UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 23, 2021

Dr. Gregory Piefer, Ph. D.
Chief Executive Officer
SHINE Medical Technologies, LLC
101 East Milwaukee Street, Suite 600
Janesville, WI 53545

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – REQUEST FOR ADDITIONAL INFORMATION RELATED TO HUMAN FACTORS ENGINEERING AND CONDUCT OF OPERATIONS (EPID NO. L-2019-NEW-0004)

Dear Dr. Piefer:

By letter dated July 17, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19211C044), as supplemented by letters dated November 14, 2019 (ADAMS Accession No. ML19337A275), March 27, 2020 (ADAMS Accession No. ML20105A295), August 28, 2020 (ADAMS Accession No. ML20255A027), November 13, 2020 (ADAMS Accession No. ML20325A026), December 10, 2020 (ADAMS Package Accession No. ML20357A084), December 15, 2020 (ADAMS Package Accession No. ML21011A264), and March 23, 2021 (ADAMS Accession No. ML21095A235), SHINE Medical Technologies, LLC (SHINE) submitted to the U.S. Nuclear Regulatory Commission (NRC) an operating license application for its proposed SHINE Medical Isotope Production Facility in accordance with the requirements contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities."

During the NRC staff's review of SHINE's operating license application, questions have arisen for which additional information is needed. The enclosed request for additional information (RAI) identifies information needed for the NRC staff to continue its review of the SHINE final safety analysis report, submitted in connection with the operating license application, and prepare a safety evaluation report. The specific technical areas of the SHINE operating license application covered by this RAI are Human Factors Engineering and Chapter 12, "Conduct of Operations."

It is requested that SHINE provide responses to the enclosed RAI within 30 days from the date of this letter. To facilitate a timely and complete response to the enclosed RAI, the NRC staff is available to meet with SHINE to clarify the scope of information and level of detail expected to be included in the RAI response and corresponding final safety analysis report update. SHINE may coordinate the scheduling and agendas for any such meetings with the responsible project manager assigned to this project.

In accordance with 10 CFR 50.30(b), "Oath or affirmation," SHINE must execute its response in a signed original document under oath or affirmation. The response must be submitted in accordance with 10 CFR 50.4, "Written communications." Information included in the response that is considered sensitive or proprietary, that SHINE seeks to have withheld from the public, must be marked in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests

for withholding." Any information related to safeguards should be submitted in accordance with 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements." Following receipt of the additional information, the NRC staff will continue its evaluation of the subject chapters and technical areas of the SHINE operating license application.

As the NRC staff continues its review of SHINE's operating license application, additional RAIs for other chapters and technical areas may be developed. The NRC staff will transmit any further questions to SHINE under separate correspondence.

If SHINE has any questions, or needs additional time to respond to this request, please contact me at 301-415-1524, or by electronic mail at Steven.Lynch@nrc.gov.

Sincerely,


Signed by Lynch, Steven
on 09/23/21

Steven T. Lynch, Senior Project Manager
Non-Power Production and Utilization Facility
Licensing Branch
Division of Advanced Reactors and Non-Power
Production and Utilization Facilities
Office of Nuclear Reactor Regulation

Docket No. 50-608
Construction Permit No. CPMIF-001

Enclosure:
As stated

cc: See next page

cc:

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SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – REQUEST FOR ADDITIONAL INFORMATION RELATED TO HUMAN FACTORS ENGINEERING AND CONDUCT OF OPERATION (EPID NO. L-2019-NEW-0004) DATED: SEPTEMBER 23, 2021

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ADAMS Accession No.: ML21253A234 **NRR-088**

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REQUEST FOR ADDITIONAL INFORMATION

