

APPENDIX A. EVALUATION OF THE SHINE MEDICAL TECHNOLOGIES, LLC PHASED APPROACH TO STARTUP

1 THE FACILITY

Section 1, “The Facility,” of this appendix to the SHINE Medical Technologies, LLC (SHINE, the applicant) operating license application safety evaluation report (SER) discusses SHINE’s proposed phased approach to startup and provides the U.S. Nuclear Regulatory Commission (NRC, the Commission) staff’s evaluation of the overall impact of this approach on the SHINE facility.

1.1 Introduction

By letter dated February 26, 2021 (ADAMS Accession No. ML21057A340), SHINE stated that it intends to pursue a phased approach to startup of the SHINE facility. SHINE stated that this approach consists of four phases of process equipment installation and operation. The phases are defined as follows.

Phase 1 consists of the equipment necessary to support operation of irradiation units (IUs) 1 and 2. The anticipated equipment to be installed during Phase 1 includes:

- All auxiliary and support systems, except as noted below for the instances of primary closed loop cooling system (PCLS), light water pool system (LWPS), and radiological ventilation zone 1 (RVZ1) equipment located in the cooling room;
- All radioisotope production facility (RPF) systems except the capability of iodine and xenon purification and packaging (IXP) and radioactive liquid waste immobilization (RLWI) selective removal;
- IUs 1 and 2, including the associated instances of the subcritical assembly system (SCAS), neutron flux detection system (NFDS), target solution vessel (TSV) offgas system (TOGS), PCLS, LWPS, and radiological ventilation zone 1 recirculating system (RVZ1r); and
- Tritium purification system (TPS) train A.

Phase 2 adds the equipment necessary to support operation of IUs 3, 4, and 5. The anticipated equipment to be installed during Phase 2 includes:

- IUs 3, 4, and 5, including the associated instances of the SCAS, NFDS, TOGS, PCLS, LWPS, and RVZ1r; and
- TPS train B.

Phase 3 adds the equipment necessary to support operation of IUs 6, 7, and 8. Phase 3 also adds the capability for selective removal in the RLWI system and waste staging. The anticipated equipment to be installed during Phase 3 includes:

- IUs 6, 7, and 8, including the associated instances of the SCAS, NFDS, TOGS, PCLS, LWPS, and RVZ1r;
- TPS train C;

- RLWI selective removal components; and
- The material staging building (MATB).

Phase 4 adds the IXP capability.

To incorporate its proposed phased approach to startup, SHINE supplemented its operating license application by letter dated January 27, 2022 (ADAMS Accession Nos. ML22027A354 and ML22027A356), as supplemented by letters dated May 23, 2022 (ADAMS Accession No. ML22143A814), August 1, 2022 (ADAMS Accession No. ML22213A049), August 31, 2022 (ADAMS Accession Nos. ML22249A125 and ML22249A143), September 19, 2022 (ADAMS Accession No. ML22263A027), September 20, 2022 (ADAMS Accession No. ML22263A344), and September 28, 2022 (ADAMS Accession Nos. ML22271A963 and ML22271A967) (hereafter, the SHINE FSAR Supplement). The SHINE Supplement describes new or different information from the facility descriptions and analyses provided in the SHINE final safety analysis report (FSAR) resulting from the phased approach to startup. In its letter dated August 31, 2022, SHINE revised the information related to its phased approach to startup because of design changes and responses to NRC staff RAIs, as follows:

- Updated the disabling of inputs as described in SHINE Supplement Section 7.4.5, “Highly Integrated Protection System Design”;
- Removed “Group 1,” “Group 2,” and “Group 3” isolation from the title of the safety function associated with the carbon delay beds in SHINE Supplement Section 7.5.3, “Design Basis”;
- Revised “High PVVS Carbon Delay Bed Exhaust Carbon Monoxide” to “High PVVS Carbon Delay Bed Exhaust Temperature,” as a result of a design change in SHINE Supplement Section 7.5.4, “Operation and Performance”;
- Described the adequacy of bore hole storage space for waste streams until the MATB is available in Phase 3 in SHINE Supplement Section 9b.7.5, “Solid Radioactive Waste Packaging System”; and
- Updated the estimated waste stream and disposal during phased startup activities in SHINE Supplement Table 11.2-1, “Estimated As-Generated Annual Waste Stream Summary During Phased Startup Operations,” and Table 11-2.2, “Estimated As-Disposed Annual Waste Stream Summary During Phased Startup Operations.”

This appendix to the SER documents the results of the NRC staff’s technical and safety review of the SHINE Supplement and its proposed phased approach to startup.

1.1.1 Areas of Review

For its technical and safety review of SHINE’s proposed phased approach to startup, the NRC staff reviewed the information in the SHINE Supplement against applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, as discussed below. The staff evaluated the effect of the phased approach to startup on the sufficiency of the SHINE facility description and the design bases, the limits on facility operation, and the safety analysis of the structures, systems, and components (SSCs) and of the facility as a whole presented in the SHINE FSAR. The staff also reviewed the kinds and quantities of radioactive materials expected to be produced in the operation of the SHINE facility and the means for controlling and limiting radioactive effluents and radiation exposures within the limits in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, “Standards for Protection Against Radiation” during the phased approach to startup. Additionally, the staff reviewed the effect of

the phased approach to startup on the final analysis and evaluation of the design and performance of SSCs with the objective of assessing the risk to public health and safety resulting from such startup of the facility.

1.1.2 Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed the SHINE Supplement against the applicable regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the proposed phased approach to startup for the issuance of an operating license.

The applicable regulatory requirements for the evaluation of the SHINE Supplement are as follows:

- 10 CFR 50.2, “Definitions.”
- 10 CFR 50.22, “Class 103 licenses; for commercial and industrial facilities.”
- 10 CFR 50.33, “Contents of applications; general information,” paragraph (f).
- 10 CFR 50.34, “Contents of applications; technical information,” paragraph (b), “Final safety analysis report.”
- 10 CFR 50.36, “Technical specifications.”
- 10 CFR 50.40, “Common standards.”
- 10 CFR 50.50, “Issuance of licenses and construction permits.”
- 10 CFR 50.54, “Conditions of licenses.”
- 10 CFR 50.57, “Issuance of operating license.”
- 10 CFR Part 50, Appendix E, “Emergency Planning and Preparedness for Production and Utilization Facilities.”
- 10 CFR Part 20, “Standards for Protection Against Radiation”

In determining the regulatory guidance and acceptance criteria to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content,” issued February 1996.
- 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.

- “Final Interim Staff Guidance 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.
- “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.
- NUREG-0711, “Human Factors Engineering Program Review Model,” Revision 3, issued November 2012
- NUREG/CR-7126, “Human-Performance Issues Related to the Design and Operation of Small Modular Reactors,” issued June 2012
- NUREG/CR-7202, “NRC Reviewer Aid for Evaluating the Human-Performance Aspects Related to the Design and Operation of Small Modular Reactors,” issued June 2015

As stated in the interim staff guidance (ISG) augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogenous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its Supplement. The staff’s use of reactor-based guidance in its evaluation of the SHINE Supplement is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers (IEEE) standards, American National Standards Institute/American Nuclear Society (ANSI/ANS) standards, etc.) in the review of the SHINE Supplement. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE Supplement. Additional guidance documents used to evaluate the SHINE Supplement are provided as references in Appendix B, “References,” of this SER.

