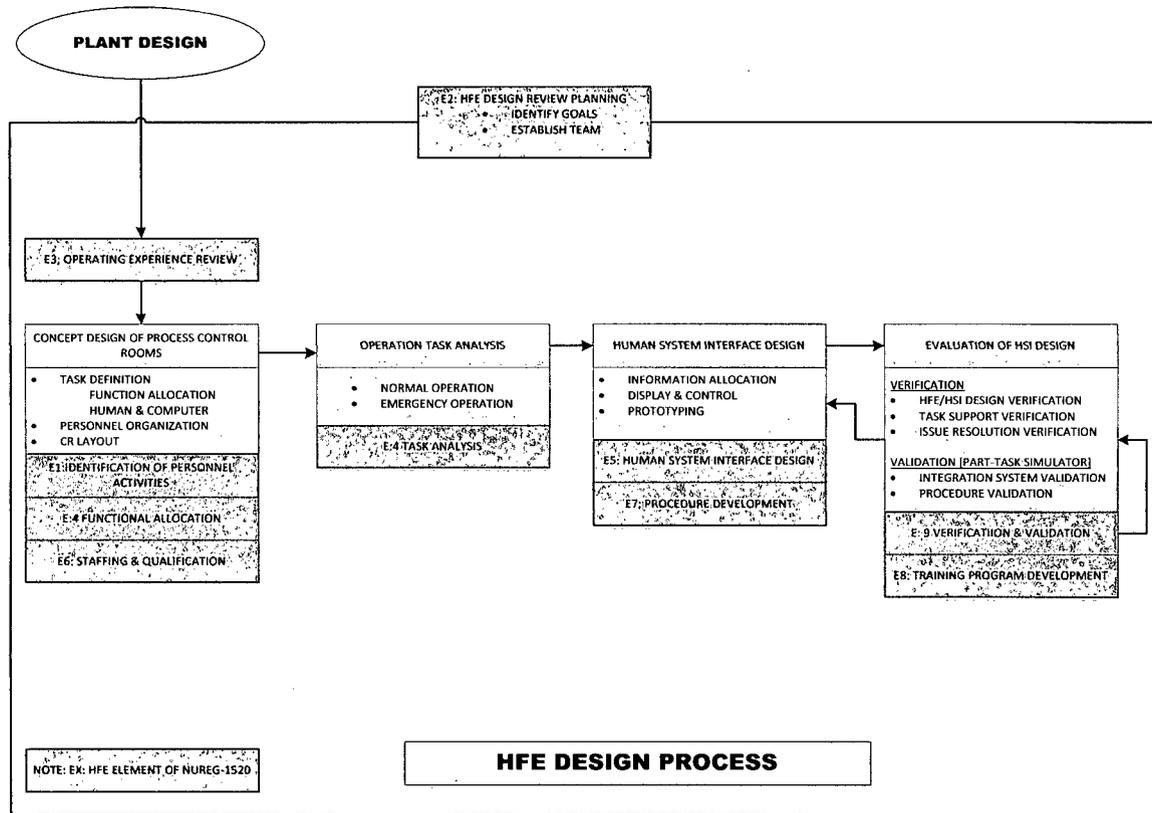


Figure 4-1 IIFP Facility Human Factors Engineering Design Process

4.6.1 Identification of Personnel Activities

The ISA Summary will be the guidance document used to identify personnel activities which are safety significant. There are some IROFS which involve primarily human actions, namely the Administrative Control (AC) and Enhanced Administrative Control (EAC) IROFS. Personnel actions involved with these IROFS will be addressed primarily through training and procedures as human-system interfaces (HSIs) for these IROFS are minimal and do not involve complex equipment or systems. For Engineered Control (EC) and Passive Engineered Control (PEC) IROFS, the equipment and systems are more complex and additional consideration is warranted. IROFS boundary definitions of structures, systems and components (SSCs) are critical in the identification of personnel activities and corresponding HSIs.

4.6.1.1 Identification of Personnel Activities - Implementation Actions

Members of the HFE/ISA team will review, consider and evaluate the IROFS to identify personnel activities, human-systems interfaces, and consequences after the IROFS SSCs boundaries are defined but prior to HSI design activities.

4.6.2 HFE Design Review Planning

4.6.2.1 Scope and Goal Identification

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The HFE program for the IIFP Facility will be developed in accordance with the nine elements specified in Appendix E of NUREG-1520. Design goals will be used that assure the following are accomplished:

- 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.