REGARDING OPERATING LICENSE APPLICATION FOR

SHINE MEDICAL TECHNOLOGIES, LLC

CONSTRUCTION PERMIT NO. CPMIF-001

SHINE MEDICAL ISOTOPE PRODUCTION FACILITY

DOCKET NO. 50-608

By letter dated July 17, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19211C044), as supplemented by letters dated November 14, 2019 (ADAMS Accession No. ML19337A275), March 27, 2020 (ADAMS Accession No. ML20105A295), August 28, 2020 (ADAMS Accession No. ML20255A027), November 13, 2020 (ADAMS Accession No. ML20325A026), December 10, 2020 (ADAMS Package Accession No. ML20357A084), December 15, 2020 (ADAMS Package Accession No. ML21011A264), and March 23, 2021 (ADAMS Accession No. ML21095A235), SHINE Medical Technologies, LLC (SHINE) submitted to the U.S. Nuclear Regulatory Commission (NRC) an operating license application for its proposed SHINE Medical Isotope Production Facility in accordance with the requirements contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities."

During the NRC staff's review of SHINE's operating license application, questions have arisen for which additional information is needed. The enclosed request for additional information (RAI) identifies information needed for the NRC staff to continue its review of the SHINE final safety analysis report (FSAR), submitted in connection with the operating license application, and prepare a safety evaluation (SE) report. The specific technical areas of the SHINE operating license application covered by this RAI are Human Factors Engineering and Chapter 12, "Conduct of Operations."

Applicable Regulatory Requirements and Guidance Documents

The NRC staff is reviewing the SHINE operating license application, which describes the SHINE irradiation facility (IF), including the irradiation units, and radioisotope production facility (RPF), using the applicable regulations, as well as the guidance contained in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (ADAMS Accession No. ML042430055), and NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (ADAMS Accession No. ML042430048). The NRC staff is also using the "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ADAMS Accession No. ML12156A069), and "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for

Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ADAMS Accession No. ML12156A075). As applicable, additional guidance cited in SHINE's FSAR or referenced in NUREG-1537, Parts 1 and 2, or the ISG Augmenting NUREG-1537, Parts 1 and 2, has been utilized in the review of the SHINE operating license application.

Furthermore, the NRC staff has, where appropriate, also referenced NUREG-0700, "Human-System Interface Design Review Guidelines," Revision 2, issued May 2002 (ADAMS Package No. ML021700373), NUREG-0711, "Human Factors Engineering Program Review Model," Revision 3, issued November 2012 (ADAMS Accession No. ML12324A013), and NUREG-1520, "Standard Review Plan for Fuel Cycle Facilities License Applications," Revision 2, issued June 2015 (ADAMS Accession No. ML15176A258), as guidance applicable to its human factors engineering (HFE) review of SHINE's operating license application.

For the purposes of this review, the term "reactor," as it appears in NUREG-1537, the ISG Augmenting NUREG-1537, and other relevant guidance can be interpreted to refer to SHINE's "irradiation unit," "irradiation facility," or "radioisotope production facility," as appropriate within the context of the application and corresponding with the technology described by SHINE in its application. Similarly, for the purposes of this review, the term "reactor fuel," as it appears in the relevant guidance listed above, may be interpreted to refer to SHINE's "target solution."

Human Factors Engineering

The following regulatory requirements and guidance are applicable to RAIs HFE-1 through HFE-8:

Paragraph (a)(3) of 10 CFR 50.34, "Contents of Applications; Technical Information," states, in part, that the minimum information to be included in a preliminary safety analysis report (PSAR) shall consist of the preliminary design of the facility, including the principal design criteria for the facility. Paragraph (b) of 10 CFR 50.34 states, in part, that an operating license application should include all current information, which has been developed since the issuance of the construction permit, as well as "[a] description and analysis of the structures, systems, and components of the facility, with emphasis upon performance requirements, the bases, with technical justification therefor, upon which such requirements have been established, and the evaluations required to show that safety functions will be accomplished. The description shall be sufficient to permit understanding of the system designs and their relationship to safety evaluations."

