



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

May 18, 2022

Dr. Gregory Piefer  
Chief Executive Officer  
SHINE Technologies, LLC  
3400 Innovation Court  
Janesville, WI 53545

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – SUMMARY OF AUDIT RELATED TO  
HUMAN FACTORS ENGINEERING (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 Accession No. ML20357A084), December 15, 2020 (ADAMS 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* Part 50, "Domestic Licensing of Production and Utilization Facilities."

To enhance the review of human factors engineering associated with the SHINE operating license application, the NRC staff conducted a regulatory audit on November 5, 2020, and May 19, 2021. A summary of the regulatory audit is enclosed.

Attachment 1 to the Enclosure of this letter contains Proprietary Information.  
When separated from Enclosure, this letter is DECONTROLLED.

If SHINE has any questions, please contact me at 301-415-2856, or by electronic mail at [Michael.Balazik@nrc.gov](mailto:Michael.Balazik@nrc.gov).

Sincerely,



Signed by Balazik, Michael  
on 05/18/22

Michael Balazik, 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

SHINE Medical Technologies, LLC

Docket No. 50-608

cc:

Jeff Bartelme, Director of Licensing  
SHINE Technologies, LLC  
3400 Innovation Court  
Janesville, WI 53545

Nathan Schleifer, General Counsel  
SHINE Technologies, LLC  
3400 Innovation Court  
Janesville, WI 53545

Christopher Landers, Director  
Office of Conversion  
National Nuclear Security Administration, NA 23  
U.S. Department of Energy  
1000 Independence Avenue, SW  
Washington, DC 20585

Mark Paulson, Supervisor  
Radiation Protection Section  
Wisconsin Department of Health Services  
P.O. Box 2659  
Madison, WI 53701-2659

Test, Research and Training Reactor Newsletter  
Attention: Amber Johnson  
Dept. of Materials Science and Engineering  
University of Maryland  
4418 Stadium Drive  
College Park, MD 20742-2115

Mark Freitag, City Manager  
P.O. Box 5005  
Janesville, WI 53547-5005

Bill McCoy  
1326 Putnam Avenue  
Janesville, WI 53546

Alfred Lembrich  
541 Miller Avenue  
Janesville, WI 53548

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DATED: MAY 18, 2022

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**ADAMS Accession No.: Pkg. ML22124A075; Non-Prop. ML22124A073; PROP. ML22124A074**

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AUDIT SUMMARY FOR THE REGULATORY AUDIT OF  
TOPICS REGARDING HUMAN FACTORS ENGINEERING  
DESCRIBED IN THE OPERATING LICENSE APPLICATION  
FOR SHINE MEDICAL TECHNOLOGIES, LLC  
SHINE MEDICAL ISOTOPE PRODUCTION FACILITY DOCKET NO. 50-608

## **1.0 BACKGROUND**

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 Accession No. ML20357A084), December 15, 2020 (ADAMS 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." Additionally, by letter dated January 29, 2021 (ADAMS Accession No. ML21029A038), SHINE submitted a related request for exemption from the monitoring requirements of 10 CFR 70.24, "Criticality accident requirements," paragraph (a).

The purpose of this regulatory audit was to review additional information necessary in determining that a reasonable assurance of adequate protection of public health and safety exists, that applicable regulatory requirements are met, and to identify information that requires docketing to support a regulatory finding regarding human factors engineering (HFE). The audit entrance meeting was held on November 5, 2020, via teleconference. The audit included the NRC staff's review of docketed and non-docketed information via the SHINE electronic reading room (ERR) and teleconferences with SHINE.

Following the audit and prior to the issuance of this report, the NRC staff issued request for additional information (RAI) on September 23, 2021 (ADAMS Accession No. ML21253A234), as discussed in more detail below. On October 15, 2021, SHINE submitted responses to these RAIs (ADAMS Accession No. ML21288A050).

## **2.0 REGULATORY AUDIT BASIS**

### 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 (IUs), 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 final safety analysis report (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, including NUREG-1520, “Standard Review Plan for Fuel Cycle Facilities License Applications,” Revision 2, issued June 2015 (ADAMS Accession No. ML15176A258).

