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

February 1, 2023

Dr. Gregory Piefer
Chief Executive Officer
SHINE Technologies, LLC
3400 Innovation Court
Janesville, WI 53546

SUBJECT: SHINE TECHNOLOGIES, LLC REGULATORY REPORT ON THE AUDIT OF PHASED STARTUP OPERATIONS APPLICATION SUPPLEMENT (EPID NO. L-2022-NEW-0004)

Dear Dr. Piefer:

By letter dated July 17, 2019 (Agencywide Documents Access and Management System Accession No. ML19211C044), SHINE Medical Technologies, LLC (SHINE) submitted its application for an operating license. The application was supplemented with the "Application for an Operating License Supplement No.15, Submittal of the Phased Startup Operations Application Supplement," dated January 27, 2022 (ML22027A354).

Enclosed is a report on the regulatory audit conducted by staff of the U.S. Nuclear Regulatory Commission (NRC) in connection with its review of the application, in addition to the review of the phased startup operations supplement of the SHINE operating license application. This regulatory audit was held to close technical gaps identified during the review of the supplement.

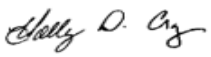
The audit report does not make any licensing conclusions or findings, but it is part of the administrative record of the NRC staff's review of the application and may provide information supporting the NRC staff's safety evaluation. Unless otherwise noted in the enclosed report, the audit followed the plans provided by letters dated:

- May 24, 2022 (ML22094A114), and
- August 25, 2022 (ML22061A212).

The enclosed report constitutes the final report on the audit and provides a closure path for each of the identified open technical items.

If you have any questions, please contact me at (301) 415-1053, or by email at Holly.Cruz@nrc.gov.

Sincerely,


Signed by Cruz, Holly
on 02/01/23

Holly D. Cruz, Senior Project Manager
Non-Power Production and Utilization
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Office of Nuclear Reactor Regulation

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

Enclosure:
As stated

cc: See next page

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SUBJECT: SHINE TECHNOLOGIES, LLC REGULATORY REPORT ON THE AUDIT OF PHASED STARTUP OPERATIONS APPLICATION SUPPLEMENT (EPID NO. L-2022-NEW-0004) DATED: FEBRUARY 1, 2023

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ADAMS Accession No.: ML22287A185 **NRR-106**

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DATE	10/6/2022	10/21/2022	2/1/2023	2/1/2023

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OFFICE OF NUCLEAR REACTOR REGULATION

REGULATORY AUDIT REPORT

REGARDING THE PHASED STARTUP OPERATIONS SUPPLEMENT OF THE

OPERATING LICENSE APPLICATION

SHINE TECHNOLOGIES, LLC

DOCKET NO. 50-608

Location:	Virtual (audit activities were also conducted via the electronic reading room)
Dates:	**Session 1:** May 24, 2022, from 1:30pm to 2:00pm **Session 2:** May 26, 2022, from 2:00pm to 2:30pm **Session 3:** July 14, 2022, from 4:30pm to 5:00pm **Session 4:** August 2, 2022, from 1:30pm to 2:00pm **Session 5:** August 25, 2022, from 11:00am to 12:00pm **Session 6:** September 7, 2022, from 10:00am to 11:00am **Session 7:** September 15, 2022, from 2:00pm to 3:00pm **Session 8:** September 23, 2022, from 10:30am to 11:00pm **Session 9:** September 28, 2022, from 3:00pm to 3:30pm
Audit Team Members:	Dinesh Taneja (NRR/DEX) Michael Waters (NRR/DEX) Michael Balazik (NRR/DANU) Zachary Gran (NRR/DRA) Gordon Curran (NRR/DSS) Nageswara (Rao) Karipineni (NRR/DSS) Mike Call (NMSS/DFM) Jesse Seymour (NRR/DRO)
Licensee Representatives:	Jeff Bartelme, SHINE Technologies, LLC (SHINE), et al.

Background

By letter dated July 17, 2019 (Agencywide Documents Access and Management System Accession No. ML19211C044), SHINE Medical Technologies, LLC (SHINE) submitted its application for an operating license. The application was supplemented with the “Application for an Operating License Supplement No.15, Submittal of the Phased Startup Operations Application Supplement,” dated January 27, 2022 (ML22027A354).

This report summarizes the regulatory audit conducted by staff of the U.S. Nuclear Regulatory Commission (NRC) in multiple sessions from May through September 2022, and provides a closure path for each of the identified open technical items.

This audit was conducted in connection with the NRC staff's review of the application. This audit report does not make any licensing conclusions or findings, but it is part of the administrative record of the NRC staff's review of the application and may provide information supporting the NRC staff's safety evaluation. Unless otherwise noted in this enclosed report, the audit followed the plans provided by letters dated:

- May 24, 2022 (ML22094A114), and
- August 25, 2022 (ML22061A212).

Regulatory Bases for the Audit

The purpose of the audit was to close technical gaps identified during the review of the phased startup operations supplement of the SHINE operating license application. The licensee's operating license application and corresponding phased startup operations supplement is being reviewed in accordance with the applicable regulatory requirements of Title 10 of the *Code of Federal Regulations* Part 50, "Domestic Licensing of Production and Utilization Facilities," and applicable guidance provided in NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," Part 1, "Format and Content," and Part 2, "Standard Review Plan and Acceptance Criteria" (ML042430055 and ML042430048, respectively).

Audit Activities

The following activities were performed during the audit:

1. Entrance Meeting

At the entrance meeting on May 24, 2022, the NRC staff explained the scope and desired outcomes for the audit. The NRC staff stated that after completion of the audit, an audit report will be prepared and sent to SHINE.

2. Review of Audit Topics and Questions

This audit was held to: (1) gain a better understanding of information underlying the application and phased startup operations supplement, (2) identify specific information that will require docketing to support the basis of the licensing or regulatory decision; and (3) close open technical items or identify a closure path in the Audit Topics and Questions section of this audit plan. Closure paths for the Audit Topics and Questions provided in the audit plan are noted in the enclosure.