1.2 Summary and Conclusions on Principal Safety Considerations

The NRC staff evaluated the sufficiency of the summary and conclusions on principal safety considerations of the SHINE facility, as presented in SHINE Supplement Section 1.2, “Summary and Conclusions of Principal Safety Considerations,” using the guidance and acceptance criteria from Section 1.2, “Summary and Conclusions on Principal Safety Considerations,” of NUREG-1537, Parts 1 and 2, and Section 1.2, “Summary and Conclusions on Principal Safety Considerations,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE Supplement Section 1.2 states, in part, that the listing of locations in which radioactive materials are primarily present provided in the SHINE FSAR is not affected by the phased approach to startup, with the exception that the MATB, which is not operational until Phase 3 and, therefore, which does not contain radioactive material during Phases 1 and 2. The NRC staff evaluates the impact of the unavailability of the MATB during Phases 1 and 2 in Section

9b, "Radioisotope Production Facility Auxiliary Systems," and Section 11, "Radiation Protection Program and Waste Management," of this appendix to the SER.

SHINE Supplement Section 1.2 states, in part, that the SHINE Safety Analysis (SSA) methodology described in Chapter 13 of the SHINE FSAR was used to evaluate whether any new or different hazards are introduced by the phased approach to startup. The NRC staff evaluates the revised SSA as a result of the phased approach to startup in Section 13, "Accident Analyses," of this appendix to the SER.

1.3 General Description

The NRC staff evaluated the sufficiency of the general description of the SHINE facility, as presented in SHINE Supplement Section 1.3, "General Description of the Facility," using the guidance and acceptance criteria from Section 1.3, "General Description," of NUREG-1537, Parts 1 and 2, and Section 1.3, "General Description of the Facility," of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE Supplement Section 1.3 states, in part, that the information provided in SHINE FSAR Section 1.3 is not affected by the phased approach to startup, with the exception of the specific number of operational IUs during each phase. SHINE Supplement Section 1.3 describes general system isolations and further describes the impact to the IUs, instrumentation and control (I&C) systems, and radiological ventilation from the phased approach to startup. The NRC staff evaluates the general system information in SHINE Supplement Section 1.3 in Sections 4, "Irradiation Unit and Radioisotope Production Facility Description," 5, "Cooling Systems," 6, "Engineered Safety Features," 7, "Instrumentation and Control Systems," and 9, "Auxiliary Systems," of this appendix to the SER.

1.4 Shared Facilities and Equipment

The NRC staff evaluated the sufficiency of the SHINE shared facilities and equipment, as presented in SHINE Supplement Section 1.4, "Shared Facilities and Equipment," using the guidance and acceptance criteria from Section 1.4, "Shared Facilities and Equipment," of NUREG-1537, Parts 1 and 2, and Section 1.4 of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE Supplement Section 1.4 states that the information provided in the SHINE FSAR is not affected by the phased approach to startup.

The NRC staff determined that the information provided in SHINE FSAR Section 1.4 is not affected by the phased approach to startup. Therefore, the staff technical evaluation provided in SER Section 1.4, "Shared Facilities and Equipment," is applicable to the phased approach to startup without further supplementation.

1.5 Comparison with Similar Facilities

The NRC staff evaluated the sufficiency of the comparison of the SHINE facility with similar facilities, as presented in SHINE Supplement Section 1.5, "Comparison with Similar Facilities,"

using the guidance and acceptance criteria from Section 1.5, “Comparison with Similar Facilities,” of NUREG-1537, Parts 1 and 2, and Section 1.5, “Comparison with Similar Facilities,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE Supplement Section 1.5 states that the information provided in the SHINE FSAR is not affected by the phased approach to startup.

The NRC staff determined that the information provided in SHINE FSAR Section 1.5 is not affected by the phased approach to startup. Therefore, the staff technical evaluation provided in SER Section 1.5, “Comparison with Similar Facilities,” is applicable to the phased approach to startup without further supplementation.

1.6 Summary of Operations

The NRC staff evaluated the sufficiency of the SHINE summary of operations, as presented in SHINE Supplement Section 1.6, “Summary of Operations,” using the guidance and acceptance criteria from Section 1.6, “Summary of Operations,” of NUREG-1537, Parts 1 and 2, and Section 1.6 of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE Supplement Section 1.6 states that the information provided in the SHINE FSAR is not affected by the phased approach to startup.

The NRC staff determined that the information provided in SHINE FSAR Section 1.6 is not affected by the phased approach to startup. Therefore, the staff technical evaluation provided in SER Section 1.6, “Summary of Operations,” is applicable to the phased approach to startup without further supplementation.

1.7 Compliance with the Nuclear Waste Policy Act of 1982

The NRC staff evaluated the sufficiency of SHINE’s compliance with the Nuclear Waste Policy Act of 1982, as presented in SHINE Supplement Section 1.7, “Compliance with the Nuclear Waste Policy Act of 1982,” using the guidance and acceptance criteria from Section 1.7, “Compliance with the Nuclear Waste Policy Act of 1982,” of NUREG-1537, Parts 1 and 2, and Section 1.7 of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE Supplement Section 1.7 states that the information provided in the SHINE FSAR is not affected by the phased approach to startup.

The NRC staff determined that the information provided in SHINE FSAR Section 1.7 is not affected by the phased approach to startup. Therefore, the staff technical evaluation provided in SER Section 1.7, “Compliance with the Nuclear Waste Policy Act of 1982,” is applicable to the phased approach to startup without further supplementation.

1.8 Facility Modifications and History

The NRC staff evaluated the sufficiency of SHINE’s description of facility modifications and history, as presented in SHINE Supplement Section 1.8, “Facility Modifications and History,”

using the guidance and acceptance criteria from Section 1.8, "Facility Modifications and History," of NUREG-1537, Parts 1 and 2, and Section 1.8 of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE Supplement Section 1.8 states that the information provided in the SHINE FSAR is not affected by the phased approach to startup.

The NRC staff determined that the information provided in SHINE FSAR Section 1.8 is not affected by the phased approach to startup. Therefore, the staff technical evaluation provided in SER Section 1.8, "Facility Modifications and History," is applicable to the phased approach to startup without further supplementation.

1.9 License Condition for the Phased Approach to Startup

By letter dated February 26, 2021 (ADAMS Accession No. ML21057A340), as amended, SHINE informed the NRC staff of, among other things, its intent to pursue a phased approach to initial operations of the SHINE facility. This approach would consist of four phases of process equipment installation and operation. Phase 1 would include (1) the completion of the entire main production facility structure and the nitrogen purge system structure, (2) IUs 1 and 2, including the associated instances of the subcritical assembly system (SCAS), neutron flux detection system (NFDS), target solution vessel (TSV) off-gas system (TOGS), PCLS, LWPS, and RVZ1r; and, (3) the completion of the RPF with the exception of the IXP and RLWI selective removal, (4) the installation of tritium purification system (TPS) train A, and (5) all auxiliary and support systems, except as noted below for the instances of primary closed loop cooling system (PCLS), light water pool system (LWPS), and radiological ventilation zone 1 (RVZ1) equipment located in the cooling room;. At the completion of Phase 1, the SHINE facility would be capable of commencing production of molybdenum-99 (Mo-99) using IUs 1 and 2 and TPS train A. Phase 2 would include (1) the installation of IUs 3, 4, and 5 and all associated auxiliary and support systems and (2) the installation of TPS train B. At the completion of Phase 2, the SHINE facility would be capable of producing additional Mo-99 using IUs 3, 4, and 5 and TPS train B. Phase 3 would include (1) the installation of IUs 6, 7, and 8 and all associated auxiliary and support systems and (2) the installation of TPS train C. At the completion of Phase 3, the SHINE facility would be capable of producing additional Mo-99 using IUs 6, 7, and 8 and TPS train C. Phase 3 would also include the installation of RLWI selective removal components and the MATB. Phase 4 would include the installation of iodine and xenon purification and packaging components.