4.6.2.2 ISA Team and Qualifications

A single ISA team completed all aspects of the ISA activities. Team member qualifications were consistent with guidance provided in NUREG 1520 (USNRC, 2002b). The ISA team was made up of a diverse group of individuals with expertise in engineering, safety, safety analysis, and UF₆ and general uranium chemistry. The team possessed expertise in the following range of specialties, at a minimum:

- 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;
- UF₆ and chemical/nuclear processing; and
- Fire safety.

The ISA team members are trained, knowledgeable and experienced in a wide array of ISA methods including hazards identification, process hazards analysis (PHA), and safety analysis and risk assessment at various chemical/nuclear facilities. The team was ultimately responsible for the methods and approach of the overall ISA development.

4.6.2.3 HFE Expertise Added to Project Team

An Engineer with experience in human factors engineering is being added to the ISA team through the Design and Build Contractor. 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 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

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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 also includes development of instruments and control criteria including HFE criteria and HFE references used in nuclear power plants' control room designs such as EPRI NP-3659 (Kincaide, 1984), NUREG-0700 and NUREG-0711 as well as ANS/IEEE Standard 1023 (IEEE, 2004).

4.6.2.4 HFE Design Review Planning - Implementation Actions

During the design and construction stages of the facility, IIFP will rely heavily on the HFE expertise of the Design and Build Contractor and the ISA/HFE team to accomplish the above goals. Various aspects of personnel activities including the HSIs will be developed, designed, and evaluated on the basis of a structured approach using HFE as depicted in the HFE Design Process shown above. As the facility nears operating status, the staffing, training development, and procedure development elements will be implemented by the IIFP team. The tracking and maintenance of HFE elements will naturally transition to the Quality Assurance and Configuration Management programs designed and maintained by IIFP personnel. In this way, HFE will be applied to any subsequent changes of equipment, controls, or systems affecting IROFS and human-system interfaces.

The HFE Implementation Plan will be developed in accordance with the nine elements of the HFE design process described in NUREG-1520, Rev.1 Appendix E (USNRC, 2010) and encompass the elements of Sections 1.0 through 9.0. The scope of the HFE Implementation Plan includes the applicable Process Control Room, alarm and control instrumentation, and local panels, supporting procedures, training, applicable operations, accident management, emergency response management, maintenance, tests, 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.

4.6.3 Operating Experience Review (OER)

The 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. This knowledge base will be used in identifying safety-related issues.

4.6.3.1 Review of HFE-Related Events - Implementation Actions

NRC and DOE event reports will be reviewed to identify potential safety issues especially as they relate to HFE. Internet searches of recognized databases (to include the DOE Office of Scientific and Technical Information (OSTI) Information Bridge) will also be performed to find safety and HFE related information.

4.6.3.2 HSI Technology Review - Implementation Actions

Searches for relevant HFE events or potential events will focus not only on personnel actions involved but also on HSI technology employed at these facilities so that the same issues can be prevented in the IIFP Facility. It is recognized that improper design or equipment selection may be a root cause of safety and HFE related issues.

4.6.3.3 Review of Similar Facilities – Implementation Actions

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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.

4.6.4 Functional Allocation Analysis (FAA) and Task Analysis (TA)

4.6.4.1 Functional Allocation Analysis

Actual operating experience provides a good basis for determining personnel allocation to accomplish necessary work tasks in a safe and efficient manner. IIFP will use Functional Allocation Analysis to take advantage of human strengths and to avoid placing demands on personnel which are not compatible with human capabilities.

4.6.4.2 Functional Allocation Analysis - Implementation Actions

The OER including Design and Build Contractor experience will be used to functionally allocate personnel activities and to assign these activities to worker categories. The OER will be based primarily on reviews of operations and experience at facilities involving UF₆, UF₄ and uranium oxides and interviews about hazard and related controls with technical, operations, and maintenance function workers with experience at such facilities. These reviews will also provide a good basis for initial staffing requirements for both operations and maintenance personnel.

4.6.4.3 Task Analysis

Task analysis involves determining the requirements of personnel to successfully and safely perform complex real-time control actions as part of the job assignments which result from functional allocation. Task analysis is also used extensively in procedure development.

4.6.4.4 Task Analysis - Implementation Actions

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.

4.6.5 HSI Design, Inventory, and Characterization

The HSI design process uses inputs from the OER, the FAA, and the TA to translate function and task requirements into HSI characteristics and functions. A structured methodology will be used to identify and select the HSI approach, define the detailed design, and perform validation and verification testing. The minimum inventory of HSIs, displays, alarms and control instruments for each control process involving IROFS will be developed from structured review and evaluation of the IROFS control function, the -IROFS functional information and input derived from OER,

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FAA and TA results. The ISA Summary change control process that is implemented through the IIFP configuration management measures will be the method of ensuring the inventory list is kept up to date during design stage and later during facility maintenance. This structured methodology and its results will be documented in accordance with requirements of the IIFP Quality Assurance Program Description.