As discussed in the audit plan, the NRC staff conducted document reviews using the electronic reading room as part of the audit. The NRC staff provided a list of the documents to be reviewed in its audit plan. The NRC staff did not review any additional documents in the electronic reading room beyond those listed. Therefore, any additional information identified from the audit that is needed to address a regulatory finding has been documented in this audit report.

3. Exit Briefing

An exit briefing was held on September 28, 2022. During this exit briefing, the audit team restated the purpose of the meeting, recapped the closure paths of the audit items, and highlighted areas where additional information may be warranted. It was noted that during the

audit, SHINE had stated that it would provide supplemental information on the docket to address additional information needs identified by the NRC staff. Based on SHINE providing this supplemental information to address information needs identified by the NRC staff, the NRC staff considers the audit items provided in the audit plan closed. However, the NRC staff noted that it is still continuing its review of the SHINE operating license application, including the supplemental information, and that additional audits may be necessary. No disagreements with this audit summary were noted by the licensee during the exit briefing.

Audit Session: May 24, 2022 – September 28, 2022

Audit Topics and Questions:

The material below is a summary of the discussions held during the audit.

May 24, 2022, Audit Plan (ML22094A114)

SHINE Safety Analysis

1. Explain how the current proposed phased approach to construction and operations is consistent with the commitment to maintain the SHINE safety analysis (SSA) and the commitment in technical specification (TS) 5.5.4, "Configuration Management," to follow 10 CFR Section 70.72, "Facility changes and change process" (as modified to use appropriate regulatory citations and terminology for SHINE), such that the SSA and the safety program derived from it are consistent with the as-built and as-operated facility at any given time.

   The following is information the NRC staff provided to SHINE to provide further clarification to the SSA audit questions or that revises the questions. Over the course of the two SSA audit calls with SHINE, SHINE provided responses based on this information.

   Confirm that the implementation of phased construction and operations will be done in accordance with the commitments to maintain the SSA and follow the processes in TS 5.5.4. This would include the change control process, which, based on a previous audit call, includes appropriate elements or concepts from 10 CFR 70.72. Explain how that implementation will be done at each phase to ensure the SSA (the accident sequences, likelihoods, consequences, and safety-related controls with their reliability management measures) and safety program are consistent with and appropriate for the as-built facility and the activities and operations in a given phase.

   Response - SHINE confirmed that phased construction and operations will be implemented per the commitments described in the question, including implementing of a change control process that includes appropriate elements of 10 CFR 70.72. This also includes maintaining of the SSA and its supplement and verification that the facility and operations are consistent with the SSA and its supplement will be done at each phase.

2. Explain how the SSA, with its supplement, reflects (or will reflect) and is (or will be) an analysis that is applicable to the as-built and as-operated facility in each phase, including consideration of the following:

   - differences in the facility's systems, operations, and configurations,
   - impacts to accident sequences (likelihoods, consequences, new sequences),
   - impacts to safety controls (new controls, different configurations/roles of controls, different reliability management measures, non-safety related controls becoming safety related controls),
   - examples for the preceding include: Phases 1 and 2 – no material staging building (MATB) and no radioactive liquid waste immobilization system (RLWI) selective removal process; isolations for iodine and xenon purification and packaging (IXP) hot cell; valves (and dampers) in installed systems that lead to connections to uninstalled systems, and

- multiple concurrent analyses for the same accident sequence depending on the phase (e.g., FRI-2 and FRI-23; FRI-10 and FRI-22; 13b.2.7-A and 13b.2.7-C; 13a2.1.12-O and 13a2.1.12-U; 13a2.1.12-Q and 13a2.1.12-T).

The following is information the NRC staff provided to SHINE to provide further clarification to the SSA audit questions or that revises the questions. Over the course of the two SSA audit calls with SHINE, SHINE provided responses based on this information.

For each accident sequence, identify the consequence type(s) for the accident (as was done in the main SSA).

MATB

- Clarify how safety-related controls (specific administrative controls (SACs) with the MATB label) are implemented during phases without the MATB for storage of materials in the radiologically controlled area (RCA).
- Clarify whether and how preparations for offsite shipment inside the RCA versus the MATB affects evaluations and operations (impacts to other RCA activities).

RLWI selective removal process

- Explain how accidents in the main SSA cover leakage of solution into the RLWI area via the connection(s) to the missing selective removal process portion of the RLWI and how the valve(s) at the connection(s) aren't needed as a new engineered control (active engineered controls/passive engineered controls (AEC/PEC).
- Confirm whether there are any impacts to consequences of other events involving solution, with the solution retaining the radionuclides that would otherwise have been removed. (It seems like extra holding time in the RCA is used to ensure that the consequences of relevant analyzed accidents are not increased, which would seem to be a SAC. It would be good to confirm whether or not this is covered by an existing SAC such RLWI-SAC-14 or if a new SAC is needed.)

IXP (hot cell)

- Confirm the locked transfer doors between the IXP cell and the neighboring cell are treated as part of the production facility biological shield (PFBS)-PEC-01 and get the leak rate testing for that PEC to ensure the allowable leak rate is not exceeded, just like the rest of the supercell confinement.
- Confirm how an accident sequence like 13b2.4-X, but for a criticality consequence is considered and evaluated to be highly unlikely per SHINE's SSA method. It appears that the SSA supplement should include an appendix F-like event sequence evaluation since it seems that a new credible sequence involving criticality as a consequence has been introduced.

Clear distinction of accident sequences needed (in accident descriptions). Current descriptions of some accident sequences in the SSA supplement make it seem that the same accident sequence from the main SSA has two evaluations with two different outcomes for the same accident (for same sequence or initiating event). The SSA supplement accident descriptions (accident or cause description) should be sufficiently different to clearly be a distinct accident from the counterpart in the main SSA. Two examples are:

- FRI-10 versus FRI-22 (both have maintenance or hot work described as the cause). It seems that FRI-22 should have a cause that is more like the cause description for FRI-23.
- 13a2.1.12-Q versus 13a2.1.12-T, the second accident has an increased frequency and an added safety-related control for a sequence that is described in a way that makes it identical to the first accident.