By letter dated January 27, 2022 (ADAMS Package Accession No. ML22027A353), SHINE supplemented its operating license application to describe the impacts of its proposed phased approach to startup of the SHINE facility. SHINE explained that the phasing was developed to minimize the complexities of maintaining process isolation and confinement requirements and to limit the number of physical locations where remaining equipment installation would occur during operation to minimize impacts on the operating portions of the facility. SHINE also explained that each grouping of IUs and their associated auxiliary and support systems and TPS train (i.e., IUs 1 and 2 and TPS train A; IUs 3, 4, and 5 and TPS train B; and IUs 6, 7, and 8 and TPS train C) is capable of operating independently. SHINE specified that isolations at interface points with uninstalled systems would generally consist of one or more valves and blind flanges or caps. To install systems for the subsequent phases, the blind flanges and caps would be removed, and the appropriate process connections would be made. The confinement boundaries for operating systems would not be impacted by installation activities. Similarly, the

I&C systems would be installed as part of Phase 1 such that sufficient isolation would exist between the portions of the systems for which construction and installation is complete and are operating and the portions that are still under construction/being installed. Portions of the systems that are not completely constructed/installed when other portions are ready to operate would subsequently be brought online when construction and installation is complete. In the supplement, SHINE FSAR Figure 1.1-1, "Physical Layout of Phased Approach to Operation," which shows the SHINE main production facility and the portions of it that would be installed at each phase.

On August 25, 2022 (ADAMS Accession No. ML22105A110), the NRC staff requested additional information on how SHINE intended to satisfy the NRC's regulations for licensing the SHINE facility under its proposed phased approach to startup. The staff explained that 10 CFR 50.57(a) states that the Commission may issue an operating license upon finding that, among other things, "[c]onstruction of the facility has been substantially completed, in conformity with the construction permit and the application as amended...." Additionally, 10 CFR 50.57(b) states that "[e]ach operating license will include appropriate provisions with respect to any uncompleted items of construction and such limitations or conditions as are required to assure that operation during the period of the completion of such items will not endanger public health and safety." Finally, NRC Inspection Procedure (IP) 69022, "Inspections of Operational Readiness during Construction of Non-Power Production and Utilization Facilities" (ADAMS Accession No. ML19193A110), provides that licensees are expected to notify the NRC in writing when construction of the facility is substantially complete and to provide to the NRC a complete list of remaining construction and preoperational test activities that must be addressed prior to operation. The IP further states:

At the time a licensee notifies the NRC that construction is substantially complete, the NRC expects that the safety-related [SSCs] required for initial startup; handling and storage of special nuclear material; shutdown of the facility; and prevention of accidents and the mitigation of consequences of accidents of the [facility] will have been installed at the site. The NRC also expects that the construction and pre-operational tests necessary to ensure the functionality of safety-related SSCs will have been performed and documented by the licensee in accordance with a formal plan. The licensee should have developed the operational test programs necessary to demonstrate that safety-related SSCs will remain functional during normal conditions and during and following design basis events.

Accordingly, the NRC staff asked SHINE how it interprets the term "facility" in 10 CFR 50.57(a) with respect to the SHINE facility, how it interprets the term "substantially completed" in 10 CFR 50.57(a) with respect to SHINE's proposed phased approach to startup, and how any SHINE operating license would include appropriate provisions with respect to any "uncompleted items of construction" pursuant to 10 CFR 50.57(b).

By letter dated September 20, 2022 (ADAMS Accession No. ML22263A344), SHINE responded that it considers the "facility" as used in 10 CFR 50.57(a) regarding the NRC's finding of substantial completion to be that described in the SHINE operating license application, as amended, to include the SSCs of the entire facility described in Chapter 1 of the SHINE FSAR and that SHINE's proposed phased approach to startup did not affect this definition of the facility. The NRC staff determined that this interpretation of "facility" in 10 CFR 50.57(a) is acceptable because it is consistent with the history of the licensing of the SHINE facility, which is summarized as follows. By letters dated March 26, 2013, May 31, 2013, and September 25, 2013 (ADAMS Accession Nos. ML13088A192, ML13172A361, and ML13269A378,

respectively), as supplemented, SHINE submitted to the NRC a construction permit application for the SHINE facility. The SHINE construction permit application proposed a single facility for the manufacture of medical radioisotopes that would include both an irradiation facility (IF) and an RPF. In turn, the IF would consist of eight IUs and the RPF would consist of hot cell structures and systems. The NRC staff assigned this application for the SHINE facility to a single docket number, Docket No. 50-608. The staff determined that, although they are not reactors, the IUs within the SHINE facility would achieve a fission rate with a thermal power level comparable to non-power reactors and would also have many safety considerations similar to those of non-power reactors. Therefore, in order to license the IUs using the NRC regulations applicable to non-power reactors, the staff amended the NRC's definition of "utilization facility" at 10 CFR 50.2 to include "[a]n accelerator-driven subcritical operating assembly used for the irradiation of materials containing special nuclear material and described in the application assigned docket number 50-608" (79 FR 62329; October 17, 2014). This rulemaking also identified the SHINE facility as a single building in which the IUs and the RPF would be housed. On February 29, 2016, the NRC issued a single construction permit under Docket No. 50-608 (Construction Permit No. CPMIF-001) authorizing the construction of the SHINE facility and its eight utilization facilities and one production facility, designed for the production of medical radioisotopes.

SHINE also stated that the construction of the SHINE facility, as defined above, would be substantially completed pursuant to 10 CFR 50.57(a) upon the installation and functional testing of the safety-related SSCs required for initial startup (i.e., Phase 1 operations), the safe handling and storage of special nuclear material, safe shutdown of operational IUs (as defined in technical specifications (TSs)), and the prevention of accidents or the mitigation of consequences of accidents involving installed equipment. SHINE stated that substantial completion of the SHINE facility represents the point in time in which the facility can safely produce medical isotopes (i.e., the facility is functionally complete, as defined in CPMIF-001). The NRC staff determined that this interpretation of "substantially completed" as being prior to the commencement of Phase 1 operations is acceptable because at that time, the SHINE facility would be functionally complete with respect to its purpose, stated in CPMIF-001 as "the production of medical radioisotopes, as described in the [construction permit] application...." Additionally, as indicated in Figure 1.1-1 of the SHINE FSAR, at this time a significant portion of the SHINE facility will be completed, with uncompleted items of construction at discrete locations within the facility.