4.6.5.1 HSI Design - Implementation Actions

The HSI design will incorporate the FAA and the TA processes into the detailed design of safety-significant HSI components (e.g. alarms, displays, controls, and operator aids) through the systematic application of HFE. The work environment will also be considered to include Control Room and remote shutdown area layouts, control panel and console design, control and display device layout, and information and control interface design details. Extraneous controls and displays will be identified through the above described process techniques and eliminated.

A structured, systematic approach will be applied to the human factors considerations for the Process Control Room 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 Function Allocation, and
- Staffing and Qualification

The Process Control Rooms will be designed based on the OER findings and the experience of the HFE/ISA team and the project design engineers as applicable. The HSI will be based on designs in similar facilities but modernized using the ergonomic and digital technology such as Visual Display Units (VDU) integrated into work stations, soft controls, large panel displays, adequate work surfaces, performance enhancing furniture, etc. with the layouts being determined based on 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 and design review criteria derived from published standards. Design review criteria and style guidance with consideration for human factors for layouts, locations and configurations of alarms, displays and control instrumentation will be developed for use by the design engineers prior to beginning actual Control Room and associated instrumentation designs.

Ergonomics of the human-system interface will include determination of environmental conditions (lighting, noise, ambient working temperatures, radiation, air quality, and humidity) in the Process Control Rooms, and at local control stations. Designs will employ well-accepted International Building Code (IBC) standards with consideration for the ergonomic design aspects.

Extraneous controls and displays will be identified during the Task Support Verification process. Unnecessary HSI components will be identified for HSIs that are available in the HSI but are not needed for any task. Unnecessary HSIs introduce clutter and can distract personnel for the selection of appropriate HSIs. It is important to verify that the HSI is actually unnecessary. If an HSI component has no associated personnel tasks because the function and task analysis was incomplete, then any shortcomings in that analysis are identified and resolved.

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4.6.6 Staffing

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 to be considered in the development of staffing goals. The conceptual design team and the Design and Build Contractor have extensive staffing experience in facilities where similar work is performed such as UF₆ cylinder handling and feeding, drum handling and filling, chemical process operations, waste treatment operations, radiation monitoring, and laboratory sampling and analysis.

4.6.6.1 Staffing - Implementation Actions

The OER, the FAA, and the TA are initially used to determine staffing requirements, and consideration will be given to these requirements throughout the design process. Qualifications for skilled positions will be established 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 facility layout and required worker activities are better defined. Categories of personnel will be based on types of personnel activities and issues identified in the OER, the FAA and TA. HSI design, procedure development, and verification and validation will be used to address staffing considerations. Regulatory requirements will also be considered and may impact staffing.

4.6.7 Procedure Development

IIFP will incorporate HFE principles and criteria and design requirements into procedures that are technically accurate, comprehensive, explicit, user-friendly, and validated. The elements of HFE set forth in Appendix E of NUREG-1520 will be considered in procedure development. Procedures may include generic technical guidance, plant and system operations, abnormal and emergency operations, system or process testing (e.g. pre-operational, startup, and surveillance), and alarm response.

Procedures are developed or modified through a formal process incorporating the change controls described in Section 11.1.5 of the License Documentation (IIFP, 2009a). The procedures process utilizes nine basic elements to accomplish procedure development, review, approval, and control. These elements are Identification, Development, Verification, Review and Comment Resolution, Approval, Validation, Issuance, Change Control, and Periodic Review. See Chapter 11 of the License Application (IIFP, 2009a) for details of these elements.

4.6.7.1 Procedure Development - Implementation Actions

Production work aside from routine custodial and office duties will be governed by approved procedures. Additionally, program requirements will be implemented via procedures, where applicable. Procedures are necessary to provide consistent and reliable performance of site-wide activities.

Applicable safety limits and IROFS will be clearly identified in the procedures. IIFP will incorporate methodology for identifying, developing, approving, implementing, and controlling operating procedures. Identifying needed procedures will include consideration of ISA results. The method will ensure that, as a minimum:

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- Operating limits and IROFS are specified in the procedure.
- Procedures include required actions for off-normal conditions of production, as well as normal production.
- Needed safety checkpoints are identified at appropriate steps in the procedure.
- Procedures are validated through field tests.
- Procedures are approved by functional managers responsible and accountable for the operation.
- A mechanism is specified for revising and reissuing procedures in a controlled manner.
- The QA elements and CM program at the facility provide reasonable assurance that current procedures are available and used at all work locations.