Response - For the points related to MATB, SHINE identified the SACs that would not apply during the early phases of operations. For those controls that will apply, SHINE described how they would be met. This includes continuing to implement specific requirements from 10 CFR 71.15, "Exemption from classification as fissile material," paragraph (c) on the stored waste and controls storage locations and materials stored in those locations (e.g., bore holes). SHINE described the characteristics and quantities of waste materials that are anticipated during early phases when the MATB is not built and available for use. Some shipments are expected during these early phases, and SHINE described how it expects to conduct those activities and that they do not present a hazard that the application does not already account for, though some specific analyses (e.g., a criticality safety evaluation) are being developed.

For the points regarding the RLWI, SHINE described how the analyses for the RLWI system in the SSA bound the impacts of accidents that would involve leak of material through the valves that isolate connections to the selective removal process equipment and the presence of radionuclides that would otherwise be removed by this equipment. Some aspects of this include that the analyses already include these nuclides. They also include that there is a SSA accident sequence involving a spill into the RLWI cell of a volume of material that bounds the amount of material available for such a spill, including through isolations to the selective removal process equipment.

For the IXP, SHINE confirmed that the transfer doors are part of the passive engineered safety-related control for the supercell confinement and will be tested to meet the leak criterion for this control just like the rest of the structures, systems, and components (SSCs) that comprise this control. SHINE also discussed how spills in the IXP cell are to be controlled. During the discussion it was identified that one control, the drain to the RDS, would not be available because it is plugged in the phases in which the IXP is not installed. Thus, SHINE was going to take an action to revisit the evaluations for the IXP to see if anything new may be needed for controlling spills in the IXP cell.

For those accident sequences identified by the NRC staff that seem to evaluate the same initiating event with different outcomes, SHINE stated they will modify the event descriptions to clearly distinguish the accident sequences in the SSA supplement from the similar sequences in the main SSA.

3. Clarify and explain how the SSA supplement and safety analysis report (SAR) supplement are consistent with regard to the description and evaluation of accident sequences and safety controls, including:

   - valves and other (system interface) isolation mechanisms; many more discussed in the SAR supplement than the SSA supplement (e.g., IXP, radiological ventilation zone 1 exhaust subsystem (RVZ1e) isolation outside irradiation unit (IU) cells, RVZ1e – IXP cryotrap interface, radiological ventilation zone 2 (RVZ2) – tritium purification system (RVZ2 – IXP, RLWI selective removal process connections),

- possibly new valves on some system connections/interfaces (e.g., RVZ1e outside the cooling room for connections to IU specific primary closed loop cooling system; radioisotope process facility cooling system to neutron driver assembly system cooling cabinet interfaces),
- RLWI selective removal part (e.g., section 13b.1.1),
- SAC, description including minimized lift height (e.g., section 13a2.1.12), and
- meaning of statements that no new accident sequences were identified that result in radiological release (or chemical release) (e.g., sections 13b.2, 13b.3) versus. new/revised accident sequences and new safety controls.

The following is information the NRC staff provided to SHINE to provide further clarification to the SSA audit questions or that revises the questions. Over the course of the two SSA audit calls with SHINE, SHINE provided responses based on this information.

Valves and other system interface isolation mechanisms

It is not clear why only two of the valves identified in the final safety analysis report (FSAR) supplement are new safety-related controls. The FSAR supplement identifies several valves (as well as a few other isolation mechanisms) for isolating connections/interfaces of installed and operating systems to uninstalled systems during phased construction/operations. Yet, the SSA supplement only identifies two of them as new and as new safety-related controls. The NRC staff looked through the main FSAR and SSA summary to see if the other valves discussed in the FSAR supplement were already identified in the main FSAR and, where needed, identified and evaluated as safety-related controls in the main SSA summary, but it is not clear that this is the case. Thus, the NRC staff is seeking information/clarification to explain how/why only two of the many valves identified in the FSAR supplement are identified and evaluated as new safety-related controls in the SSA supplement. Provide a few examples of valves on safety-related systems as well as a few on systems that aren't safety-related but interface with safety-related systems and so could impact the safety-related systems or cause/initiate an accident with the potential to challenge the SHINE safety criteria. The NRC staff noticed that there are some safety-related controls (e.g., those that are for confinement boundaries) in the SSA summary that seem to include multiple items, such as valves; however, the SSA summary still identifies some of these items as separate safety-related controls. So, it is not clear if the various valves in the FSAR supplement are part of these multi-item controls in the SSA summary or, if they should not be identified as separate controls.

Also, confirm that there aren't valves that aren't safety-related controls for the full facility but become safety-related controls during phased operations because they are now used to isolate a connection/interface to an as yet installed system. Also, explain how consideration was given to differences in configuration (e.g., the connection/interface is to an uninstalled system in phased operations versus in the full facility, the valve configuration or manner of performing its function) and the implications for accident consequences and the needed management measures for determinations that the evaluations of relevant accidents and availability/reliability of the safety-related controls did not need to change. Provide an example(s) of where these kinds of considerations were evaluated and the outcome turned out as not needing to identify a non-safety-related item as a safety-related item or not needing to modify the evaluation of an accident sequence or the safety-related controls for that accident.

RLWI
This point is covered by the Question 2 [i.e., Session 2, Question 2] points on the RLWI above.

SAC descriptions
The SAR supplement appears to neglect that a minimum lift height is part of SAC needed to prevent accidents identified for phased operations such as is described in section 13a2.1.12 of the SAR supplement. This should be clarified.

Statements on no new accidents being identified (in SAR supplement sections 13b.2 and 13b.3)
Clarify how these statements are consistent with the SAR supplement and the SSA supplement identifying new or revised accident sequences and new safety-related controls (engineered controls and SACs).