Regarding uncompleted items of construction, SHINE provided a phase-specific listing of installation and functional testing activities required to support operation of Phase 2, Phase 3, and Phase 4. The NRC staff reviewed this listing and determined that the installation activities are consistent with the phase descriptions provided in the SHINE Supplement. Further, the staff determined that the functional testing activities to support construction completion are consistent with the TS surveillance requirements associated with the equipment to be installed for each phase. Additionally, as explained in Sections 4, 6, and 9 of this appendix to the SER, the staff determined that the completion of the uncompleted items of construction during the operation of the SHINE facility, as proposed in the SHINE operating license application and the SHINE FSAR, as amended, would not endanger public health and safety.

10 CFR 50.57(b) requires each operating license issued by the Commission to include appropriate provisions with respect to uncompleted items of construction and such limitations or conditions as are required to ensure that operation during the period of the completion of such items will not endanger public health and safety. Accordingly, in addition to the NRC staff's determination regarding the reasonableness of SHINE's description of the uncompleted items of

construction and the safety of completing the uncompleted items of construction during operation, the staff is imposing a license condition to ensure that the operation of the subsequent phases of the SHINE facility will not be commenced until the associated uncompleted items of construction have been completed and that appropriate NRC oversight of the completion of the uncompleted items of construction is maintained.

The license condition is as follows:

The Licensee shall conduct activities for startup of facility operations in Phases, as described in SHINE Technologies, LLC Application for an Operating License Supplement No. 31, Enclosure 3, Phased Startup Operations Application Supplement, dated September 29, 2022 (ADAMS Accession Nos. ML22271A963 and ML22271A966), as amended. Operation of Phase 2 or of any subsequent Phase shall not commence prior to satisfaction of conditions (a) and (b) below:

- (a) No later than 14 days before the planned commencement of operation of Phase 2, and thereafter no later than 14 days before the planned commencement of operation of each subsequent phase, the Licensee shall notify the NRC in writing that all uncompleted items of construction related to that Phase have been completed.
- (b) Prior to the operation of Phase 4, the Licensee shall provide to the NRC in writing, six months after the issuance of this operating license and every six months thereafter, information on the status and schedule for completion of uncompleted items of construction.

Based on the above, including the imposed license condition, the NRC staff concludes that SHINE's phased approach to startup satisfies 10 CFR 50.57 and is, therefore, acceptable.

2 SITE CHARACTERISTICS

Section 2, "Site Characteristics," of this appendix to the SER provides the NRC staff's evaluation of the impact of SHINE's proposed phased approach to startup on the site selection, as presented in SHINE Supplement Chapter 2, "Site Characteristics."

SHINE Supplement Chapter 2 states that the information provided in the SHINE FSAR is not affected by the phased approach to startup.

The NRC staff evaluated the sufficiency of SHINE's description of site characteristics using the guidance and acceptance criteria from Chapter 2, "Site Characteristics," of NUREG-1537, Parts 1 and 2, and Chapter 2, "Site Characteristics," of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff determined that the information provided in SHINE FSAR Chapter 2 is not affected by the phased approach to startup. Therefore, the staff technical evaluation provided in SER Chapter 2, "Site Characteristics," is applicable to the phased approach to startup without further supplementation.

3 DESIGN OF STRUCTURES, SYSTEMS, AND COMPONENTS

Section 3, "Design of Structures, Systems, and Components," of this appendix to the SER provides the NRC staff's evaluation of the impact of SHINE's proposed phased approach to startup on the design bases of the SSCs, as presented in SHINE Supplement Chapter 3, "Design of Structures, Systems, and Components."

SHINE Supplement Chapter 3 states that the information provided in the SHINE FSAR is not affected by the phased approach to startup.

The NRC staff evaluated the sufficiency of SHINE's description of the design bases of the SSCs using the guidance and acceptance criteria from Chapter 3, "Design of Structures, Systems, and Components," of NUREG-1537, Parts 1 and 2, and Chapter 3, "Design of Structures, Systems, and Components," of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff determined that the information provided in SHINE FSAR Chapter 3 is not affected by the phased approach to startup. Therefore, the staff technical evaluation provided in SER Chapter 3, "Design of Structures, Systems, and Components," is applicable to the phased approach to startup without further supplementation.

4 IRRADIATION UNIT AND RADIOISOTOPE PRODUCTION FACILITY DESCRIPTION

Section 4, "Irradiation Unit and Radioisotope Production Facility Description," of this appendix to the SER provides the NRC staff's evaluation of the impact of SHINE's proposed phased approach to startup on the final design of the SHINE IF and RPF, as presented in SHINE Supplement Chapter 4a2, "Irradiation Facility Description," and Chapter 4b, "Radioisotope Production Facility Description."

4a Irradiation Facility Description

Section 4a, "Irradiation Facility Description," of this appendix to the SER provides the NRC staff evaluation of the final design of the SHINE IF as affected by the proposed phased approach to startup, as presented in SHINE Supplement Chapter 4a2.

4a.1 Summary of the Supplement to the Application

SHINE Supplement Section 4a2.1, "Summary Description," identifies and describes the systems and equipment that support IF operation at the IU level. The SHINE Supplement further describes the methods of isolation during Phase 1 and Phase 2 operations. For Phase 3 operations, IUs 1–8 are fully operational with supporting systems and equipment as described in SHINE Supplement Section 1.1.

4a.2 Technical Evaluation

The NRC staff performed an evaluation of the technical information presented in SHINE Supplement Chapter 4a2 using the guidance and acceptance criteria from Section 4a2, "Aqueous Homogeneous Reactor Description," of the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE Supplement Section 4a2.1 states that each IU is designed and operated at the unit level. Each IU contains its own instances of the SCAS, NFDS, TSV, TOGS, neutron driver assembly system (NDAS), irradiation cell biological shield (ICBS), PCLS, LWPS, and RVZ1 equipment. Therefore, each IU can operate independently of the other IUs in the IF, and the descriptions of each IU and the associated nuclear and thermal-hydraulic design are not affected by the phased approach to startup.

SHINE Supplement Section 4a2.5, "Irradiation Facility Biological Shield," states that the ICBS, other than shield plugs, is installed and that IU-specific instances of the shield plugs are installed prior to IU operation to support phased startup operations. The IU cells and the associated primary cooling rooms have biological shields that are designed to allow for maintenance activities to be performed while adjacent IUs are operating, and to meet the as low as is reasonably achievable (ALARA) radiation exposure goals and meet or exceed the requirements in 10 CFR Part 20. This will allow for the IU-specific installation of equipment for the next phase of operation during the preceding phase of operation.

SHINE FSAR Section 4a2.1 states that the interfaces to external systems for IUs 3–8 will be isolated during Phase 1 operation. For Phase 2, the interfaces to external systems for IUs 6–8 will be isolated. The isolation at the interfaces is attained by using one or more valves and blind

flanges or caps. The systems that are isolated are the vacuum transfer system (VTS), the process vessel vent system (PVVS), the radioisotope process facility cooling system (RPCS), the facility nitrogen handling system (FNHS), the nitrogen purge system (N2PS), and the RVZ1 exhaust lines. Trains B and C of the TPS, which interface with the NDAS in IUs 3–5 and 6–8, respectively, will be implemented in Phases 2 and 3, respectively.