IROFS and other safety related items will be highlighted in work procedures, typically as “cautions” and “warnings.” Procedures will be developed and approved by the responsible organizations. Employees will be trained on all procedures they follow as part of their work assignments, and work procedures and supplemental safety related procedures are expected to be located in the general work areas. Temporary work shall be performed under temporary work orders or radiation work permits (RWPs).

Facility and process changes will require procedure updates in the form of revisions, and such revisions shall be in place before restart of the operation can commence. Changes to safety systems and safety basis documentation shall also be incorporated into respective procedures. Employees will be retrained on the revised procedures before the restart of work.

4.6.8 Training Program Development

The principle objective of the IIFP training program system is to ensure job proficiency of facility personnel through effective training and qualification. The training program system is designed to accommodate future growth and meet commitments to comply with applicable established regulations and standards. Employees are provided with training to establish the knowledge foundation and on-the-job training (OJT) to develop work performance skills. Continuing training will be provided, as required, to maintain proficiency in these knowledge and skill components, and to provide further employee development.

4.6.8.1 Training Program Development - Implementation Actions

Training program development will address all personnel activities in the performance of job tasks involving IROFS. It is anticipated that training will involve familiarization with procedures, equipment, systems, controls, alarms, etc. The personnel will be trained in all areas involving IROFS necessary to perform their job assignments safely and efficiently. The evaluation of personnel knowledge and skill requirements will be a part of this process. It is intended that the training program development will be coordinated with other activities of the HFE design process and will be implemented in an effective manner consistent with human factors principles and practices.

Qualifications and training requirements will be established for each functional type of work. Qualifications will include minimum education, technical background, experience, etc., along with physical skills needed to perform individual tasks. Employees will be provided formal classroom training and on-the-job training specific to their duties, as applicable. Workers shall read, understand, and follow formal area procedures when performing work. Additionally, workers shall understand and obey requirements in work orders, hot work permits, and radiation work permits (RWPs) along with posted limits and controls. Job Task Analysis will be used to

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supplement training when tasks associated with IROFS are involved.

Job qualification will be indicated by successful completion of prescribed training, demonstration of the ability to perform assigned tasks, and the maintenance of requirements established by regulation. A graded approach to systematic training will be used that applies the level of detail needed relative to safety. This graded approach incorporates methods to accomplish the analysis, design, development, implementation, and evaluation of training.

Along with job specific training mentioned above, all employees will be given formal general employee training and safety training, as needed. General worker training includes site access information and an overview of site hazards, emergency alarms, and evacuation plans. Safety training may include radiation worker training, hazards communication, and general health and safety training. Training and qualification related documentation will be maintained as quality records. Continuing training and continuous improvement will be an emphasis for the entire workforce.

4.6.9 Verification and Validation (V&V)

4.6.9.1 HSI Task Support Verification

HSI 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 all alarms, information, and control capabilities and procedures required for personnel tasks. It verifies that all monitoring and operating functions are available, and that all operational controls are both possible and functional.

4.6.9.2 HSI Task Support Verification - Implementation Actions

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 to be used is as follows:

- i. *General Methodology* - The HSIs and their characteristics (as defined in the HSI inventory and characterization) will be 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, or
 - 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. Unnecessary HSIs introduce clutter and can distract personnel for the selection of appropriate HSIs. It is important to verify that the HSI is actually unnecessary.

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

4.6.9.3 HFE Design Verification

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HFE design verification is used to determine whether HFE has been used in the design HSI.

4.6.9.4 HFE Design Verification - Implementation Actions

HFE design verification will be performed to determine that each HSI identified for personnel activity has HFE incorporated into the design. Deviations from accepted HFE principles and guidelines will either be justified or documented for resolution.

4.6.9.5 Integrated System Validation

The HFE 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 using performance-based tests 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 through such analytical means as HSI task-support verification and HFE design verification” (NUREG-0711).

4.6.9.6 Integrated System Validation - Implementation Actions

It is anticipated that the validation testing will be performed using a test bed that is a “part-task” simulator. The part-task simulator is not a “full scope, high realism” simulator but one that will provide a suitable representation of the Process Control Rooms and local control panels using analytical means that will adequately validate and test the design. It will have a high degree of physical, functional, data completeness, data content, and data dynamics fidelity. The part-task simulator will also be used as a training tool as well as a design tool for developing new or upgraded software.