Furthermore, the NRC staff have, where appropriate, also referenced NUREG-0700, “Human-System Interface Design Review Guidelines,” Revision 2, issued May 2002 (ADAMS Accession No. ML021700337), NUREG-0711, “Human Factors Engineering Program Review Model,” Revision 3, issued November 2012 (ADAMS Accession No. ML12324A013), as guidance.

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 “IU,” “IF,” or “RPF,” 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.”

### Regulatory Basis

As required by 10 CFR 50.34, “Contents of applications; technical information,” each application for a construction permit shall include a preliminary safety analysis report. Specifically, 10 CFR 50.34(a)(3) states, in part, that the minimum information to be included in a preliminary safety analysis report shall consist of the preliminary design of the facility, including the principal design criteria for the facility. In the final safety analysis report, 10 CFR 50.34(b) 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.*”

As required by 10 CFR Part 50, Section 50.57, “Issuance of operating license,” paragraph (a)(3), an operating license may be issued upon finding that, “There is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public....”

### 3.0 AUDIT LOCATION AND DATES

The audit was conducted via SHINE's ERR and a teleconference bridge  
 Dates: November 5, 2020 – May 19, 2021  
 Locations: SHINE ERR

### 4.0 AUDIT TEAM MEMBERS

Brian Green, NRR/DRO/IOLB/HFT  
 Jesse Seymour, NRR/DRO/IOLB/HFT  
 April Smith, NMSS/DFM/NARAB  
 Hanh Phan, NRR/DANU/JART  
 Steven Lynch, NRR/DANU/UNPL

### 5.0 APPLICANT PARTICIPANTS

Jeff Bartelme, SHINE Medical Technologies, LLC  
 Catherine Kolb, SHINE Medical Technologies, LLC  
 Jamie Getchius, SHINE Medical Technologies, LLC  
 Brent Waller, SHINE Medical Technologies, LLC  
 Tracey Radel, SHINE Medical Technologies, LLC  
 Jim Costedio, SHINE Medical Technologies, LLC  
 Jamie Pierce, SHINE Medical Technologies, LLC  
 Kris Ruetz, SHINE Medical Technologies, LLC

### 6.0 AUDIT DOCUMENTS

The NRC staff audited the following documents provided by SHINE in the ERR:

Document Number	Document Title
1200-09-03	Human Factors Engineering Program, Revision 2, dated April 27, 2020
Draft SP-IP-01	Extraction Cell Operations, Revision 0
Draft SP-TS-01	Facility Receipt of Uranium Metal, Revision 0
FRM 1200-09-03-01	Human Factors Engineering Design Checklist, Revision 1
TECRPT-2020-0016	SHINE Safety Analysis Summary Report, Revision 2, dated December 30, 2020
TECRPT-2020-0018	Human Factors Engineering (HFE) Design Guidelines, Revision 1, dated October 22, 2020
TECRPT-2020-0025	Main Production Facility Control Room Design Description, Revision 0
HFE-FSTR-0001	HFE Checklist for Facility Control Room Design
0300-09-01	Licensed Operator Initial Training Program, Revision 0
0300-09-02	Licensed Operator Continuing Training Program, Revision 0
OPS-01-01-01	Operations Procedure Development, Revision 0

## 7.0 DESCRIPTION OF AUDIT ACTIVITIES AND SUMMARY OF OBSERVATIONS

The focus areas for the audit and the NRC staff's observations are discussed below.

### **Audit Topics 1 – 6: Human Factors Engineering Program**

- 1. The NRC staff requested that SHINE provide additional detail on its HFE program. As part of this, the NRC staff also requested that SHINE provide details on any guidance (such as NUREG-0711) used as a basis for SHINE's HFE program.***

The NRC staff reviewed a written summary that SHINE provided in response to the question above. In their response, SHINE indicated that the design process is used to ensure the safe operation and functionality of the control room, associated instrumentation and control systems, and human-system interfaces (HSIs). SHINE also stated that a checklist is used for verifying SHINE's HFE design guidelines during equipment design, as well as again after installation to verify that system and component installation complies with the guidelines.