SHINE FSAR Section 4a2.1 states that, for each IU, the VTS line to fill the TSV, the VTS line to the TSV dump tank, and the VTS line to the TOGS vacuum all have two isolation valves. The PVVS line that exits the IU cell has one locked closed isolation valve. The FNHS supply lines include one isolation valve. The facility chemical reagent system (FCRS) supply lines include one isolation valve. The N2PS purge lines include one isolation valve and a blind flange or cap. The RPCS interface lines are addressed in Chapter 5 of this appendix to the SER and the RVZ1 exhaust lines are addressed in Chapter 9 of this appendix to the SER.

SHINE Supplement Chapter 13a2, "Irradiation Facility Accident Analysis," identifies, for the IF, three new accident sequences and the increased likelihood of three existing scenarios related to the proposed phased approach to startup. The new accident scenarios are: (1) improper target solution routing to an uninstalled IU cell; (2) damage to a PVVS to TOGS interface line during installation of the SCAS in an IU; and (3) damage to an installed TPS train during the installation of another TPS train. The existing accident sequences with increased likelihood are: (1) a heavy load drop on an in-service IU or TOGS cell; (2) a heavy load drop on the TPS; and (3) a fire in the IF general area. These are discussed in Chapter 13 of this appendix to the SER.

Based on its review, the NRC staff finds that each IU is capable of operating independently of the other IUs and that uncompleted items of construction in the IF can be completed without impacting the operating IUs. The staff also finds that the biological shielding and isolation of systems that interface with the IUs is adequate to allow the completion of uncompleted items of construction during the operation of those IUs.

4a.3 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE's IF as affected by the proposed phased approach to startup, as described in SHINE Supplement Chapter 4a2, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

- (1) SHINE described the design of the IF and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.
- (2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected during the phased approach to startup.
- (3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's IF as affected by the phased approach to startup are sufficient and meet the applicable

regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

4b Radioisotope Production Facility

Section 4b, “Radioisotope Production Facility,” of this appendix to the SER provides the NRC staff evaluation of the final design of the SHINE RPF as affected by the proposed phased approach to startup, as presented in SHINE Supplement Chapter 4b.

4b.1 Summary of the Supplement to the Application

SHINE Supplement Section 4b.1, “Facility and Process Description,” states that the RPF and RPF process descriptions provided in SHINE FSAR Section 4b.1 are not affected by the proposed phased approach to startup, with the exception of the following:

- The IXP system described in SHINE FSAR Subsection 4b.1.3.3 is not available during Phase 1 through Phase 3.
- The RLWI selective removal process described in SHINE FSAR Subsection 4b.1.3.8.2 is not available during Phase 1 and Phase 2.
- Solidified waste drums are not transported to the MATB as described in SHINE FSAR Subsection 4b.1.3.8.2 during Phase 1 and Phase 2.

SHINE Supplement Section 4b.2, “Radioisotope Production Facility Biological Shield,” states that the production facility biological shield (PFBS) for the hot cells within the supercell, including the biological shield for 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. During Phase 1 through Phase 3, the supercell confinement boundary is isolated from the IXP hot cell, and the IXP hot cell drain to the radioactive drain system (RDS) is plugged.

SHINE Supplement Section 4b.2 further states that the solid waste drum storage bore holes description provided in the SHINE FSAR is not affected by the phased approach to startup.

SHINE Supplement Section 4b.3, “Radioisotope Extraction System,” states that the radioisotope extraction process descriptions provided in SHINE FSAR Section 4b.3 are not affected by the phased approach to startup, with the exception that the IXP system is not available to extract iodine and xenon and is isolated during Phase 1 through Phase 3. This isolation of the IXP system within the RPF is provided as follows:

- The process line from the molybdenum extraction and purification system (MEPS) is isolated with manual valves and a blind flange or cap.
- The process line to the target solution staging system (TSSS) is isolated with a manual valve and a blind flange or cap.
- The VTS line is isolated with a manual valve and a blind flange or cap.

- Each waste line to the radioactive liquid waste storage system (RLWS) is isolated with a manual valve and a blind flange or cap.
- Each FNHS supply line is isolated with a manual valve and a blind flange or cap.
- Each PVVS vent line is isolated with a manual valve and a blind flange or cap.
- Each FCRS supply line is isolated with a manual valve and a blind flange or cap.
- The zone 2 supply air to the IXP elute hold tank (also the N2PS supply) is isolated with a manual valve and a blind flange or cap.
- The RVZ1 cryotrap exhaust line is isolated with a manual valve and a blind flange or cap.
- The molybdenum isotope product packaging system (MIPS) does not receive product from the IXP system.
- The solid radioactive waste packaging system does not receive waste from the IXP system.

SHINE Supplement Section 4b.4 “Special Nuclear Material Processing and Storage,” states that the special nuclear material processing and storage description provided in SHINE FSAR Section 4b.4 is not affected by the phased approach to startup, with the exception that the IXP system is not available during Phase 1 through Phase 3. During Phase 1 through Phase 3, the IXP system does not extract iodine and xenon, and reagents are not added to target solution by the IXP system. In addition, the IXP system does not contain the special nuclear material (SNM) identified in SHINE FSAR Table 4b.4-2.

4b.2 Technical Evaluation

The NRC staff performed an evaluation of the technical information presented in SHINE Supplement Chapter 4b using the guidance and acceptance criteria from Section 4b, “Radioisotope Production Facility Description,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

The NRC staff evaluated the effects of the proposed phased approach to startup on the descriptions associated with the RPF from the standpoint of completeness and allowing safe operation and the completion of uncompleted items of construction during the four phases as described in SHINE Supplement Section 4b.1. Specifically, the staff evaluated the descriptions associated with the isolation of the supercell confinement boundary from the IXP hot cell during Phase 1 through Phase 3, the unavailability of the RLWI selective removal process during Phase 1 and Phase 2, and the lack of transport of solidified waste drums to the MATB during Phase 1 and Phase 2.

Since the IXP system described in SHINE FSAR Subsection 4b.1.3.3 is not available during Phase 1 through Phase 3, target solution is not directed to the IXP hot cell and the PVVS does not interface with the IXP. In addition, the RLWS system does not collect liquid wastes from the IXP system, and the MIPS does not receive product from the IXP system. The isolation of the IXP hot cell from the RPF will ensure that there are no pathways for radioactive material to enter

the IXP system.

Based on the above, the NRC staff finds that accessing the IXP system prior to Phase 4 for purposes such as to install and connect the systems in the IXP to the RPF, will not result in a radiation hazard to the workers from direct or inhalation exposures. Additionally, the staff finds that the description of the IXP system is sufficiently detailed to allow the staff to conduct its safety evaluation addressed in other sections of this appendix to the SER. Therefore, the staff concludes that the description in SHINE Supplement Section 4b.1 is in accordance with the ALARA requirement and limits of 10 CFR Part 20, and 10 CFR Part 50, and is consistent with the guidance in the ISG and thus is acceptable.