Response - SHINE provided a lengthy explanation in response to the NRC staff's questions regarding the valves being used to isolate connections to uninstalled SSCs, there only being a few of these valves identified as new safety-related controls, and considerations for management measures for those valves that are safety-related controls (in the main SSA) that would perform their function differently in early phases. The response included points that address specific aspects of the clarification provided by the NRC staff. SHINE indicated that each accident sequence in the SSA was analyzed to determine if adjustment was necessary based on the phased approach, whether that included changes in things such as initiating event frequencies or the available controls in any given phase or duration changes. SHINE also pointed to some safety-related controls that involve multiple SSCs (e.g., controls identified for confinement functions). It is the NRC staff's understanding from SHINE's response that various valves identified in the FSAR supplement will be part of these multi-SSC safety-related controls. The discussion also indicated, acknowledging some related discussion from the preceding audit call, that in some instances valves in the FSAR supplement do not need to be safety-related controls because the accident sequence evaluations in the main SSA cover or bound an accident where material spills through the connection isolated by the valves. SHINE explained that its analysis for the SSA supplement did include consideration of backflow and pointed to an example of a sequence (to be added based on the previous audit call) that involves backflow of material.

In terms of the management measures, the discussion pointed to configuration management as the management measure to ensure the valves that are safety-related controls perform their required function in the correct manner for any given phase.

SHINE also acknowledged the inconsistency noted by the NRC staff regarding the particular SACs' descriptions. These SACs and their relevant accident sequences are being revised in response to the NRC staff questions discussed in the September 7, 2022, audit call (i.e., the previous audit call). SHINE also explained the FSAR supplement statements that the NRC staff had questioned and thus showed they are consistent with the rest of the FSAR supplement and the SSA supplement.

4. Clarify how the TSs address phased approach, including the new safety controls, and how changing from different phases will not necessitate changes to TSs. If the TSs address all safety-related SSCs needed to prevent accidents, with accident sequences and controls changing from phase to phase (added, removed, changed configuration), it would seem the TSs would also need to change from phase to phase.

   Response - The question was withdrawn by the NRC staff; therefore, no response was provided.

5. Explain how heavy load drops were reevaluated for the phased approach and how the SSA supplement and SAR supplement both address these events. It is unclear why the SSA supplement does not identify and evaluate more accident sequences involving heavy load drops (either revised accident sequences from the SSA or new sequences versus what is in the SSA). Examples include drops onto operating IU cells (13a2.1.12-P), open IU cells after having operated (13a2.1.12-O), and open or operating target solution vessel off-gas system (TOGS) cells.

   The following is information the NRC staff provided to SHINE to provide further clarification to the SSA audit questions or that revises the questions. Over the course of the two SSA audit calls with SHINE, SHINE provided responses based on this information.

   It is unclear why there are not more heavy load drop sequences affected by phased operations (either revised or new accidents). For example, it would seem that 13a2.1.12-P would have an increased frequency (possibly changing the uncontrolled accident failure probability index number (FPIN) from -4 to -3). Also, the SSA supplement has 13a2.1.12-U as a modified 13a2.1.12-O sequence, but only for open IUs that have not operated yet. It seems that 13a2.1.12-U should include drops over open IUs that have operated too unless it is somehow not credible without any kind of control (PEC, AEC, or SAC, or something that should be identified as a control). Also, confirm that a heavy load drop onto an open or operating TOGS cell causing damage to the TOGS leading to a release is not credible and the basis for that. Or, if it is credible, provide an evaluation of such an event in the main SSA and, for impacts from phased operations, in the SSA supplement.

   Response - SHINE indicated that it had evaluated increased crane operations and heavy load lifts around open IU cells already in operation and determined the increase did not change the likelihood score for the event as already analyzed in the main SSA. SHINE said it would add a sequence in the SSA supplement to explicitly show this evaluation. With regard to heavy load drops onto TOGS cells, SHINE pointed to the construction of the TOGS cell lid and that this lid has similar capability to withstand heavy load drops as the IU cell lid. SHINE also described operations that are done to prepare the TOGS cell for lid removal, which result in the potential radiological hazard in the open TOGS cell being minimal. SHINE indicated it would look to confirm it had treated the TOGS cell lid in its evaluations as the IU cell lid had been treated for drops over the closed cell (e.g., if treated as a safety-related control or defense-in-depth control). SHINE also indicated it would modify the relevant heavy load drop accident sequence in the SSA to include drops onto the TOGS cell as well as the IU cell.

6. Clarify or describe the following with respect to the accident sequences, safety controls, and their reliability management measures identified and evaluated in the SSA supplement:

- management measures for engineered controls (Table 2): any added information on maintenance (type, frequency), any surveillances/monitoring,
- management measures: appropriate measures listed in accident sequences (e.g., FRI-22 and FRI-23; 13a2.1.4-K, 13b.2.4-X; lockout/tagout; material handling system (MHS)-AEC-01; 13a2.1.4-K),
- safety control descriptions (e.g., PHASED-PEC-01, 13b.2.4-X),
- meaning and impact of possibility/practicality of control on its FPIN (e.g., PHASED-SAC-03, 13b.2.7-C),
- valve as PEC, not AEC (e.g., 13a2.1.4-K accident cause),
- redundant AEC (e.g., 13a2.1.12-T crane – depends on how meet single failure proof; possible impact on SSA accident sequences (e.g., 13a2.1.12-P)),
- frequency increase differences FRI-22 versus FRI-10 versus heavy load drop accidents' frequency increase, and
- FRI-23, SAC with a FPIN=-2 (should get -1 per SSA method).

The following is information the NRC staff provided to SHINE to provide further clarification to the SSA audit questions or that revises the questions. Over the course of the two SSA audit calls with SHINE, SHINE provided responses based on this information.