These evaluations will be performed, where IFOFS are involved, by knowledgeable personnel to perform task walkthroughs, reviews of task analysis and functional analysis findings, engineering drawing reviews against field conditions, flow charting of procedural steps, operational task charts, and analysis of simulator results. These techniques, where applicable, will be used to validate the following (as a minimum):

- Validate the role of plant personnel,
- Validate staffing assignments,
- Validate each human ergonomic function,
- Validate specific personnel tasks,
- Validate that the integrated system performance is tolerant of failures, and
- Validate procedure adequacy, allocation, and fidelity.

4.6.9.7 HFE Issue Resolution Verification

The HFE Implementation Plan will be subject to the requirements of the Quality Assurance Program Description (QAPD) and all 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 analysis, specifications, and drawings.

Additionally, a corrective action program is described in Chapter 11, Section 11.6 (IIFP, 2009a) and in the QAPD (IIFP, 2009d), 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

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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.

4.6.9.8 HFE Issue Resolution Verification - Implementation Actions

The check and review process will be performed by qualified, independent reviewers (other than those who performed the design) as described in the QAPD. The results of HFE V&V activities will be summarized in a summary report and any discrepancies will be identified in a Human Engineering Discrepancy (HED) report. The HED report will also include the resolutions. 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 HSIs may be implemented for the following reasons:

- Obsolescence,
- Lack of spare parts,
- Lack of vendor support,
- New functionality requirements,
- Improved process performance,
- Enhanced operator performance, and
- 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 Implementation Plan.

License Documentation Impact (3): Renummer ISA Summary, Section 4.6 "References" to Section 4.7 References" and revise or add references, as applicable for ISA Summary Chapter 4.

4.6.4.7 References

IIFP, 2009a. International Isotopes Fluorine Products, Inc., "Fluorine Extraction Process & Depleted Uranium De-conversion Plant (FEP/DUP) License Application.", December 2009.

IIFP, 2009b. International Isotopes Fluorine Products, Inc., "'Fluorine Extraction Process & Depleted Uranium De-conversion Plant (FEP/DUP) Emergency Plan", 2009.

IIFP, 2009c. International Isotopes Fluorine Products, Inc., "'Fluorine Extraction Process & Depleted Uranium De-conversion Plant (FEP/DUP) Integrated Safety Analysis Summary.", December, 2009.

IIFP, 2009d. International Isotopes Fluorine Products, "'Fluorine Extraction Process & Depleted Uranium De-conversion Plant (FEP/DUP) Quality Assurance Program Description." December 2009.

IEEE, 2004. Institute of Electrical and Electronic Engineers, IEEE-1023. "IEEE Recommended Practice for The Application of Human Factors Engineering to Systems, Equipment, and Facilities of Nuclear Power Generating Stations and Other Nuclear Facilities." 2004.

Kincaide, 1984. Kincaide, R.G., and Anderson J., Electric Power Research Institute. "Human Factors Guide for Nuclear Power Plant Control Room Development." EPRI/NP-3659, 1984

Official Responses to Human Factors RAIs

USNRC, 2002a. U. S. Nuclear Regulatory Commission, NUREG-0700, "Human-System Interface Design Review Guidelines," Revision 2, May 2002.

USNRC, 2002b. US Nuclear Regulatory Commission, NUREG-1520. "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility.", 2002.

USNRC, 2004. U.S. Nuclear Regulatory Commission, NUREG-0711, "Human Factors Engineering Program and Review Model," Revision 2, February 2004.

USNRC, 2010. US Nuclear Regulatory Commission, NUREG-1520. "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility" Revision 1, Appendix E, "Human Factors Engineering for Personnel Activities," May, 2010.

Official Responses to Human Factors RAIs

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 the ISA accident scenarios used their many years of plant operating experience in those evaluations. The ISA team conducted the PHA accident analysis by organizing each of the processes into system and unit operations nodes based on conceptual design of the IIFP Facility. Each node was reviewed by a team with relative experience in 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-1(a)).

As part of the PHA “what if” analysis, the team members considered their operating experiences and lessons learned in facilities involving processing and handling of UF₆, UF₄, uranium oxides and fluorine compounds, but did not formally conduct and document a separate operational experience review. Team members have been involved with various facets of plant and unit operations and are familiar with actions and activities performed by operations and maintenance personnel. The HFE Implementation Plan discusses the basis process that IIFP will use for performing a more structured formal operational experience review prior to starting detail design of IROFS structures, systems and components.