The NRC staff evaluated the effects of the phased approach to startup on the description of the biological shielding within the RPF from the standpoint of completeness and allowing safe operation and the completion of uncompleted items of construction during the four phases as described in SHINE Supplement Section 4b.2. Specifically, the staff evaluated the timing of the installation of the biological shield and the isolation of the supercell confinement boundary from the IXP hot cell during Phase 1 through Phase 3.

The PFBS hot cells (supercell), including the IXP hot cell, is installed prior to Phase 1. However, during Phase 1 through Phase 3, the IXP system is not installed within the IXP hot cell, and the IXP hot cell is isolated from the supercell confinement boundary. Since most shielding and hot cell construction activities will occur prior to operation (i.e., prior to Phase 1), the potential for radiation exposures to construction workers prior to Phase 4 will be minimized in accordance with the ALARA principle. During Phase 1 through Phase 3, the IXP hot cell does not provide a confinement function and the other hot cells are isolated from the IXP hot cell. The IXP hot cell transfer doors to the adjacent hot cell are locked closed and the IXP hot cell drain to RDS is plugged. The IXP hot cell is isolated from radiological ventilation systems. The purpose of these features is to ensure that there is no pathway for radioactive materials to be introduced into the IXP hot cell thereby minimizing the potential for unintentional radiation exposures emanating from the IXP system to workers and the public during Phase 1 through Phase 3 in accordance with the ALARA principle.

Based on the above, the NRC staff finds that the IXP hot cell is adequately isolated during Phase 1 through Phase 3, such that there is no pathway for radioactive materials to be introduced into it thereby protecting the workers from unintentional exposures and the public and environment from any releases of radioactivity. Additionally, the staff finds that the storage waste drum boreholes installed prior to Phase 1 are a stand-alone system and are not affected by the phased approach to startup. The staff also finds that the description provided in SHINE Supplement Section 4b.2 is sufficiently detailed to allow the staff to conduct its safety evaluation addressed in other sections of this appendix to the SER. Therefore, the staff concludes that the description in SHINE Supplement Section 4b.2 is in accordance with the ALARA requirement and limits of 10 CFR Part 20, and 10 CFR Part 50, and is consistent with the guidance in the ISG and thus is acceptable.

The NRC staff evaluated the effects of the phased approach to startup on the description of the radioisotope extraction process from the standpoint of completeness and allowing safe operation and the completion of uncompleted items of construction during the four phases as described in SHINE Supplement Section 4b.3. The only system within the radioisotope extraction system that would be affected by the phased approach to startup is the IXP system, in that it would be isolated during Phase 1 through Phase 3. As discussed above, the staff evaluated the isolation of the interfacing process and supporting system connections to the IXP

system during Phase 1 through Phase 3. Specifically, the staff evaluated the isolation methods using valves and blind flanges or caps and determined that there is no pathway for radioactive materials to be introduced into the IXP system during Phase 1 through Phase 3.

Based on the above, the NRC staff finds that unintentional exposure of workers and the public to radioactive material from the radioisotope extraction system will be prevented during the phased approach to startup. Additionally, the staff finds that the description provided in SHINE Supplement Section 4b.3 is sufficiently detailed to allow the staff to conduct its safety evaluation addressed in other sections of this appendix to the SER. Therefore, the staff concludes that the description in SHINE Supplement Section 4b.3 is in accordance with the ALARA requirement and limits of 10 CFR Part 20, and 10 CFR Part 50, and is consistent with the guidance in the ISG and thus is acceptable.

The NRC staff evaluated the description of the SNM processing and storage systems within the RPF from the standpoint of completeness and allowing safe operation and the completion of uncompleted items of construction during the four phases as described in SHINE Supplement Section 4b.4.

The IXP system does not extract iodine and xenon and reagents are not added to target solution by the IXP system during Phase 1 through Phase 3. The IXP system does not contain the SNM identified in SHINE FSAR Table 4b.4-2 during Phase 1 through Phase 3. TSSS interfaces with the IXP system are isolated as identified in SHINE Supplement Section 4b.3.

Based on the above, the NRC staff finds that unintentional exposure of workers and the public to radioactive material as a result of SNM processing and storage will be prevented during the phased approach to startup. Additionally, the staff finds that the description provided in SHINE Supplement Section 4b.4 is sufficiently detailed to allow the staff to conduct its safety evaluation addressed in other sections of this appendix to the SER. Therefore, the staff concludes that the description in SHINE Supplement Section 4b.4 is in accordance with the ALARA requirement and limits of 10 CFR Part 20, and 10 CFR Part 50, and is consistent with the guidance in the ISG and thus is acceptable.

4b.3 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE's RPF as affected by the proposed phased approach to startup, as described in SHINE Supplement Chapter 4b, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

- (1) SHINE described the design of the RPF and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.
- (2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected during the phased approach to startup.
- (3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's RPF as affected by the phased approach to startup are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

5 COOLING SYSTEMS

Section 5, “Cooling Systems,” of this appendix to the SER provides the NRC staff’s evaluation of the impact of SHINE’s proposed phased approach to startup on the final design of the SHINE cooling systems, as presented in SHINE Supplement Chapter 5a2, “Irradiation Facility Cooling Systems,” and Chapter 5b, “Radioisotope Production Facility Cooling Systems.”

5a Irradiation Facility Cooling Systems

Section 5a, “Irradiation Facility Cooling Systems,” of this appendix to the SER provides the NRC staff’s evaluation of the final design of the SHINE IF cooling systems as affected by the phased approach to startup, as presented in SHINE Supplement Chapter 5a2.

5a.1 Summary of the Supplement to the Application

SHINE Supplement Section 5a2.2, “Primary Closed Loop Cooling System,” states that each IU is supported by an IU-specific instance of the PCLS during phased startup. Unit-specific instances of PCLS are operational for IUs 1 and 2 in Phase 1, IUs 1 through 5 in Phase 2, and IUs 1 through 8 in Phases 3 and 4. Interfaces between instances of PCLS that have not yet been installed and non-IU-specific supporting systems (i.e., RPCS, facility demineralized water system (FDWS), and RVZ1 exhaust subsystem (RVZ1e)) will be isolated during the phased approach to startup with a manual valve and a blind flange or cap.

SHINE Supplement Section 5a2.3, “Radioisotope Process Facility Cooling System,” states that the RPCS is installed to support Phase 1 operations. The RPCS is isolated from uninstalled IU-specific systems (PCLS, TOGS, NDAS cooling cabinets, and RVZ1r IU supplemental cooling) with a manual valve and a blind flange or cap.

SHINE Supplement Section 5a2.4, “Process Chilled Water System” states that the process chilled water system (PCHS) is installed to support Phase 1 operations. The PCHS is a closed chilled system that removes heat from the RPCS from within the radiologically controlled area (RCA) and rejects the heat to the environment. The PCHS is a nonsafety-related system and is not credited with preventing or mitigating any design basis events.

SHINE Supplement Section 5a2.5, “Primary Closed Loop Cooling System Cleanup Side Stream,” states that each IU is supported by an IU-specific instance of the PCLS (including an IU-specific instance of the PCLS cleanup side stream) installed to support phased startup. Phased startup of the PCLS is described in SHINE Supplement Section 5a2.2.