Paragraph (a)(3) of 10 CFR 50.57, "Issuance of Operating License," states, in part, that an operating license may be issued upon the NRC staff finding that "[t]here is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public…"

NUREG-1537, Part 2, provides review criteria that the NRC staff has determined to be within the scope of an HFE review for SHINE's operating license application. Specifically, the NRC staff's HFE review is covered by the applicable review criteria from NUREG-1537, Part 2, Sections 7.4, "Reactor Protection System," 7.6, "Control Console and Display Instruments," 12.1, "Organization," and 12.3, "Procedures." Additionally, Section 13b.1, "Radioisotope Production Facility Accident Analysis Methodology," of the ISG Augmenting NUREG-1537, Part 2, states, in part, that an application may be found acceptable if the applicant demonstrates that the proposed equipment and facilities to prevent or mitigate accidents are adequate to protect health and minimize danger to life or property, and that proposed procedures to prevent or mitigate accidents are adequate to protect health and minimize danger to life or property.

RAI HFE-1 SHINE FSAR Chapter 7, "Instrumentation and Control Systems," Section 7.1.5, "Control Console and Displays," states, in part, that "SHINE uses human factors engineering principles to facilitate the safe…performance of operations…and to ensure the implementation of operator interfaces…are standardized across vendors." Specifically, the SHINE FSAR contains the following characterizations related to the role of operators at the SHINE facility:

- "The main control board, PICS [process integrated control system]and NDAS [neutron driver assembly system] operator workstations, and supervisor workstation are not credited with performing safety functions and only assisting operators in performance of normal operations or diverse actuations to the safety systems." (SHINE FSAR Section 7.6, "Control Console and Display Instruments")

- "Manual actuations are not required to ensure adequate safety of the facility…" (SHINE FSAR Section 7.6.1.1, "Main Control Board")

- "There are no time constrained operator-required responses" (SHINE FSAR Section 7.6.2.2.3, "General I&C Requirements")

- "Operator action inside the facility is not required to stabilize accident conditions." (SHINE FSAR Section 13a2.2, "Accident Analysis and Determination of Consequences")

- "…safe shutdown conditions can be achieved without operator actions." (SHINE FSAR Section 13b.2.3, "External Events")

- "Appropriate preventative or mitigative controls were identified to reduce the overall risk of the evaluated scenarios to within acceptable limits." (SHINE FSAR Section 13b.1.2, "Accident Initiating Events")

- "Radiological consequences of criticality accidents are not included in the accident analysis because of preventative controls being used to ensure criticality events are highly unlikely." (SHINE FSAR Section 13b.1.2.4, "RPF Inadvertent Nuclear Criticality")

While the SHINE FSAR presents a number of individual statements of related to an operator's role in ensuring safety at the SHINE facility, this information is not presented in a cohesive, comprehensive manner for the NRC staff to conduct a risk-informed, graded, and appropriately scoped review of SHINE's HFE considerations.

(a) Revise the SHINE FSAR to explain, in a consolidated manner, the operator role in the SHINE facility safety as it pertains to both Irradiation Facility and Radioisotope Production Facility operations.

(b) Revise the SHINE FSAR to explain, in a comprehensive manner, how this operator role in facility safety is supported by human factors engineering.

This information is necessary for the NRC staff to fully understand the role of the operator in ensuring the safe operation of the SHINE facility and that SHINE has comprehensively identified all safety-significant aspects of facility operations for which HFE considerations are warranted. Specifically, this information will support the NRC staff in finding that, consistent with 10 CFR 50.57(a)(3), "[t]here is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public…"

RAI HFE-2 SHINE FSAR Section 7.4.2.2.14, "Human Factors," describes, in part, that "[h]uman factors is a design consideration for development of the TRPS. *Changes to the design throughout the lifecycle process include human factors considerations*" (emphasis added). SHINE FSAR Section 7.5.2.2.14, "Human Factors," similarly addresses HFE considerations for the engineered safety features actuation system (ESFAS).

NUREG-1537, Part 2, Section 7.6, "Control Console and Display Systems," contains, in part, the following acceptance criteria:

- "The outputs and display devices showing reactor nuclear status should be readily observable by the operator while positioned at the reactor control and manual protection systems."

- "Other controls and displays of important parameters that the operator should monitor to keep parameters within a limiting value, and those which can affect the reactivity of the core should be readily accessible and understandable to the reactor operator."

- "Annunciators or alarms on the control console should clearly show the status of systems such as operating systems, interlocks… ESF initiation, radiation fields and concentration, and confinement or containment status."