Management measures

- Clarify what kind of maintenance will be conducted for the reliability management measures for the new safety-related controls (PHASED-PECs) and where that is described. Consider whether table 2 of the SSA supplement should include a brief description of that maintenance. Particularly for valves, appendix D of the SSA summary includes some description of the maintenance that is credited as a reliability management measure.
- Clarify why training and qualification is identified in table 2 of the SSA supplement as a management measure for MHS-AEC-01, which is about crane characteristics, and how that ensures the availability and reliability of this control (see also accident sequence 13a2.1.12-U).
- The accident sequence tables in the SSA supplement have a management measures column (this differs from the accident sequence tables in the main SSA summary), which in several cases include items that don't appear to be reliability management measures or are missing items that would be reliability management measures. They are also not consistent with the reliability management measures described for the safety-related controls in table 2 of the SSA supplement. These should be clarified or modified as needed, including:

    - FRI-22, FRI-23 – the items listed in this column seem to be part of PROG-SAC-05 or are otherwise safety-related controls (SACs). If this control(s) is needed to meet the SHINE safety criteria, it should appear in the available controls column with the appropriate index score. Or if it is defense in depth, it could be so identified.
    - 13a2.1.4-K, 13b.2.4-X – it is not clear how some items listed in this column are appropriate for the credited safety-related controls for these accident sequences. At the same time, items such as lockout/tagout that are identified in the notes part of the accident sequence table, would be appropriate reliability management measures but aren't identified as such.

Safety control description and implementation in accident sequence
The description of PHASED-PEC-01 and the accident sequence in which it appears (13b.2.4-X) need clarification and appropriate modification. It is not clear whether the PHASED-PEC-01 includes both locked valves on the line from MEPS to IXP or just the second locked valve. Its description refers to “valves.” The accident sequence 13b.2.4-X describes failure of one of the valves on this line as the cause of the accident. If PHASED-PEC-01 includes both valves, then the accident is caused by a degradation of the very control being relied on to prevent the accident. It should be that each valve is a separate control, with the SSA supplement identifying them as two separate controls, with the accident sequence being caused by failure of one of these controls with the other control preventing the accident. The failing valve is relied on also and is scored in the uncontrolled accident sequence just like a passive engineered control. Thus, it too should be identified as a safety-related control (in the SSA supplement).

Safety-related controls that are not firm requirements
The description of PHASED-SAC-03 and its application in accident sequence 13a2.1.12-T and the application of MHS-SAC-01 in accident sequence 13b.2.7-C include that the control is implemented “if possible” or similarly “as practical.” These phrases mean that the control cannot be relied on, that it is not a firm requirement. This includes that there may be times when the control cannot be implemented versus the control fails because it is not implemented correctly. Thus, it cannot be relied on to control (prevent or mitigate) an accident. Another control(s) is needed to ensure the accidents are controlled sufficiently to not exceed the SHINE safety criteria. While such phrases may have been included in the same, or similar, safety-related controls’ descriptions in the main SSA summary, the phrases appear only where the control is a defense in depth. If, however, there are instances where implementation of the control that is credited for preventing or mitigating an accident in the main SSA summary is not possible or practical, then the accident sequences in the main SSA summary also need to be reevaluated and new controls identified for them to ensure they do not exceed the SHINE safety criteria, where necessary.

Passive engineered control versus *Active engineered control*
For example, sequence 13a2.1.4-K’s cause is failure of a valve. The index score is for a PEC. Valves would typically be AECs. There was discussion of this topic in a previous audit call. Confirm that this treatment is consistent with the outcome of that discussion and that the part of the valve being relied on as a passive control is consistent with that discussion as well.

Redundant AEC
Clarify how the single-failure proof crane qualifies as a redundant AEC versus an AEC with high availability (per FSAR table 13a2.1-5). There are two ways that a crane may be qualified as single-failure proof. One way is that the crane has two lift devices of the necessary lift capacity. The other is that the crane has a single lift device with double the needed load capacity. A crane with the two lift devices for which there is assurance of no common cause failure would be a redundant AEC (and get an FPIN = -4). However, a crane with the single lift device configuration would seem to be a single AEC with high availability per SHINE’s SSA method (and get a FPIN = -3). Depending on how SHINE’s crane meets single-failure proof, the accident evaluations for which this crane is a safety-related control may need to be reevaluated (in the SSA supplement and the main

SSA). Additional controls may be needed for those sequences to ensure they do not exceed the SHINE safety criteria.

Frequency increase differences for fire sequences versus heavy load drop sequences Clarify why frequencies of fires (e.g., for FRI-22 versus FRI-10) don't increase to the same extent as the heavy load drop frequencies, and so result in the FPIN increasing for the fire sequences analyzed in the SSA supplement like the FPIN increases for the heavy load drop sequences analyzed in the SSA supplement. It seems like the increase in frequency of heavy load lifts and hot work would be relatively equivalent for phased construction and operations. For FRI-22, for example, the notes indicate that hot work in TOGS cells and cooling rooms is not considered in the accident evaluation because they are separate fire areas. Some clarification is needed to understand how construction hot work in the TOGS cells/cooling rooms can be considered as being in a separate fire area (any differences in configuration of the TOGS cells/cooling rooms under construction versus operating/maintenance that could affect whether they are separate fire areas or not – completely enclosed from the area external to the cells/rooms or not; e.g., the TOGS cells' removable shield plugs are in place).

Sequence FRI-23 and SAC with FPIN=-2 – the question is removed. It seems that the SAC would be for a routine planned operation, in which case, the FPIN score is consistent with SHINE's SSA method.

Note: It seems that there is an error in the public consequence category for the controlled accident for sequence 13b.2.7-C (should be a 2 instead of a 3 unless the uncontrolled accident and the category in 13b.2.7-A are incorrect).

Response - With regard to management measures, SHINE discussed some of the management measures and identified some specific examples of actions entailed in those measures. These include things such as valves being locked, closed and removed from power, using configuration management to ensure the valves are in this configuration, and replacement of leaking valves. SHINE explained that training and qualification were appropriate management measures for using the irradiation facility (IF) crane (the safety-related control is that the IF crane is single-failure-proof) because these measures ensure that the features making the crane single-failure-proof are employed properly. For the two fire accident sequences, SHINE said it would modify them to move the descriptions of items that are part of the fire protection program SAC from the management measures and identify the SAC as a defense-in-depth control for the accident sequences. For sequence 13a2.1.4-K, SHINE stated it would include appropriate actions in the management measures for the controls for this sequence. The NRC staff questioned the appropriateness of procedures and training/qualification as management measures for the controls in this sequence and the 13b.2.4-X sequence. SHINE described the intent of those management measures. Based on the discussion with the NRC staff that these items, as described by SHINE, do not have bearing on the performance of the controls in these sequences (the controls are locked closed valves), SHINE stated it would reevaluate the management measures.