SHINE Supplement Section 5a2.6, “Facility Demineralized Water System,” states that the FDWS is installed to support Phase 1 operations and interface points with IU-specific systems (i.e., the PCLS and LWPS) are isolated to support phased startup (i.e., interfaces with IU-specific systems supporting IUs 3 through 8 are isolated during Phase 1 operation, and interfaces with IU-specific systems supporting IUs 6 through 8 are isolated during Phase 2 operation). The FDWS supply interfaces with the PCLS and LWPS are isolated with a manual valve and a blind flange or cap.

5a.2 Technical Evaluation

The NRC staff performed an evaluation of the technical information presented in SHINE Supplement Chapter 5a2 using the guidance and acceptance criteria from Section 5a2, "Aqueous Homogeneous Reactor Cooling Systems," of the ISG augmenting NUREG-1537, Parts 1 and 2.

Because the designs of the PCLS and LWPS are IU-specific, the NRC staff finds that the conclusions reached in SER Section 5a.4.2.7, "Primary Closed Loop Cooling System Conclusion," are not affected by the proposed phased approach to startup. Additionally, based on its review of SHINE Supplement Section 5a2.2, the staff finds that the PCLS and LWPS systems for IUs 3 through 8 will be appropriately isolated from non-IU-specific systems prior to their installation.

Due to the limited number of IUs in operation during Phase 1 and Phase 2, the heat removal capability of the PCHS will exceed the RPCS heat loads generated. Because the PCHS is installed prior to operation, the NRC staff finds that the PCHS can operate as an independent system and meet plant demands during the phased approach to startup.

The PCLS cleanup side stream maintains the required water quality limits of the PCLS. The PCLS cleanup side stream components are in the primary cooling room, directly adjacent to the IU cells. The location, shielding, and radiation monitoring of the water cleanup system are consistent with PCLS design. Because the design of the cleanup system is IU-specific and an integral part of the PCLS, the cleanup system can perform its function through all phases of startup. Therefore, the NRC staff finds that the conclusions reached in SER Section 5a.2.5 are not affected by the proposed phased approach to startup.

The FDWS is a non-safety system providing makeup of cooling water loss in the IU-specific instances of the PCLS and LWPS, which occurs gradually from radiolysis and evaporation. Water loss in the PCLS, RPCS, FCHS, MEPS hot water subsystem, and PCHS may also occur from off-normal events such as leaks or for maintenance. The FDWS is supplied water from the facility potable water system (FPWS), which is described in SHINE Supplement Section 9b.7.7, "Facility Potable Water System," and is not affected by the phased approach to startup. Therefore, the FDWS supply will be available during phased startup. Because the FDWS is installed to support Phase 1 and interface points with IU-specific systems are isolated, the FDWS can perform its function and the conclusions reached in SER Section 5a.2.6 are not affected by the proposed phased approach to startup.

SHINE FSAR Section 5a2.3.1, "Design Bases and Functional Requirements," states that the RPCS rejects heat to the PCHS. Makeup water is supplied by the FDWS. The RPCS removes heat from the:

- PCLS;
- NDAS cooling cabinets;
- TOGS;
- Recirculating heating, ventilation, and air conditioning (HVAC) fan-coil units that are part of RVZ1r;
- Recirculating HVAC fan-coil units that are part of the radiological ventilation zone 2 (RVZ2) recirculating cooling subsystem (RVZ2r);
- Target solution preparation system (TSPS);
- PVVS; and
- MEPS.

These system interfaces are also depicted in SHINE FSAR Figure 5a2.3-1. The SHINE Supplement indicates that non-IU specific systems that interface with the RPCS, including PCHS, FDWS, PVVS, and all RPF systems, excluding the IXP and RLWI (e.g., MEPS and TSPS), are available for operation in Phase 1.

The NRC staff reviewed SHINE Supplement Section 5a2.3 and finds that the RPCS will be appropriately isolated from IU-specific systems prior to their installation. Non-IU-specific systems that interface with the RPCS will be installed with the RPCS prior to Phase 1 and, therefore, no isolations are required.

The NRC staff concluded in SER Section 5a.4.3.2, "Radioisotope Process Facility Cooling System Conclusion," that the RPCS meets the acceptance criteria in Section 5a2.3, "Secondary Cooling System," of the ISG augmenting NUREG-1537, Part 2, with respect to that the SHINE facility is designed to ensure that the RPCS pressure is maintained higher than the PCLS pressure across the heat exchangers under all anticipated conditions to avoid potential leakage of contaminants to the RPCS, and that the secondary cooling system (i.e., the RPCS) is closed. In its letter dated May 23, 2022, SHINE confirmed that this pressure cascade will be maintained in each RPCS piping configuration employed during the phased approach to startup.

Based on the above, the NRC staff concludes that the conclusions reached in SER Section 5a.4.3.2 are not affected by the phased approach to startup.

5a.3 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE's IF cooling systems as affected by the proposed phased approach to startup, as described in SHINE Supplement Chapter 5a2, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

- (1) SHINE described the design of the IF cooling systems and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.
- (2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected during the phased approach to startup.
- (3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's IF cooling systems as affected by the phased approach to startup are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

5b Radioisotopes Production Facility Cooling Systems

SHINE Supplement Chapter 5b states that the cooling systems are integrated throughout the SHINE facility. Therefore, the summary of the supplement to the application, technical evaluation, and review findings provided in Section 5a of this appendix to the SER are applicable to both the IF and the RPF.

6 ENGINEERED SAFETY FEATURES

Section 6, “Engineered Safety Features,” of this appendix to the SER provides the NRC staff’s evaluation of the impact of SHINE’s proposed phased approach to startup on the final design of the SHINE engineered safety features (ESFs), as presented in SHINE Supplement Chapter 6a2, “Irradiation Facility Engineered Safety Features,” and Chapter 6b, “Radioisotope Production Facility Engineered Safety Features.”

6a Irradiation Facility Engineered Safety Features

Section 6a, “Irradiation Facility Engineered Safety Features,” of this appendix to the SER provides the NRC staff’s evaluation of the final design of the SHINE IF ESFs as affected by the proposed phased approach to startup, as presented in SHINE Chapter 6a2.

6a.1 Summary of the Supplement to the Application

SHINE Supplement Section 1.1 states that the proposed phasing was developed to minimize the complexities of maintaining process isolation and confinement requirements and to limit the number of physical locations where remaining equipment installation is occurring during different phases to minimize impacts on the operating portions of the facility. Each IU has a dedicated IU cell, TOGS cell, and primary cooling room. This design results in an installation area for the nonoperating IUs that is physically separate from the operating IUs. The IU cells and primary cooling rooms are designed to allow access for maintenance or other operational needs while adjacent IUs are operating.

The phased approach to startup is divided into four phases. Phase 1 brings the Mo-99 production capability online and Phases 2 and 3 increase this capability. During Phase 1, the equipment necessary to support the operation of IUs 1 and 2 are functional and available for operation. During Phase 2, the equipment necessary to support the operation of IUs 1 through 5 are functional and available for operation. During Phase 3, the equipment necessary to support the operation of all IUs (i.e., IUs 1 through 8) are functional and available for operation. Phase 4 adds iodine and xenon production capability. The SHINE Supplement describes the sequence in which the IUs will become operational during the phased approach to startup and the configuration of the IF ESFs during the different phases of startup. SHINE Supplement Section 6a2.1 states that the summary descriptions provided in SHINE FSAR Section 6a2.1 are not affected by the phased approach to startup.