The information provided in the SHINE FSAR describes how human factors is considered during the design and verification processes of SHINE's safety-related instrumentation and control (I&C) systems (i.e., the target solution vessel (TSV) reactivity protection system (TRPS) and ESFAS), however, it is unclear how it will be ensured that human factors considerations will be addressed for subsequent modifications to safety-related I&C systems once the SHINE facility is in operation. Failure to consider human factors during the operation of the SHINE facility may allow for the introduction of new human error modes which may, in turn, affect safety.

(a) Revise the SHINE FSAR to describe how it will be ensured that changes to the TRPS and ESFAS design throughout the lifecycle of the SHINE facility will include human factors considerations.

(b) Revise the SHINE FSAR to describe how HFE-related discrepancies that occur during human-system interface design, installation, and modification will be tracked and evaluated.

The information is necessary for the NRC staff to find that, consistent with 10 CFR 50.57(a)(3), "[t]here is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public…". Specifically, the information requested is necessary to support the following evaluation finding in Sections 7.6 NUREG-1537, Part 2: "[t]he applicant has shown that all nuclear and process parameters important to safe and effective operation…will be displayed at the control console. The display devices for these parameters are easily understood and readily observable by an operator positioned at the reactor controls. The control console design and operator interface are sufficient to promote safe reactor operation."

RAI HFE-3 Several SHINE FSAR sections (e.g., SHINE FSAR Sections 7.3.1.3.11, "Target Solution Vessel Reactivity Protection System and Engineered Safety Features Actuation System," 7.6.4.2, "Alarms," 7.6.1.5, "Other Control Room Interface Equipment," and 7.6.2.2.8, "Annunciators") discuss alarms associated with systems such as TRPS, ESFAS, PICS, the criticality accident alarm system, and fire protection. These sections provide descriptions, in part, of the visible indications associated with these alarms.

NUREG-1537, Part 2, Section 7.6 contains, in part, the following acceptance criterion:

- "Annunciators or alarms on the control console should clearly show the status of systems such as operating systems, interlocks… ESF initiation, radiation fields and concentration, and confinement or containment status."

As part of its review of SHINE's annunciators and alarms, the NRC staff also considered Section 4.2.3-2, "Unacknowledged Alarm Indication," of NUREG-0700, which sates, in part that "[u]nacknowledged alarms should be indicated both by visual (e.g., flashing) and audible means."

While the provided descriptions of Human Systems Interface (HSIs) indicate that alarms are visible to operators, no other information has been provided regarding whether the alarms are also audible. Human factors design principles, such as those discussed above from NUREG-0700, suggest that important alarms should be audible so that they will reliably call operator attention to them as needed. In contrast, using only visual alarms could increase the probability of alarms going unnoticed should an operator happen to not be oriented in a direction where the visual alarm can be observed when it occurs. This has the potential to delay operators from noticing safety-significant conditions that warrant attention.

(a) Revise the SHINE FSAR to describe how it will be ensured that audible alarm sounds are generated in order to alert operators to safety-significant conditions.

(b) Clarify how the audibility of alarms is addressed by SHINE's HFE principles.

The information is necessary for the NRC staff to find that, consistent with 10 CFR 50.57(a)(3), "[t]here is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public…". Specifically, the information requested is necessary to support the following evaluation findings in Sections 7.6 NUREG-1537, Part 2:

- "The applicant has shown that all nuclear and process parameters important to safe and effective operation…will be displayed at the control console. The display devices for these parameters are easily understood and readily observable by an operator positioned at the reactor controls. The control console design and operator interface are sufficient to promote safe reactor operation."

- "The annunciator and alarm panels on the control console give assurance of the operability of systems important to adequate and safe reactor operation…"

RAI HFE-4 SHINE FSAR Section 12.3, "Procedures," states, in part, that "[p]rocedures for the operation and use of the SHINE facility provide appropriate direction to ensure that the facility is operated normally within its design basis and in compliance with technical specifications. These procedures are written, reviewed, and approved by appropriate management, as well as controlled and monitored to ensure that the content is technically correct, and the wording and

format are clear and concise." Additionally, it is stated that "[t]he extent of detail in a procedure is dependent on the complexity of the task; the experience, education, and training of the users; and the potential significance of the consequences of error…. Activities and tasks are performed in accordance with approved implementing procedures."