The NRC staff reviewed 1200-09-03, "Human Factors Engineering Program." During the review of this document, the NRC staff observed that the SHINE HFE program is described as consisting of the style guidelines contained in TECRPT-2020-0018, "Human Factors Engineering (HFE) Design Guidelines." The NRC staff observed that the HFE style guidelines serve a programmatic function that is generally similar to that of NUREG-0700. The NRC staff noted that the document included a checklist (FRM 1200-09-03-01, "Human Factors Engineering Design Checklist," which, in turn, references the HFE style guide) for use in verifying the incorporation of HFE principles for initial design implementation or for subsequent modifications. In general, the NRC staff observed that this checklist fills a role that has similarities with elements of HFE design verification under NUREG-0711. The NRC staff also observed that the design implementation objectives are listed as confirming the as-built design conforms to HFE design guidelines and ensuring that future modifications both consider personnel performance effects and support a reasonable assurance of safety. Furthermore, the NRC staff also noted that design implementation confirmation is described as verifying conformance to design documents and procedures, in addition to the resolution of identified discrepancies. The NRC staff made an observation that this programmatic aspect appeared to serve a similar overall function as that of design implementation under NUREG-0711.

The NRC staff discussed 1200-09-03 with SHINE during a teleconference on November 5, 2020. During that discussion, SHINE clarified that a reference made to "Important Human Actions" in 1200-09-03, section 2.2.2.c, was not intended to have the same meaning as the term would have within the context of NUREG-0711. Rather, they indicated that the intended meaning was that this term (within the context of 1200-09-03) is related to Specific Administrative Controls (SACs). The NRC staff also observed that 1200-09-03 was subsequently revised between the November 2020 and May 2021 HFE audit meetings. Specifically, it was noted that following the revision, section 2.2.2.c no longer referred to "features supporting important human actions" and, instead, subsequently made reference to "supporting Specific Administrative Controls identified in the Safety Analysis."

The NRC staff reviewed TECRPT-2020-0018. In general, the NRC staff noted that the guidelines (i.e., a style guide) have a primary focus of the HSIs within the control room and implementation of the HSI design element of the HFE program. The NRC staff observed that



the guidelines incorporate both NRC guidance as well as that from other standards. (The detailed observations from this discussion are contained in the Attachment.)

The NRC staff discussed TECRPT-2020-0018 with SHINE during a teleconference on November 5, 2020. SHINE indicated that references in addition to NUREG-0700 are used in the TECRPT-2020-0018 because a decision was made when the guide was prepared that certain aspects of the facility were better represented by those other references.

The NRC staff requested that SHINE explain the application of ISA-RP60.3-1985, "Human Engineering for Control Centers," as part of TECRPT-2020-0018 with SHINE during a teleconference on May 19, 2021. In general, the NRC staff noted that SHINE provided a justification for why this particular standard had been applied in this manner; this justification included details regarding the scope and context in which portions of this guidance were used. (The detailed observations from this discussion are contained in the Attachment.)

The NRC staff reviewed the FRM 1200-09-03-01 HFE checklist. In general, the NRC staff noted that the checklist summarizes HFE guidelines from TECRPT-2020-0018 and indicates that it may be used in conjunction with the detailed criteria of the style guide for ensuring HFE design implementation. The NRC staff noted that the categories of guidelines contained within the checklist included, in part, control panel design considerations, user interface design considerations, HSI display considerations, and alarm considerations. (The detailed observations from this review are contained in the Attachment.)

Although the observations above suggested the consideration and application of human factors insights by SHINE, it was unclear to the NRC staff how these insights are intended to support the overall ability of SHINE operators to contribute to the safe and reliable operation of the facility. Therefore, following the audit, the NRC staff issued RAI HFE-1 in which SHINE was asked, in part, to revise the FSAR to explain, in a comprehensive manner, how the operator role in facility safety is supported by HFE.

- 2. The NRC staff requested that SHINE provide additional detail on how operator interfaces will be standardized across vendors. Additionally, the NRC staff requested that SHINE provide additional detail on the means by which the incorporation of HFE principles into the HSI design will be ensured.***

The NRC staff reviewed a written summary that SHINE provided in response to the question above. SHINE stated that the operator interfaces are standardized across vendors via the HFE style guidelines of TECRPT-2020-0018 and that the vendors supplying both the process integrated control system (PICS) and the Neutron Driver Assembly System (which SHINE indicated as being the main interfaces that control room operators will utilize) have been provided with those guidelines. SHINE also indicated that the HFE program described in 1200-09-03 establishes the verification process for vendor HFE design compliance. Additionally, SHINE described that an HFE design checklist is completed after both interface design and interface installation to verify compliance with the HFE style guidelines.