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

Official Responses to Human Factors RAIs

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 project through the Design and Build Contractor. This arrangement and approach provides 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 through the detailed design. This Engineer will be involved in the development of the HFE Implementation Plan that applies a structured approach to HFE. This role will be filled early in the scope of work of detail design and engineering once the Design and Build Contract is agreed and signed.

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 experience involved 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, & 0711 as well as ANS/IEEE Std. 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;
- UF₆ and chemical/nuclear processing;
- Fire safety; **and**
- Human Factors

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

Note : Add the following to bottom of Table 5.1:

Official Responses to Human Factors RAIs

<u>Design Engineer with HFE experience</u>	<u>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, control system design, and instrumentation specifications and detail engineering. Experience and development of HFE criteria, control room designs and HFE Implementation Plan or including guidance provided NUREG 0700 and NUREG 0711.</u>
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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.

Table 0-1. ISA Team Members PHA Qualifications

Team Member	Role(s)	Radiological Safety	Fire Safety	Chemical Process Safety	Process Engineering	Environmental Safety	<u>Human Factors Engineering</u>
Ron Green	Team Leader	X		X	X		
Carol Mason	Safety Analyst, Chemical Process Safety			X	X	X	
Tammy Wheeler	Safety Analyst, Health Physics	X				X	
<u>Daniel Theisen</u>	<u>Safety Analyst, Environmental Safety</u>			<u>X</u>		<u>X</u>	
Mike Balmert	Facility safety, PHA			X	X		
Andy O'Connor	Fire safety		X				
Jim Thomas	Chemical, mechanical, and electrical engineering ; plant operations and maintenance; UF ₆ and chemical-nuclear processing			X	X	X	
Don Chumbler	Quality Assurance, Environmental Safety, Radiation Protection	X			X	X	
Tommy Thompson	Fire Hazard Analyst		X		X		
Gary Holland	UF ₆ and chemical-nuclear processing			X	X		
To be Added	<u>Human Factors Engineer</u>						<u>X</u>

Official Responses to Human Factors RAIs

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, ~~and~~
- ISA methods, and
- Human Factors.

Official Responses to Human Factors RAIs

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 Summary Section 2.1.4.1 appears to be incorrect.

RESPONSE: The fifth paragraph of Section 2.4 of the ISA Summary provides a general description of the Control Rooms (CR). The current concept is that three (3) Control Rooms will be provided to support the major processes and one (1) control area is provided to support the supporting utilities. The Control Rooms will be located in the following areas:

- DUF₄ Process Building, (the DUF₄ process and autoclave operations are controlled in this CR);
- FEP Process Building, (this building has its own process joint CR for the SiF₄ and BF₃ processes);
- AHF Staging Containment Building and Fluoride Products Trailer Loading Building share a CR, (Neither of these buildings contain licensed material and does not affect areas containing licensed material).

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.

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 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 details of the Process Control Rooms have not yet been developed and will be subject to locations where licensed materials are involved or licensed materials may be affected. Concepts will be based on experience of the ISA team with information from similar projects that will be upgraded using modern digital control and information systems and subject to the HFE

Official Responses to Human Factors RAIs

Implementation Plan.

License Documentation Impact: The fifth paragraph of ISA Summary Section 2.4, referred to in the response above will be revised as follows for clarification of the locations of the facility Control Rooms (see RAI GI-6B), see also License Documentation Impact in HF-1(a). Also, a discussion is added on the process of how the control instrumentation, alarms, etc. will be determined to provide relevant information and response to the Control Room Operator.

Process Control Rooms are provided, including ~~appropriate~~ monitoring, recording, alarm notification and control instrumentation. During the detail design of Control Room alarms, displays, and control instrumentation, the design review (style guide) and the standards criteria developed from the HFE Implementation Plan will be used as guidance for the design engineers in the consideration of human-system interfaces and human factors. The guidance will be developed prior to beginning detail design of affected Control Room instrumentation. The affected Control Room alarms, displays and control instrumentation will be determined from: 1) the reviews and evaluations of the IROFS, 2) the tasks that involve human interaction relative to IROFS functions and responses including development of written procedures and operator aids, 3) the functional analysis of the IROFS structures, systems and components and how those functions involve human tasks in support or response of the function, 4) evaluation of the alarm, readout, display and instrumentation interface with the Operator for effective and accurate communications and 4) the consequences of human action responses relative to an IROFS SSC functionality.

A Control Room is, ~~and are~~ located in the DUF₄ Process Building. The DUF₆ Autoclave Building is controlled from the DUF₄ Process Building. The FEP Process Building, has its own process joint Control Room for the SiF₄ and BF₃ processes, and The AHF Staging Containment Building and the Fluoride Products Trailer Loading Building share a Control Room (Neither of these buildings contain licensed material and does not affect areas containing licensed material).