NUREG-1537, Part 2, Section 12.3, "Procedures," contains, in part, the following acceptance criteria:

- "The applicant should propose a minimum list of procedural topics as given in ANSI/ANS 15.1-1990." (The NRC staff notes that SHINE is using ANSI/ANS 15.1-2007.)

- "The applicant should discuss the method for the review and approval of procedures. The method should involve staff from reactor operations, radiation protection, and reactor administration and the review committee, as appropriate to the procedure under review and approval."

The categories of procedures described within the SHINE FSAR do not appear to address abnormal and emergency operations. Safe facility operation requires that operations personnel have procedural guidance available to address abnormalities and emergency situations that may occur. For example, it may be necessary to have procedures for addressing manual actuations of the TRPS and ESFAS when warranted by facility conditions, including when required as a means of diversity and defense-in-depth.

(a) Revise the SHINE FSAR to include the establishment and summary of both abnormal and emergency operating procedures for the SHINE facility.

(b) Clarify what means will be used to verify and validate procedures, including those associated with abnormal and emergency operations. As part of this, describe how it will be verified and validated that the SHINE facility design will support the implementation of procedures for manual operator actuations of TRPS and ESFAS.

The information is necessary for the NRC staff to find that, consistent with 10 CFR 50.57(a)(3), "[t]here is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public…". Specifically, the information requested is necessary to support the following evaluation finding in Section 12.3 of NUREG-1537, Part 2: "The applicant has proposed a set of required procedures that is appropriate to operation of the facility as proposed in the SAR and is acceptable to the staff."

RAI HFE-5 SHINE FSAR section 12.1.3, "Staffing," states, in part, that "[t]he minimum staffing when the SHINE facility is not secured shall be:

(a) A senior licensed operator present in the facility,

(b) A second senior licensed operator or licensed operator present in the control room, and

(c) An additional designated person present at the facility able to carry out prescribed written instructions."

Additionally, the SHINE Technical Specifications Section 5.1.3, "Facility Staffing Required," states the following:

> 1. The minimum staffing when the facility is not secured shall be:
>   a. A Senior Licensed Operator present in the facility,
>   b. A second Senior Licensed Operator or Licensed Operator present in the control room, and
>   c. An additional designated person present at the facility able to carry out prescribed written instructions.
>
> Unexpected absence of any of the minimum staffing positions for as long as two hours to accommodate a personal emergency may be acceptable provided immediate action is taken to obtain a replacement.

NUREG-1537, Part 2, Section 12.1, "Organization," contains, in part, the following acceptance criteria:

- "The applicant should discuss the staffing at the reactor facility for various reactor modes, especially when the reactor is not secure. At a minimum, the staffing requirements shall meet the requirements of 10 CFR 50.54…"

The SHINE staffing model described in the SHINE FSAR and in the SHINE Technical Specifications appears to be similar to that which would be implemented at a non-power reactor. However, unlike a non-power reactor where an operator is responsible for a single reactor, the SHINE facility operations would involve managing the operations of eight irradiation units and the Radioisotope Production Facility. The workload associated with operation of the eight irradiation units is likely to be quite different than operating a single non-power reactor. SHINE's basis for the described staffing model is unclear and needs to be supported in order to demonstrate that the scope of operations can be accommodated by the available staffing.

Additionally, the allowance provided in Technical Specification Section 5.1.3 for unexpected absences would potentially permit the Facility Control Room to be unattended for up to 2 hours during facility operations. Allowing the Facility Control Room to remain unstaffed in this manner would not support implementation of manual TRPS and ESFAS actuations for diversity and defense-and-depth.

(a) Clarify how the number and qualifications of operations personnel for the full range of SHINE facility conditions and tasks was determined, as well as how it will be ensured that the operational tasks (under normal, abnormal, and emergency conditions), facility maintenance, facility surveillance, and testing will be supported by this staffing model. Update the FSAR, as necessary.