The NRC staff reviewed TECRPT-2020-0025, "Main Production Facility Control Room Design Description." In general, the NRC staff noted that the document discusses details associated with the physical layout of the control room. (The detailed observations from this discussion are contained in the Attachment.)

The NRC staff also reviewed the HFE-FSTR-0001, "HFE Checklist for Facility Control Room Design." In general, the NRC staff noted that this checklist consists of a completed version of FRM 1200-09-03-01 that is listed as covering the "Facility Control Room Design." The categories covered by the checklist included, in part, control panel design considerations, as well as environmental, display, alarm, and control considerations. (The detailed observations from this discussion are contained in the Attachment.)

**3. The NRC staff requested that SHINE provide additional detail on any planned testing related to HFE.**

The NRC staff reviewed a written summary that SHINE provided in response to the question above. In the response SHINE indicated that their HFE program describes the process for verifying compliance with the HFE design guidelines and that this verification is completed using FRM 1200-09-03-01 both during design and after installation. SHINE also stated that the implementation of FRM 1200-09-03-01 following installation serves as the documented verification of as-built systems and components for HFE design guideline compliance purposes. Additionally, SHINE also indicated that, while other verification activities (e.g., inspections, walkdowns, and tests) may be used to confirm design implementation, no additional testing related to HFE is planned.

**4. The NRC staff requested that SHINE explain, as it relates to target solution vessel (TSV) reactivity protection system (TRPS) *Criterion 51* and engineered safety features actuation system (ESFAS *Criterion 52*, what functions are allocated to operators for these systems, how was this determined, and how will it be verified that they can be accomplished.**

The NRC staff discussed this topic with SHINE during a teleconference on May 19, 2021. During that discussion, SHINE stated that the TRPS and ESFAS functions allocated to humans include technical specification (TS) surveillances, placing channels in trip, facility operations, and manual actuations for diversity. SHINE discussed their intention to include verification as part of facility startup. However, SHINE also noted that the validation of procedures still needs to be incorporated into startup testing.

**5. The NRC staff requested that SHINE discuss what process exists for the tracking and resolution of any identified HFE discrepancies.**

The NRC staff discussed this topic with SHINE during a teleconference on May 19, 2021. During that discussion, SHINE stated that issues associated with HFE discrepancies are input into their "Issue Management Reports" system, which is also used for information associated with the SHINE corrective action program. SHINE indicated that a specific trending code can be applied to HFE-specific issues within this system for tracking purposes.

Following the audit, the NRC staff issued RAI HFE-2 in which SHINE was asked, in part, to clarify how HFE-related discrepancies that occur during HSI design, installation, and modification will be tracked, evaluated, and resolved.

**6. The NRC staff requested that SHINE discuss how will it be ensured that HFE guidelines will be applied to future HSI modifications such that the ability of the operator to reliably implement defense-in-depth actions is maintained over the life of the facility.**

The NRC staff discussed this topic with SHINE during a teleconference on May 19, 2021. During that discussion, SHINE stated that implementation of the HFE checklist during design and installation ensures that future changes will be reviewed against HFE criteria and that this is stated in section 2.1.2 of 1200-09-03.

Following the audit, the NRC staff issued RAI HFE-2 in which SHINE was asked, in part, to clarify how it will be ensured that changes to the TRPS and ESFAS design throughout the lifecycle process will include human factors considerations.

### **Audit Topics 7 – 8: Principle Design Criteria 6**

**7. *The NRC staff requested that SHINE provide additional information demonstrating how principle design criteria (PDC) 6 is supported by the SHINE HFE program.***

The NRC staff reviewed a written summary that SHINE provided in response to the question above. In their response, SHINE indicated that the HFE program is not required to meet PDC 6; instead, the program serves to enhance control room and HSI usability, as well as to ensure that the control room and HSIs conform to the SHINE HFE style guide. Additionally, SHINE stated that the SHINE Safety Analysis (SSA) does not identify any required operator actions for mitigating the accident consequences.