Likewise, one control area is located in the Utilities Building for monitoring and controlling the steam boiler system, air compressors and other utility supply equipment. Control Room areas and electrical and instrument rooms are typically of concrete block construction with concrete or metal roofs. Ceiling assemblies and fire walls separate these areas from production areas of the facilities. Process Control Rooms, where routinely occupied by workers, have environments maintained for comfort and safety. Control Rooms located in process areas, where uranium or hazardous chemicals are processed, stored or handled, have separate heating, ventilation and air conditioning (HVAC) systems. The Control Rooms are maintained at a slight positive pressure with respect to the surrounding areas and are provided with low pressure alarms to notify occupants should a loss of pressure inside a Control Room occur.

Official Responses to Human Factors RAIs

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: Anticipated displays, alarms and HSIs have been considered during the conceptual stage of the design by the ISA team members. Team members have experience in these types of process systems. The basis for the concepts is from team member past experience with similar process plants. A conceptual listing will be used as a preliminary starting point of the design for the systems and subsystems. Each display and supporting instrumentation and controls involving IROFS will be developed, designed, and implemented using a structured approach as detailed in the HFE Implementation Plan (See Section 4.6.5 of the revised ISA Summary discussed in RAI HF-1(a) above). 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.

License Documentation Impact: None

Official Responses to Human Factors RAIs

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 approach will be applied to the human factors considerations 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 and local control stations;
- Functional requirements analysis and functional allocation; and
- Staffing and qualifications.

The Process Control Rooms will be designed based on the experience of the HFE/ISA team and the project design engineers as appropriate. The HSI will be based on similar process plants (involving UF₆ and uranium materials) which are already known; such as the Paducah Gaseous Diffusion Plant, a commercial conversion plant, centrifuge enrichment facilities and the SFC conversion and de-conversion plants. IIFP will use the past experiences coupled with modernized and ergonomic 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 Implementation Plan. Design review criteria and (style) guidance will be developed prior to actual detail design and used by the design engineers for the control room, panels, and instrumentation layouts (See RAI HF-1(a) License Documentation Impact, ISA Summary Section 4.6.5.1 above).

Determination of Control Room environmental conditions and ergonomics is also discussed in the added Section 4.6.5.1 of the IIFP ISA Summary.

License Documentation Impact: See RAI HF-1(a).

Official Responses to Human Factors RAIs

HF-3

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

RESPONSE: Extraneous controls and displays will be identified and addressed during the Task Support Verification process (See Section 4.6.9 of the revised ISA Summary as described in response to RAI HF-1(a) above. Unnecessary HSI Components will be identified for HSIs that are available in the HSI but are not needed for any task. Unnecessary HSIs introduce clutter and can distract personnel for the selection of appropriate HSIs. It is important to verify that the HSI is actually unnecessary.

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

License Documentation Impact: See RAI HF-1(a).

Official Responses to Human Factors RAIs

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 Implementation Plan 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 Implementation Plan will provide design goals to ensure that:

- 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, and
- Control areas minimize stressors and fatigue while assuring adequate communication.

The HFE Implementation Plan 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 Implementation Plan includes all Process Control Rooms and local panels, supporting procedures, training, all operations, accident management, emergency response management, maintenance, test, inspection and surveillance interfaces (including procedures), facility management and facility personnel.

License Documentation Impact: See RAI HF-1(a).

Official Responses to Human Factors RAIs

HF-4

- b. *Per NUREG-1520, Appendix E, criterion E: Explain the process used to incorporate 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: As stated in the response to HF-1(b), the process used to incorporate HFE into the design of HSIs will include the techniques and processes described in the IIFP ISA Summary revised Section 4.6, "Human Factors Engineering Implementation Plan". The tools and techniques of this Plan will be developed and employed by personnel with extensive design and operating expertise and experience in plants of similar designs to that of the IIFP. The conceptual design and safety analysis teams have many years of combined experience where similar systems and human systems interfaces are involved. Team members have been involved with many facets of plant operations involving uranium hexafluoride and uranium materials and are familiar with actions and activities performed by operations and maintenance personnel. They have gained that experience in the daily performance of their actual job duties as well as in response to emergency situations where non-routine activities are performed. The process that will be used to continue the incorporation of HFE into design of the HSIs, alarms, etc, is described in the response to HF-4(a) and included in the IIFP ISA Summary as Section 4.6.

License Documentation Impact: See RAI HF-1(a).