(b) Explain how the Technical Specifications will ensure that the provisions of Section 5.1.3 of Technical Specifications will not result in the Facility Control

Room being unstaffed by a licensed operator at any time while the SHINE facility is not secured (regardless of any allowance made for unplanned absences), such that the capability for the timely implementation of defense-in-depth actions will be maintained. Update the Technical Specifications, as necessary.

The information is necessary for the NRC staff to find that, consistent with 10 CFR 50.57(a)(3), "[t]here is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public…". Specifically, the information requested is necessary to support the following evaluation finding in Section 12.1 of NUREG-1537, Part 2: "The applicant has described facility staffing requirements that demonstrate its ability to safely operate the facility and protect the health and safety of the staff and the public. The staffing meets the requirements of the regulations."

RAI HFE-6 SHINE FSAR Section 13b.1.2 states, in part, that "[a]ppropriate preventative or mitigative controls were identified to reduce the overall risk of the evaluated accident scenarios to within acceptable limits." Additionally, SHINE FSAR Section 13b.1.2.4 states, in part, that the "[r]adiological consequences of criticality accidents are not included in the accident analysis because preventative controls are used to ensure criticality events are highly unlikely."

Section 13b, "Radioisotope Production Facility Accident Analyses," of the ISG Augmenting NUREG-1537, Part 2, states, in part, that an application may be found acceptable "if the applicant demonstrates that the proposed equipment and facilities to prevent or mitigate accidents are adequate to protect health and minimize danger to life or property, and that proposed procedures to prevent or mitigate accidents are adequate to protect health and minimize danger to life or property." The acceptance criteria within this section include the following:

- "For a radioisotope production facility, the results of the accident analysis should demonstrate adequate safety by either meeting the performance requirements described in 10 CFR 70.61 or propose and justify alternate performance criteria that the NRC staff determines to demonstrate adequate safety."

- "NUREG-1520, Section 3.4, provides additional criteria for adherence to the safety program and ISA performance."

NUREG-1520, Section 3.4.3.1, "Safety Program and Integrated Safety Analysis Commitments," describes, in part, that human factors engineering is generically applicable to safety controls and should generally be part of the safety program. Furthermore, it is stated that "[h]uman factors practices should be incorporated into the applicant's safety program sufficiently to ensure that… management measures perform their functions…" In addition to the HFE-related acceptance criteria presented in Section 3.4, "Acceptance Criteria," of NUREG-1520 the NRC staff notes the general methodology presented within NUREG-1520 Chapter 3, Appendix E, "Human Factors Engineering for Personnel Activities," would constitute an appropriate approach for justifying the reliability of administrative controls.

NUREG-1520 Chapter 3, Appendix E, describes the acceptance criteria that are associated with HFE within this context. These acceptance criteria include the following:

Section G – "Procedure Development"

> The applicant's procedure development for personnel activities should incorporate HFE principles and criteria, along with all other design requirements, to develop procedures that are technically accurate, comprehensive, explicit, easy to use, and validated consistent with the acceptance criteria in this Standard Review Plan. Because procedures are considered an essential component of the HSI design, they should be derived from the same design process and analyses as the other components of the HSI (for example, displays, controls, operator aids) and subject to the same evaluation processes. Procedures to support the personnel activity may include generic technical guidance, plant and system operations, abnormal and emergency operations, tests (for example, preoperational, startup, and surveillance), and alarm response.

Section H – "Training Program Development"

> The applicant's training program development should address all personnel activities. The training program development indicates how the knowledge and skill requirements of personnel will be evaluated, how the training program development will be coordinated with the other activities of the HFE design process, and how the training program will be implemented in an effective manner consistent with human factors principles and practices.
>
> The training program development should address the areas of review and acceptance criteria described in Chapter 11 of this SRP and should result in a training program that provides personnel with qualifications commensurate with their activities.