**8. *The NRC staff requested that SHINE discuss the basis for not including the RPF within the scope of PDC 6.***

The NRC staff discussed this topic with SHINE during a teleconference on November 5, 2020. During this discussion, SHINE stated that the basis for not including the RPF within the scope of PDC 6 is because PDC 6 was modeled after the General Design Criteria (GDC) and that, from SHINE's perspective, the IU were closest to the reactor used in the context of the GDC.

Following the audit, the NRC staff issued RAI HFE-8 in which SHINE was asked to clarify its basis for limiting the scope of PDC 6 to only the IUs and how this limited scope is consistent with ensuring the safe operation of the overall facility.

### **Audit Topics 9 - 12: Operator Role in Facility Safety**

**9. *The NRC staff requested that SHINE provide additional detail on how human action is credited during operation of the SHINE facility. Additionally, the NRC staff requested that SHINE provide additional detail on the role of human action as it relates to both safety and defense-in-depth.***

The NRC staff reviewed a written summary that SHINE provided in response to the question above. In the response, SHINE stated the TECRPT-2020-0016, "SHINE Safety Analysis Summary Report," designates and lists human actions that are credited as preventive controls as SACs. SHINE also stated that no SACs are performed to respond to or mitigate the consequences of potential accident sequences but are, instead, relied upon to ensure that the facility continues to operate safely and normally. SHINE also indicated that credited SACs are implemented via facility procedures, with the steps implementing SACs designated as such. Furthermore, SHINE noted that nonsafety-related defense-in-depth actions are identified as part of the SSA and that such actions are implemented via procedures and other administrative controls.

The NRC staff discussed these aspects of this topic with SHINE during a teleconference on November 5, 2020. During that discussion, SHINE stated that none of the SACs are for mitigating accidents and that, instead, they are preventative in nature. In addition to this, SHINE indicated that, although the maximum hypothetical accident occurs within the IF portion of the SHINE facility, accidents occurring on the RPF side of the SHINE facility remain bounded by all credible accidents.

The NRC staff reviewed portions of TECRPT-2020-0016, "SHINE Safety Analysis Summary Report," to better understand the analyzed role of operators within the facility safety analysis. In general, the NRC staff noted that the SSA discussed, in part, accident sequences, administrative controls, and defense-in-depth measures. (The detailed observations from this discussion are contained in the Attachment.)

Based upon this review, the NRC staff provided a sample of accident scenarios from the SSA to SHINE and requested that SHINE discuss these scenarios in greater detail. The approach used by the staff in sampling accident scenarios for this further review included the following general considerations:

- higher risk scenarios,
- scenarios involving administrative controls (i.e., SACs and enhanced SACs),
- scenarios involving defense-in-depth actions,
- scenarios involving operator error initiators; and
- scenarios involving crane accidents.

The NRC staff observations from this discussion are documented under topic 10 this report.

**10. The NRC staff requested that SHINE discuss a sample of accident sequences from the SSA, to include those sequences where the importance of human action is considered to be the highest.**

The NRC staff discussed this topic with SHINE during a teleconference on May 19, 2021. In general, the NRC staff noted that SHINE discussed the preventative and defense-in-depth roles of operators in facility safety, as well as the details associated with a sampling of specific accident sequences from the SSA. Additionally, the NRC staff noted that the sampled accident sequences were each described by SHINE as not requiring mitigative actions to be taken in response to events. (The detailed observations from this discussion are contained in the Attachment.)

Following the audit, the NRC staff issued RAI HFE-7 in which SHINE was asked, in part, to describe the processes and references used to justify the failure likelihoods in the SSA. As part of this, SHINE was also asked to include in this description 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.

**11. The NRC staff requested that SHINE characterize the roles of licensed operators and field operators during RPF operations.**

The NRC staff discussed this topic with SHINE during a teleconference on May 19, 2021. The NRC staff requested clarification in this area to better understand the nature of those operations performed by both licensed and non-licensed operators in the RPF, how those operations are carried out, and the extent to which these operations are associated with facility safety. During this discussion, SHINE stated that, while certain operator actions are manual in nature, these actions are not credited after the occurrence of an event. SHINE also noted that any mitigative actions happen before the occurrence of events (e.g., operational practices that serve to maintain the conditions necessary to reduce the consequences of subsequent events should they occur).