SHINE also provided clarification regarding the PHASED-PEC-01 safety-related control and the configuration of the piping from MEPS to IXP. The control is the valve that is inside the IXP cell whereas the valve that initiates the relevant accident through failure is a valve that is on the piping but is located outside of the IXP cell. With multiple pipe connections

between MEPS and IXP, this control and the accident sequence apply to multiple valve failure scenarios and multiple valves within the IXP cell that are the preventative safety-related control. SHINE did identify that there is a piping connection for which the valve of the safety-related control is not enough to control an accident sequence to be less than the SHINE safety criteria. So, SHINE stated it would develop a new accident sequence and safety-related control for it that would be included in the SSA supplement. The new control is the blind flange/cap on that piping connection.

In response to the NRC staff's concern about the safety-related controls that were to be done 'if possible' or 'as practical,' SHINE stated it would revise the accident sequences. The revision is based on a review of the sequence evaluation and of activities with the construction team. This review identified that the SSCs that are affected by the relevant accident sequences are not in the normal path for the crane based on the SSC's locations, that other equipment above the SSCs precludes there being any space to move loads over the SSCs, or the location of the SSCs and the nature of construction activities near them is such that there is no reason to lift anything over the SSCs. SHINE also confirmed that where the same or similar controls are used in the main SSA, there is nothing that makes their use not possible or not practical for the accident sequences in which they are credited as controls.

SHINE also clarified that valves that are credited as passive safety-related controls in the SSA supplement are those that are locked closed or disconnected from power and so cannot be actuated. They will remain in this condition until the necessary SSCs are installed.

SHINE also provided a description of the IF crane to show that the means for the crane to meet the single-failure-proof criterion is consistent with the likelihood score given the IF crane as two, redundant AEC, as defined in SHINE's SSA method, including redundant components with capacities that indicate the crane has redundant load paths with margins for the loads to be lifted by the crane.

SHINE also explained the rationale for why fire accident sequence likelihoods did not increase enough to change the likelihood scores for these sequences. This rationale includes that certain portions of the IF (i.e., the TOGS cells and cooling rooms) are surrounded by thick concrete surrounding and when the top is open there is some vertical as well as horizontal distance between the hot work that would take place in those parts of the IF and nearby equipment. The NRC staff indicated that its understanding of how fire evaluations, including designation of fire areas inside buildings, does not align with allowing credit for distance between open parts of the same building. It is NRC staff's understanding that for certain locations to not be considered in the fire evaluation of a fire area, those locations needed to be entirely closed off from the rest of the area by physical barriers. SHINE stated it would revisit the evaluation. The NRC staff also stated it would confirm its own understanding as to what is acceptable versus not as well.

No action or discussion was needed on the item that shows in the clarification description as being withdrawn. SHINE did acknowledge the identified error and stated it would be corrected.

Chapter 9, "Auxiliary Systems"

7. With respect to the heating ventilation and air conditioning system balancing to maintain the ventilation zone pressures and flows, with RVZ1e and possibly RVZ2e exhausting a

relatively smaller quantity of air, while RVZ2s is supplying close to full design quantity. Describe or explain the capability of RVZ2s to operate at a much less than full flow during early phases of startup, particularly in Phase 1.

Response - The design of the systems includes provisions for adjustment of flow. RVZ2s includes an array of fans instead of a single fan. RVZ1e and RVZ2e are equipped with variable frequency drives. These features provide the capability to adjust flow in accordance with the flow required during different phases of operation and maintain the pressure gradients in the radiological ventilation zones. This item is closed.

8. The MHS description provided in subsection 9b.7.2 of the FSAR is not affected by phased startup operations. During Phase 1 through Phase 3, the IXP hot cell is not operational. Installation of the IXP during Phases 3 & 4 will require heavy lifts that may travel in vicinity of systems containing critical components or impact radiation-controlled systems during construction.

   To ensure safe handling during construction, the NRC staff needs additional details of the following:

   a. Section 9b.7.2 of the FSAR indicates the MHS description in the FSAR is not affected by phased startup operations. Section 13b.1.2.3 of the FSAR provides discussion of accident sequence of a heavy load drop onto the RLWI shielded enclosure or supercell during phased startup operations to account for an increased likelihood of the initiating event as a result of on-going installation activities. The licensee indicates this scenario is prevented by the credited controls currently in place and application of applicable guidance from NUREG-0612, “Control of Heavy Loads at Nuclear Power Plants: Resolution of Generic Technical Activity A-36,” for control of heavy loads in the SHINE facility. Section 13b.1.2.3 of the FSAR also indicates, “Because these scenarios have preventative measures in place, there are no radiological consequences.” With use of the non-single failure proof radioisotope production facility crane, provide additional details about how the controlled range of crane motion (i.e., interlocks and stops) would function during the phased construction installation activities to continue preventing the limiting release scenarios.

   b. Section 9b.7.2 of the FSAR indicates the MHS description in the FSAR is not affected by phased startup operations. With the use of a single failure proof crane in the IF load drop is minimized. The SHINE request for additional information (RAI) response dated March 23, 2021, indicates special lifting devices are not used or defined. With lack of discussion of special lifting devices, the use of redundant slings or slings with twice the load rating is not provided. The RAI response does commit to ensuring that applicable lifting devices have redundant load paths or double the normal factors of safety, consistent with the guidance of section 5.1.6 of NUREG-0612. Similar to the above, provide additional details about how sling use within the IF would be controlled during the phase construction installation activities to continue preventing the limiting release scenarios.