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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: The process used to incorporate HFE into the design will be to rely heavily on the expertise of personnel with extensive plant operating experience in processes of similar and/or almost identical designs to that of the HFP. The conceptual design team and the Design and Build Contractor have experience in facilities where similar work is performed. The Team will review HFE programs as part of the Plan discussed in response to RAI HF-1(a) and the revised ISA Summary Section 4.6 described in that response. This will include interviews with experienced persons that have worked or are working in facilities such as DUF₆ Processing (Paducah & Portsmouth), the AREVA enrichment facility, Urenco USA, the commercial uranium conversions plants, the Paducah Gaseous Diffusion Plant and the Sequoyah Fuels Corporation (SFC) former conversion and de-conversion plants.

License Documentation Impact: See RAI HF-1(a).

Official Responses to Human Factors RAIs

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: See RAI HF-1(a)

License Documentation Impact: See RAI HF-1(a) License Documentation Impact; ISA Summary revised Sections 4.6.8.1 and 4.6.9.2).

Official Responses to Human Factors RAIs

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 responses to HF-1(a) and HF-5(a), above.

License Documentation Impact: See RAI HF-1(a) License Documentation Impact.

Official Responses to Human Factors RAIs

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 with a formal review and evaluation of each element of the HFE Implementation Plan. 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. The conceptual design team has extensive staffing experience in facilities where similar work is performed such as UF₆ cylinder handling and feeding, drum handling and filling, chemical process operations, waste treatment operations, radiation monitoring, and laboratory sampling and analysis. Regulatory requirements will also be considered and will definitely impact staffing requirements.

Qualifications for skilled positions will be established 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 (See the RAI HF-1(a) License Documentation Impact revision to IIFP ISA Summary Section 4.6.6 and its subsections).

License Documentation Impact: See RAI HF-1(a).

Official Responses to Human Factors RAIs

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: The V&V plan will be subject to the requirements of the QA Program and all HFE Plan 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 analysis, specifications, and drawings. The IIFP commitment that the V&V plan will be subject to the QA program requirements is included in the ISA Summary Section 4.6 (see 4.6.9.7) described in the License Documentation Impact of the RAI HF-1(a) response.

The check and review process will be performed by qualified, independent reviewers (other than those who performed the design) as described in the QA Program Description (QAPD). 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: See RAI HF-1(a).

Official Responses to Human Factors RAIs

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 all 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 response to this RAI has been incorporated into the IIFP ISA Summary Section 4.6. See RAI HF-1(a)

License Documentation Impact: See RAI HF-1(a).

Official Responses to Human Factors RAIs

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: IIFP believes the question refers to “system validation” and not “verification” to be consistent with NUREG-1520. The HFE Implementation Plan 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 facility. It is intended to evaluate the acceptability of those aspects of the design that cannot be determined through such analytical means as HSI task-support verification and HFE design verification” (NUREG-0711).

See the IIFP ISA Summary revised Section 4.6.9.6 discussed in RAI HF-1(a) response for a description of the process.

License Documentation Impact: See RAI HF-1(a).

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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.

The IIFP corrective action program is an integral part of the IIFP Quality Assurance Program (QAP) and is included in the HFE Implementation Plan through the QAP (See response to RAI HF-1(a), License Documentation Impact revision to ISA Summary Section 4.6.9.7.).

License Documentation Impact: See RAI HF-1(a).

Official Responses to Human Factors RAIs

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 Implementation Plan is described in HF-7, parts (a) through (d), above.

License Documentation Impact: See RAI HF-1(a) License Documentation Impact for revised IIFP ISA Section Summary 4.6 and subsections relative to V&V process.

Official Responses to Human Factors RAIs

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: See RAI HF-1(a) License Documentation Impact for revised IIFP ISA Summary Section 4.6 and subsections relative to V&V process.

Official Responses to Human Factors RAIs

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 as new paragraphs and all other paragraphs will shift down in number accordingly.

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 and human factors may be implemented for the following reasons:

- Address 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. Guidelines will be provided that will address the modification for efficient design characteristics, licensing issues, and operation and maintenance considerations, as a minimum. One efficient way to address these issues is by imposing a checklist that addresses such ergonomic areas as: information display; user interfaces; controls (hard/soft); alarms; procedures; communications; workstations; maintenance; and configuration management; among others.

This approach to assessing modifications will be included in the HFE Implementation Plan.

Detail design and engineering have not begun for the IIFP Facility and a level of detail is not available for including specific actions, design or style guides, inventory lists, Control Room displays and other details of task analysis, operating experience reviews and specifics of the V&V process.