**12. The NRC staff requested that SHINE explain the human role in safe operation of the SHINE facility in a consolidated manner.**

The NRC staff discussed this topic with SHINE during a teleconference on May 19, 2021. During this discussion, SHINE provided an overview of aspects of the human role in safe operation of the facility, which included noting, in part, that the actions contained in SACs are always assumed to occur prior to accidents and, furthermore, that nothing is required afterwards for mitigation. Additionally, SHINE also indicated that, for the purposes of defense-in-depth, two diverse methods of actuation are provided for the TRPS and ESFAS systems, with those methods being automatic and manual.

Following the audit, the NRC staff issued RAI HFE-1 in which SHINE was asked, in part, to revise the FSAR to explain, in a consolidated manner, the operator role in facility safety as it pertains to both IF and RPF operations.

**Audit Topics 13 – 17: Defense-in-Depth Support**

**13. The NRC staff requested that SHINE explain, with regard to the diverse actuations of safety systems, what demonstrates that such diverse means could be used to actuate safety systems in a time frame adequate to effectively mitigate an event where a safety system has failed.**

The NRC staff discussed this topic with SHINE during a teleconference on May 19, 2021. During the discussion, SHINE stated that procedures will provide direction in case setpoints are being approached, or exceeded, and that it is planned to verify/validate these. Additionally, SHINE stated that training will occur via the Systematic Approach to Training (SAT) process and the licensed operator training programs. SHINE also indicated that HFE principles for HSIs will be applied via application of the HFE design checklist. Furthermore, SHINE indicated that there are no specific time constraints on defense-in-depth operator actions. Lastly, SHINE discussed that operator actions for defense-in-depth will be analyzed under the training task analysis process.

**14. The NRC staff requested that SHINE explain whether operator action will be used to provide diversity to safety systems in the event that a common-cause failure of safety systems occurs.**

The NRC staff discussed this topic with SHINE during a teleconference on May 19, 2021. In general, the NRC staff noted that SHINE clarified that manual operator response is not

required for postulated accidents and that safety systems are capable of both automatic and manual actuation. The NRC staff noted that the SHINE facility was described as having safety-related systems (i.e., TRPS and ESFAS) that are designed to actuate automatically, with operator action serving as a backup to these automatic actuations (The detailed observations from this discussion are contained in the Attachment.)

**15. The NRC staff requested that SHINE explain what will ensure that operators will have the procedural guidance necessary to implement defense-in-depth actions.**

The NRC staff discussed this topic with SHINE during a teleconference on May 19, 2021. During that discussion, SHINE stated that OPS-01-01-01, "Operations Procedure Development," describes the procedure management process, with section 1.2 specifically addressing abnormal and emergency procedures. SHINE also expressed an intention to specifically annotate steps associated with defense-in-depth actions within procedures and indicated that OPS-01-01-01 would be revised to reflect this practice.

The NRC staff reviewed OPS-01-01-01. During the review of this document, the NRC staff observed that its purpose is to provide the process for developing and implementing operations procedures. The NRC staff noted that these operations procedures are listed as consisting of normal system operating procedures, abnormal procedures, emergency procedures, and TS surveillance procedures. The NRC staff also observed, in part, that general guidance is provided for procedure detail to be dependent on factors such as task complexity, user training, and the potential significance of the consequences of error. Additional observations from the review of OPS-01-01-01 are included as part of Audit Topic 23.

Following the audit, the NRC staff issued RAI HFE-4 in which SHINE was asked, in part, to revise the FSAR to include the establishment of both abnormal and emergency operating procedures for the facility. Additionally, SHINE was also asked to clarify what means will be used to verify and validate procedures, including those associated with abnormal and emergency operations. Lastly, SHINE was also asked to provide specific clarification regarding how it will be verified and validated that the facility design will support the implementation of procedures for manual operator actuations of TRPS and ESFAS.

**16. The NRC staff requested that SHINE explain whether alarms received in the facility control room (i.e., via operator PICS workstations, main control board, criticality accident alarm system (CAAS), and fire detection) will make an audible sound.**

The NRC staff discussed this topic with SHINE during a teleconference on May 19, 2021. The NRC staff noted that alarms can, in some instances, be visible without producing an audible sound to alert operators and that this was an area where greater clarification was needed. During that discussion, SHINE stated that the CAAS has separate alarms and sounds, which is also the case for fire protection. SHINE also stated that the PICS system has the capability for generating audible alarms, with the audible alarm generating device itself mounted in a location above the Main Control Board. SHINE also indicated that their intent is not for every single alarm to result in an audible alarm, but that all alarms will still create a visual indication. Furthermore, SHINE stated that, for TRPS and ESFAS systems, it is intended that all alarms would result in an audible alarm being generated. Lastly, SHINE also indicated that they have not yet determined where to capture the thresholds for what alarms will, and will not, be audible.