The SHINE application describes, in part, the use of administrative controls and how they are used to reduce the risk of certain accidents. However, it is unclear how the application, in an integrated and holistic manner, covers the use human factors engineering to reduce the risk of certain accidents. An example of an issue identified by the NRC staff within this area is that SHINE FSAR does not address the training of non-licensed personnel on administrative controls or the verification and validation of procedures containing those controls. This is of concern because the reliability of administrative controls can be affected by human factors engineering considerations. Given the preventative and mitigative nature of these controls, there is the potential to adversely impact the risk associated with certain accident sequences. NUREG-1520, Appendix E,

describes how HFE can be applied in a comprehensive manner to ensure that management measures perform their functions. While not a regulatory requirement, the use of the methodology in NUREG-1520, Appendix E, would be an acceptable means of addressing parts (a) through (c) below.

(a) Describe how SHINE's approach to management measures and administrative controls incorporates HFE in an integrated manner.

(b) Describe how the procedures used to implement administrative controls (e.g. Specific Administrative Controls) will be verified and validated such that the assumptions made about the reliability of these controls in the safety analysis is supported.

(c) Describe how non-licensed facility personnel will be trained on the implementation of administrative controls such that the assumptions made about the reliability of these controls in the safety analysis is supported.

The information is necessary for the NRC staff to find that, consistent with 10 CFR 50.57(a)(3), "[t]here is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public…". Specifically, the information requested is necessary to support the following determination in Section 13b.1 of NUREG-1537, Part 2: "The applicant has identified designated engineered and administrative [controls] necessary to provide preventive or mitigative measures that give reasonable assurance that the facility will operate in a safe manner."

RAI HFE-7 Section 13a2, "Aqueous Homogeneous Reactor Accident Analyses," of the ISG Augmenting NUREG-1537 states, in part, that the application should demonstrate "that the applicant has considered all potential accidents at the reactor facility and adequately evaluated their consequences."

Section 13b of the ISG Augmenting NUREG-1537 further states that "NRC staff have determined that the use of Integrated Safety Analysis methodologies as described in 10 CFR 70 and NUREG-1520, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of items relied on for safety, and establishment of management measures are acceptable ways of demonstrating adequate safety for the medical isotopes production facility. Applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features, and alternate methods of assuring the availability and reliability of the safety features."

In Section 2.1 in the SHINE Safety Analysis (SSA), SHINE states that it uses guidance from NUREG-1520 to implement a risk index method which includes assigning failure indices to the safety-related administrative controls cited in Appendices A and B of the SSA. The methodology applies failure indices based on Tables 2.3.4-1, 2.3.4-2, and 2.3.4-3. These tables match Tables A-9, A-10, and A-11 in NUREG-1520, which are part of an example application of a risk index method of likelihood evaluation. Data, such as operating experience, should be applied to determine the failure indices. Furthermore, NUREG-1520

states that in the absence of sufficiently detailed information about the factors that influence the failure likelihoods, appropriate conservatism should be used in assigning indices (e.g., using the highest index in the range).

Given that SHINE is a first-of-a-kind facility and in the process of developing training and procedures for many of the safety-related administrative controls, describe the processes and references (e.g., SSA team review or WSRC-TR-93-581, "Savannah River Site Human Error Data Base Development for Nonreactor Nuclear Facilities") SHINE uses to justify the current failure likelihoods. Include descriptions of the periodic audits, reviews, or analyses that will be performed to verify the selection of failure indices for and intended functionality of safety-related administrative controls, as described in the SSA.

The NRC staff is requesting this information to evaluate SHINE's accident analysis methodology and determine whether that methodology demonstrates that SHINE has considered all potential accidents and adequately evaluated their consequences. This evaluation is needed for the NRC staff to find reasonable assurance that SHINE:

- Has adequately described the SHINE facility, including those analyses and evaluations that show that safety functions will be accomplished; and

- Can conduct the activities in its application without endangering the health and safety of the public.

RAI HFE-8 In SHINE FSAR Table 3.1-3, "SHINE Design Criteria," SHINE establishes the following design criterion that is relevant to its human factors engineering program:

> Criterion 6 – Control Room
>
> A control room is provided from which actions can be taken to operate the irradiation units safely under normal conditions and to perform required operator actions under postulated accident conditions.