   Response - SHINE confirmed that section 9b.7.2 of the FSAR crane program, including safe load paths, will be implemented in Phase 1 and NUREG-0612 safety features and criteria will be applied during phased startup activities. In response to the NRC staff question on whether aspects of NUREG-0612 will be implemented, SHINE indicated that all criteria of

NUERG-0612, including sling use and controlled motion, will be applied in Phase 1 and cranes will be operated consistent with use during normal plant operation. SHINE indicated that heavy loads will not travel over SSCs that are in the normal path for the crane based on the SSC's locations, that other equipment above the SSCs precludes there being any space to move loads over the SSCs, or the location of the SSCs and the nature of construction activities near them is such that there is no reason to lift anything over the SSCs. SHINE also indicated that waste barrels will not be moved at or near safety SSC.

9. The solid radioactive waste packaging system description provided in subsection 9b.7.5 of the FSAR is not affected by phased startup operations, except that the MATB is not available during Phase 1 and Phase 2. The MATB will not be compete and the solid waste drums will be stored in the RCA, instead of MATB, prior to shipment. Additional storage may be needed within the RCA for material that would otherwise be stored in the MATB. With the MATB unavailable during Phase 1 & 2, additional waste barrels may need to be stored within the RCA area. Clarify the quantity and location of waste storage within the RCA.

   Response - According to the phased startup application supplement, the solid radioactive waste packaging system (SRWP) description provided in subsection 9b.7.5 of the FSAR is not affected by phased startup operations, except that the MATB is not available during Phase 1 and Phase 2. Section 9b.7.5 of Phased startup operations application (supplement number 30) indicates, during Phase 1 and Phase 2, solid wastes are characterized and staged for shipment in the main production facility in accordance with the radioactive waste management program. Section 11.2 of phased startup application indicates, the MATB will not be used for interim storage of wastes for decay until it is operational as part of Phase 3. Solidified waste generated during Phase 1 and Phase 2 are stored in the subgrade bore holes in the radioisotope production facility as discussed in Chapter 9b.

   During the Audit dated May 24, 2022, SHINE provided clarification that they don't plan on solidifying any wastes during Phase 1 & 2 with use of SRWP and enough storage capacity is available for any other solid waste generated within bore holes and there is no anticipated need for additional storage. Additional actions were taken by SHINE to update section 9b.7.5 as result of the audit discussion. This is reflected in the application supplement which states: "There is adequate bore hole storage space for waste streams that may require encapsulation processing until the MATB is available during Phase 3."

Chapter 11, "Radiation Protection Program and Waste Management"

10. Section 20.1101, "Radiation protection programs," paragraph (b) of 10 CFR states: "The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)."

    In review of the information contained in the phase approach supplement FSAR section 11.1.1, "Radiation Sources," SHINE states, in part:

    > During Phase 1, with IUs 1 and 2 operating, the dose rate in IU cell 3 and primary cooling room 3 is expected to be between 5 and 100 millirem per hour (mrem/hr), while the dose rate in the remaining cells (i.e., IU cells 4 through 8, TOGS cells 3 through 8, and primary cooling rooms 4 through 8) is expected to be less than 5 mrem/hr. During Phase 2, with IUs 1 through 5 operating, the dose rate in IU cell 6 and TOGS cell 6 is expected to be between 5 and 100 mrem/hr, while the

> dose rate in the remaining cells (i.e., IU cells 7 and 8, TOGS cells 7 and 8, and primary cooling rooms 6 through 8) is expected to be less than 5 mrem/hr. The probable dose rates within operating IU cells, TOGS cells, and cooling rooms during Phase 1 and Phase 2 are as provided in Figure 11.1-1 of the FSAR. The probable dose rates within the irradiation facility (IF) during Phase 3 and Phase 4 are as provided in Figure 11.1-1 of the FSAR.

In review of the above FSAR information, considering information shared during Advisory Committee on Reactor Safeguards meetings, and in review of calculational files made available during SHINE audits, the NRC staff is seeking to understand the general dose rates expected during phased operations to verify that SHINE is meeting the requirements contained in 10 CFR 20.1101(b) and adequately controlling doses to occupational workers.

It is the NRC staff's understanding that the startup times for Phase 1 and 2 operations would be at or around the same time so the NRC staff would not expect changes to the expected dose in the areas in and around cells 1-5 during operation and would typically follow the dose map provided in FSAR figure 11.1-1. If this assumption is incorrect, the NRC staff would seek information on the dose rates expected in cell 3 from cell 2 operations like the requests below.

As seen in the referenced FSAR text above, the stated dose rates for work performed in cell 6 from cell 5 operations is between 5-100 mrem/hr. The NRC staff finds that this is a broad range of doses and may not align with some of the information reviewed during previous audits. The NRC staff is looking for SHINE to provide an explanation and evaluation of what workers would expect as typical dose rates for work in cell 6 during phase operations. The NRC staff is looking for SHINE to establish expected dose rates workers would receive while performing work in cell 6 during cell 5 operations.

If the stated 5-100 mrem/hr dose rate estimates are correct, how does SHINE ensure that workers will maintain doses ALARA, consistent with the requirements contained in 10 CFR 20.1101(b)? The NRC staff seeks to understand the types of work that will be performed in the cell 6 area during cell 5 operations and how long the work in these areas will take with the understanding that the dose rates could be anywhere between 5-100 mrem/hr.

Response – SHINE outlined an approach reasonable to the NRC staff. SHINE outlined their estimates for dose rates when performing work in an adjacent IU cell to one that is operating. SHINE also states that they will follow ALARA principles with respect to work planning, by providing an example of performing work in the lower sections of the IU cell when the adjacent cell is not operating to reduce dose rates in the lower section of the IU cell. This item is closed.

11. FSAR Section 11.1.1 states, in part:

> Figure 11.1-1 of the FSAR provides probable radiation area designations within the supercell assuming each hot cell is operational. During Phase 1 through Phase 3, the iodine and xenon purification and packaging (IXP) hot cell is not operational. The dose rate in the IXP hot cell is expected to be between 5 and 100 mrem/hr during Phase 1 through Phase 3. The probable dose rates during Phase 4 are as provided in Figure 11.1-1 of the FSAR.