Following the audit, the NRC staff issued RAI HFE-3 in which SHINE was asked, in part, to revise the FSAR to include how it will be ensured that audible alarms sounds are generated in order to alert operators. Additionally, SHINE was also asked to clarify how the audibility of alarms is addressed by SHINE's HFE principles.

***17. The NRC staff requested that SHINE discuss, regarding operations that must be performed using controls and indications at the main control board, if the workstation control panels be capable of being swiveled around such that any required parameters can still be viewed while standing on the front side of the workstation.***

The NRC staff discussed this topic with SHINE during a teleconference on May 19, 2021. During that discussion, SHINE stated that it is not intended that operator workstation panels be capable of being swiveled around. SHINE also discussed that, in general, apart from manual actuations of TRPS and ESFAS, no other operations would need to be conducted from the main control board. SHINE also noted that indications are provided along the bottom row of main control board screens for the purposes of verifying these manual actuations of TRPS and ESFAS and, therefore, there would be no need to swivel the workstations to obtain indications within that context.

**Audit Topics 18 - 20: Operations Staffing**

***18. The NRC staff requested that SHINE provide additional detail on the basis for their operator staffing model, including the methodology by which the required number of operators was determined.***

The NRC staff reviewed a written summary that SHINE provided in response to the question above. In general, the NRC staff noted that SHINE discussed various operational considerations associated with the IUs and described how staffing is intended to support facility operations. This review prompted NRC staff questions regarding anticipated operator workload during varying facility conditions and types of activities that operators will need to accomplish. (The detailed observations from this discussion are contained in the Attachment.)

The NRC staff discussed this topic with SHINE during a teleconference on November 5, 2020. In general, SHINE explained the basis for their staffing conclusions. (The detailed observations from this discussion are contained in the Attachment.)

Following the audit, the NRC staff issued RAI HFE-5 in which SHINE was asked, in part, to explain how the SHINE TSs will ensure that the provisions of TSs section 5.1.3 will not result in the facility control room being unstaffed by a licensed operator at any time while the 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.

***19. The NRC staff requested that SHINE explain, with regard to those facility operations that require manual operations, whether the effect of workload on operator performance has been considered.***

The NRC staff discussed this topic with SHINE during a teleconference on May 19, 2021. During that discussion, SHINE stated that the typical staffing plan was developed based upon information derived from task time estimates. SHINE also stated that these task time

estimates will be able to be better refined as part of startup testing. Furthermore, it was also indicated that staffing numbers will be further refined, if needed, once the facility is online. The NRC staff noted that this was an area in which further clarification would be needed; this is addressed in RAI HFE-5, which is discussed in Audit Topic 20.

**20. The NRC staff requested that SHINE discuss how the minimum staffing model supports the case that operators can reliably fulfil a defense-in-depth role at the facility.**

The NRC staff discussed this topic with SHINE during a teleconference on May 19, 2021. In general, the NRC staff noted that SHINE clarified that a larger staffing complement would be used during typical facility operations, provided details regarding the size of the staffing complement and the positions comprising it, and discussed aspects of the staffing methodology used. (The detailed observations from this discussion are contained in the Attachment.)

Following the audit, the NRC staff issued RAI HFE-5 in which SHINE was asked, in part, to clarify how the number and qualifications of operations personnel for the full range of plant conditions and tasks was determined, as well as how it will be ensured that the operational tasks (under normal, abnormal, and emergency conditions), plant maintenance, plant surveillance, and testing will be supported by this staffing model.