The scope of SHINE Design Criterion 6 is limited to only the irradiation units. However, SHINE FSAR Section 7.1.1, "Process Integrated Control System," describes the PICS as providing monitoring and control of the various processes throughout the SHINE facility. The PICS is described as being used to control and monitor facility systems and components, including those in both the irradiation facility and in the radioisotope production facility. The functions of the PICS discussed include enabling the operator to perform irradiation cycles, transfer target solution to and from the irradiation units (as well as throughout the RPF), and interface with the tritium purification system, processes in the supercell, waste handling operations, and the auxiliary systems. Thus, it appears that the scope of operations performed from the control room is broader than just irradiation unit operations and extends to the overall irradiation facility and radioisotope production facility as well. It is unclear if the scope of SHINE Design Criterion 6 is appropriate based upon the nature and operations of the SHINE facility.

Clarify SHINE's basis for limiting the scope of SHINE Design Criterion 6 to only the irradiation units and how this limited scope is consistent with ensuring the safe operation of the overall facility.

This information is necessary for the NRC staff to determine that SHINE has developed an adequate set of principal design criteria for the SHINE facility, as required by 10 CFR 50.34(a) and (b).

Conduct of Operations

RAI 12-1 Paragraphs (b)(6)(i) and (ii) of 10 CFR 50.34 require that an applicant's FSAR include information regarding the "applicant's organizational structure, allocations or responsibilities and authorities, and personnel qualifications requirements" and "managerial and administrative controls used to assure safe operation."

The acceptance criteria in Section 12.2 of NUREG-1537, Part 2, state, in part, that "[t]he applicant should discuss the composition of the review and audit committee… The committee members should represent a broad spectrum of expertise (e.g., nuclear engineering, electrical engineering, mechanical engineering, and radiation protection); the exact composition of the committee will vary from facility to facility. Committee members should be appointed by the highest level of upper management. It is also desirable to have members on the committee who are not employed by the reactor owners."

SHINE FSAR Section 12.2.1, "Composition and Qualification," states that "[t]he qualifications for the review and audit committee members shall include a broad spectrum of technical, operations, and managerial expertise. Non-SHINE employees may be appointed as committee members at the discretion of the COO [Chief Operating Officer]." However, it is not clear what qualifications members of the review and audit committee will have or how SHINE will determine what circumstances it will be necessary to appoint non-SHINE employees to the committee.

Update the FSAR to include additional detail on the types of technical, operations, and managerial expertise that will be represented on the SHINE review and audit committee. Additionally, update the FSAR to describe the circumstances when a non-SHINE individual be appointed as a committee member.

This information is necessary for the NRC staff for the NRC staff to make the following evaluation finding in Section 12.2 of NUREG-1537, Part 2: "The applicant has proposed a review and audit function for the…facility. The committee members appear to be well qualified, with a wide spectrum of expertise. The committee membership includes persons from outside the university (or corporation)."

RAI 12-2 Paragraphs (b)(6)(i) and (ii) of 10 CFR 50.34 require that an applicant's FSAR include information regarding the "applicant's organizational structure, allocations or responsibilities and authorities, and personnel qualifications requirements" and "managerial and administrative controls used to assure safe operation."

SHINE FSAR Section 12.2.2, “Charter and Rules,” describes the charter and rules for the SHINE review and audit committee. This section states that “…approval of minutes shall happen in a timely manner.”

The acceptance criteria in Section 12.2 of NUREG-1537, Part 2, state that “minutes of committee meetings should be approved and distributed within three months after the meeting.” However, it is not clear what constitutes a timely manner for approval and distribution of the minutes of review and audit committee meeting minutes.

Update the SHINE FSAR to define what constitutes a timely manner for approval and distribution of the minutes of review and audit committee meeting minutes.

This information is necessary for the NRC staff for the NRC staff to make the following evaluation finding in Section 12.2 of NUREG-1537, Part 2: “The review and audit committee has proposed a charter and rules that describe the number of times the committee meets, the way the committee conducts business, the requirements for a quorum when voting, and the way the committee distributes its reports and reviews to the applicant.”