FSAR Section 4b.1, “Facility and Process Description,” states, in part:

> The PFBS hot cells (supercell), including the IXP hot cell, is installed prior to Phase 1, however the IXP system is not installed in the IXP hot cell until Phase 4. The supercell confinement boundary is isolated from the IXP hot cell and the IXP hot cell drain to radioactive drain system (RDS) is plugged during Phase 1 through Phase 3.

For the discussion pertaining to the supercell and hot cells, the NRC staff seeks to understand what types of work are expected to occur within the supercell and IXP hot cell during the phased approach. Are the described dose rate estimates provided to indicate that there is expected work within the hot cell during operations? Are there any dose concerns related to the IXP system installation during Phase 4?

Response – SHINE outlined an approach reasonable to the NRC staff. This item is closed. Phased approach assumes installation of the IXP in a hot cell that is adjacent to an operating cell. SHINE states that they will follow ALARA principles with respect to work planning during operation.

August 25, 2022, Audit Plan (ML22061A212)

1. With respect to the instrumentation and control systems review, the phased startup operations application supplement focuses on disabling inputs for various systems (such as highly integrated protection system equipment). **This item was resolved in Audit Session 2 and is closed.** SHINE confirmed there are no impacts to the design criteria in the FSAR.

   - Provide an overview of the changes/modifications SHINE is making to the platform for disabling the selected portions.
   - Provide an overview of the techniques used to disable the inputs.
   - Confirm there are no impacts to the design criteria in the FSAR. Describe how SHINE performed these evaluations.
   - To assist in the NRC staff’s understanding, please explain why this is the most nonintrusive approach.

2. Describe/clarify how it will be ensured that operators maintain a current understanding of the engineered safety features actuation system, tritium purification system, and target solution vessel reactivity protection system configurations and expected system response during successive stages of phased construction.

   Response - SHINE indicated the initial licensed operator training program will be based upon the complete facility with all equipment installed, with a subsequent set of training occurring after the licensing examination that will cover current facility status. SHINE also indicated that a combination of configuration control, turnovers, just-in-time-training, and cycle training will be utilized to address the needs of operators that are already licensed at the facility.

3. SHINE states that control consoles and displays associated with equipment that has not yet been installed will have the ability to have their displays secured/signals removed to

avoid creating operator distractions. Clarify/discuss how this will be implemented and managed.

Response - SHINE indicated that the PICS separates displays in a manner that allows operators to remove power from certain displays to minimize distractions, with power being left off until startup testing is required.

4. Clarify/discuss what is meant by “providing indication” for components that are disabled/disconnected via the process integrated control system and describe any measures to ensure that operators use those indications correctly during different operational phases.

   Response - SHINE indicated that displayed indications associated with systems that are not installed will be identified graphically. SHINE also indicated that an operator aid will be available that describes, on a progressive basis throughout phased construction, what indications will be in a status where a parameter value is displayed but has not yet been tested to verify its accuracy.

5. How will it be ensured that crane operators are trained to reliably implement any SACs associated with crane operations during continued construction due to the phased startup approach?

   Response - SHINE indicated that crane operators will consist of either operations or maintenance personnel and, furthermore, that their training and qualification process will include coverage of both the SACs and procedures that are associated with crane-related lifting and rigging operations.
   - Following the discussion, request for confirmatory information, human factors engineering question 1 (RCI HFE-1) was issued via email on September 19, 2022, to confirm the accuracy of this information regarding the training of crane operators.
     - In RCI response ML22263A027 (also dated September 19, 2022) SHINE confirmed the information regarding the personnel, qualifications, and training of crane operators was accurate.

6. Describe and clarify how the SSA and its supplement reflect the impacts of the configurations and activities discussed in Questions 1 through 4 [of Session 1].

7. Describe how the differences in configurations of instrumentation and control systems for the different phases and disabling/enabling of inputs for various systems at each phase are considered in terms of impacts to the SSA, including the potential for increasing likelihoods of currently analyzed accident sequences, reducing the reliability of AEC in consequence mitigation, and for introducing new accident sequences due to human error.

   The following is information the NRC staff provided to SHINE to provide further clarification to the SSA audit questions or that revises the questions. Over the course of the two SSA audit calls with SHINE, SHINE provided responses based on this information.

   In lieu of the original questions 6 and 7:
   Confirm that enabling/disabling of inputs to the instrumentation and control systems from the facility process systems at each phase has no impact on the portions of the facility already in operation. Explain how that was evaluated. For example, it is not clear that inadvertent disabling of inputs for a system already in operation is not a credible event

when personnel are performing actions to enable inputs for a newly installed system. If it is credible, then it could lead to impacts on the operating systems either from responses (or lack thereof) from the I&C systems or operator actions that rely on those inputs.

Response (6 and 7) - SHINE confirmed that enabling/disabling of inputs to the I&C systems for newly added SSCs in each phase will not impact SSCs already in operation. SHINE determined that such an impact is not credible based on an evaluation what would be necessary to cause such an impact. The rationale for that determination includes that at least two individuals would need to incorrectly execute and confirm three separate actions on two trains of equipment. The NRC staff also understands from SHINE's response that there is some physical separation between switches that would need to be manipulated as part of the enabling/disabling actions and there are also audio and visual indications to aid in the performance of these actions.

Discussion on Follow-up Items from September 7, 2022, audit call:
There was also discussion on some of the items identified in the previous audit call as needing follow-up or further action. This includes the new criticality safety evaluation for the IXP, some updates in the FSAR supplement and SSA supplement to address things such as the changes regarding safe load path control, updating the heavy load drops (including for TOGS cells), and adding an IXP accident sequence. SHINE indicated it was still looking into the fire hazard question about whether or not open TOGS cells and cooling rooms could be treated so as not to contribute to increased likelihoods of fire accident sequences for the IF fire area. The NRC staff did explain its view on a solution to the question for SHINE's consideration. That solution being to include the open TOGS cells and cooling rooms in the fire likelihood evaluation and credit the existing fire protection program SAC as a control for the relevant accident sequence in the SSA supplement. Such an approach would show that the accident sequence does not exceed the SHINE safety criteria.