**Audit Topics 21 - 22: Training Programs**

**21. The NRC staff were provided information related to SHINE's proposed licensed operator initial and continuing training programs.**

The NRC staff reviewed 0300-09-01, "Licensed Operator Initial Training Program," and 0300-09-02, "Licensed Operator Continuing Training Program." During the review of these documents, the NRC staff observed that both documents address, in part, the following training topics:

- design features (theory and principles of the radioisotope production process involving special nuclear material (SNM), theory and principles of radioisotope extraction and purification process, critical control features and management measures required for each process involving SNM),
- facility design including safety and emergency systems and applicable operating characteristics,
- reactivity, alterations, and control systems,
- uranium handling,
- operating procedures and limits,
- emergency and abnormal operating procedures; and
- handling and disposal of radioactive material.

The NRC staff observed that these training programs appeared to generally include topics related to both administrative controls and criticality controls.



**22. The NRC staff requested that SHINE discuss what training non-licensed operators will have to ensure that they can implement SACs reliably.**

The NRC staff discussed this topic with SHINE during a teleconference on May 19, 2021. During that discussion, SHINE stated that the training for non-licensed operators will be based upon the SAT and will be comprised of both initial and continuing phases. SHINE discussed that facility changes will be incorporated into this training program as well. However, SHINE also noted that the programmatic documents covering this are still in a draft status at this time and, therefore, documentation describing this training program is not yet available.

Following the audit, the NRC staff issued RAI HFE-6 in which SHINE was asked, in part, to clarify 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.

**Audit Topics 23 – 24: Administrative Controls**

**23. The NRC staff requested that SHINE explain how procedures will be verified and validated such that they can be expected to reliably implement SACs prior to use.**

The NRC staff discussed this topic with SHINE during a teleconference on May 19, 2021. During that discussion, SHINE stated that they are planning to validate procedures as part of facility startup and that this will be included in their startup program. SHINE discussed that they envision accomplishing this using methods such as tabletops and hand-over-hand reviews within the facility to ensure that procedures can be performed as-written. However, SHINE also noted that their facility startup program has not yet been fully developed at the present time.

The NRC staff reviewed OPS-01-01-01 with regard to SACs and noted that, when entire procedures implement SACs, this is to be identified by a statement to that effect in the introduction section of the affected procedure. Additionally, it is stated that, when only a portion of a procedure implements a SAC, a statement to that effect should be included in the introduction section for that procedure, with the applicable steps implementing the control being identified with an asterisk. Furthermore, the NRC staff also noted that OPS-01-01-01 mandates criticality safety reviews for procedures associated with fissile material handling and requires that the Review and Audit Committee review procedural SACs. Lastly, the NRC staff observed that the document specifies that the Training Department is to be informed of upcoming major revisions to operations procedures.

The NRC staff reviewed two draft procedures containing SACs in order to better understand the manner in which SACs will be implemented. In general, the NRC staff noted that the procedures listed SACs and annotated steps associated with their implementation. (The detailed observations from this discussion are contained in the Attachment.)

Following the audit, the NRC staff issued RAI HFE-6 in which SHINE was asked, in part, to clarify how the procedures used to implement administrative controls (e.g. SACs) will be verified and validated such that the assumptions made about the reliability of these controls in the safety analysis is supported. Additionally, SHINE was also asked to clarify how its approach to management measures and administrative controls incorporates HFE in an integrated manner.

***24. The NRC staff requested that SHINE discuss the operator response(s) expected in reaction to a criticality accident alarm.***

The NRC staff discussed this topic with SHINE during a teleconference on May 19, 2021. During that discussion, SHINE stated that CAAS actuation will result in sounders and beacons being activated; it is expected that all personnel within affected areas will evacuate immediately. SHINE explained that changes to the CAAS design resulted in this evacuation zone becoming the entirety of the Radiologically Controlled Area (RCA). However, SHINE also noted that the facility control room is located outside of the RCA and, therefore, control room staff would not be required to evacuate the facility in the event of a CAAS actuation. Furthermore, SHINE indicated that it is intended that procedures will direct operators to place all TRPS into a safe condition upon the actuation of CAAS.

**8.0 EXIT BRIEFING**

The NRC staff conducted an audit exit meeting via a teleconference on May 19, 2021. The NRC staff summarized their observations and described information needs that would likely be issued in a RAI as a result of the audit.

**9.0 OPEN ITEMS AND PROPOSED CLOSURE PATHS**

Not applicable.

**10.0 DEVIATIONS FROM THE AUDIT PLAN**

Not applicable.