6a.2 Technical Evaluation

The NRC staff performed an evaluation of the technical information presented in SHINE Supplement Chapter 6a2 using the guidance and acceptance criteria from Section 6a2, “Aqueous Homogeneous Reactor Engineered Safety Features,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

In its evaluation, the NRC staff reviewed the pertinent information associated with the proposed phased approach to startup as described in SHINE Supplement Chapter 6a2. The specific system-level isolations necessary for safe operation of the facility during the phased approach to startup are described in the applicable sections of this appendix to the SER that address those specific systems.

Primary Confinement Boundary

The SHINE Supplement states that the information provided in SHINE FSAR Subsection 6a2.2.1.1, including Figure 6a2.2-1, is described on a per IU basis and is, therefore, not affected by the phased approach to startup.

During Phase 1, the primary confinement boundaries for IUs 1 and 2 are operable. The passive confinement provided by physical barriers such as concrete and steel boundaries, and sealed access plugs will be in place for IUs 1 and 2 during Phase 1. The active isolations for the process and ventilation systems will also be in place for IUs 1 and 2 during Phase 1 to respond to any potential accidents/events analyzed in the SHINE FSAR. For the primary confinement boundaries that are not operable in Phase 1, system isolations will be in place to prevent a release of radiological or chemical hazards into the uninstalled IUs. During Phase 2, the primary confinement boundaries for IUs 1 through 5 are operable. A similar sequencing of passive and active isolations will be followed for IUs 1 through 5 during Phase 2, including system isolations to prevent a release of radiological or chemical hazards into the uninstalled IUs. The primary confinement boundaries for all 8 IUs will be operational during Phases 3 and 4. The isolation points are further described in SHINE Supplement Chapter 4a2 for isolation within the IU and in Chapter 4b for isolation points in systems located within the below grade confinement. The NRC staff review of Chapters 4a2 and 4b of the SHINE Supplement address these isolation features.

Based on its review, the NRC staff finds that each IU is capable of operating independently of the other IUs and that uncompleted items of construction in the IF can be completed without impacting the operating IUs. The staff also finds that the biological shielding and ESF isolations of systems that interface with the operating IUs including system isolations with the uninstalled IUs is adequate to allow the completion of uncompleted items of construction during the operation of those IUs.

Tritium Confinement Boundary

The information provided in SHINE FSAR Subsection 6a2.2.1.2 is described on a per tritium purification system (TPS) train basis and is not affected by the proposed phased approach to startup. For Phase 1 operations, only Train A of the TPS is installed, which fully and independently supports the operation of IUs 1 and 2. For Phase 2 operations, Trains A and B of the TPS are installed, with Train B fully and independently supporting the operation of the IUs installed as part of Phase 2 (i.e., IUs 3 through 5). For Phases 3 and 4 operations, the TPS trains and IUs are installed in full, with Train C fully and independently supporting the operation of the IUs installed as part of Phase 3 (i.e., IUs 6 through 8).

SHINE FSAR Figure 6a2.2-2 is not impacted by the phased approach to startup, with the exception of the number of TPS trains and IUs installed for each phase. SHINE Supplement Figure 6a2.2-1 provides an update to SHINE FSAR Figure 6a2.2-2 to reflect the number of TPS trains and IUs in operation during Phase 1 and Phase 2. The NRC staff finds that the updated Figure 6a2.2-1 is consistent with the description of the phased approach to startup of the TPS trains in the SHINE Supplement.

Combustible Gas Management

The SHINE Supplement states that the description of combustible gas management provided in SHINE FSAR Section 6a2.2.2 is not affected by the proposed phased approach to startup.

SHINE Supplement Figure 6a2.2-2 provides an update to SHINE FSAR Figure 6a2.2-3 to reflect the number of IUs in operation during Phase 1 and Phase 2. The NRC staff finds that the updated figure is consistent with the description of the phased approach to startup in the SHINE Supplement.

Conclusion

The ESFs and combustible gas management feature descriptions and the updated figures included in the SHINE Supplement provide sufficient detail and clarity to convey the interim configuration of the systems in each of Phases 1, 2, 3, and 4.

Based on its review, the NRC staff finds that each IU is capable of operating independently of the other IUs and that uncompleted items of construction in the IF can be completed without impacting the operating IUs during the phased approach to startup.

6a.3 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE's IF ESFs as affected by the proposed phased approach to startup, as described in SHINE Supplement Chapter 6a2, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

- (1) SHINE described the design of the IF ESFs and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.
- (2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected during the phased approach to startup.
- (3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's IF ESFs as affected by the phased approach to startup are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

6b Radioisotope Production Facility Engineered Safety Features

Section 6b, "Radioisotope Production Facility Engineered Safety Features," of this appendix to the SER provides the NRC staff evaluation of the final design of the SHINE RPF ESFs as affected by the proposed phased approach to startup, as presented in SHINE Supplement Chapter 6b.

6b.1 Summary of the Supplement to the Application

To support the installation of the IXP system as part of Phase 4, the IXP hot cell is not part of the supercell confinement in Phases 1, 2, and 3 operations. SSCs are installed to isolate any connections to the IXP system from other installed systems. Isolation is maintained between the IXP cell and the other hot cells using the bubble tight dampers shown in SHINE FSAR Figure 9a2.1-3. These dampers remain closed until the IXP cell is in operation to maintain the supercell confinement boundary. SHINE Supplement Figure 6b.2-1 provides a block diagram of the supercell confinement boundary in Phases 1, 2, and 3.

The subgrade equipment and confinement, as described in SHINE FSAR Chapter 6b, is installed as part of Phase 1. Isolation capability is provided to segregate the installed subgrade equipment from equipment that is installed as part of subsequent phases. These isolation SSCs remain operational during and following any design-basis accident (DBA), including seismic events and loss of offsite power.

6b.2 Technical Evaluation

The NRC staff performed an evaluation of the technical information presented in SHINE Supplement Chapter 6b using the guidance and acceptance criteria from Section 6b, “Radioisotope Production Facility Engineered Safety Features and Items Relied on for Safety,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

In its evaluation, the NRC staff reviewed the pertinent information associated with the proposed phased approach to startup as described in SHINE Supplement Chapter 6b. The specific system-level isolations necessary for safe operation of the facility during the phased approach to startup are described in the applicable sections of this appendix to the SER that address those specific systems.

SHINE Supplement Sections 6b.1 and 6b.2 provide a description of the RPF ESFs during the phased approach to startup. The subgrade equipment and confinement, as described in SHINE FSAR Chapter 6b, are installed as part of Phase 1. Isolation capability is provided to segregate the installed subgrade equipment from equipment that is installed as part of subsequent phases. These isolation SSCs remain operational during and following any DBA, including seismic events and loss of offsite power. The PVVS isolation and combustible gas management engineered safety features are not affected by the phased approach to startup. The RPF DBAs, the ESFs required to mitigate the DBAs, and the location of the bases for these determinations provided in SHINE FSAR Table 6b.1-1 are not affected by the phased approach to startup.

Confinement

The information provided in SHINE FSAR Subsection 6b.2.1 is not affected by the phased approach to startup. The engineered safety features described in SHINE FSAR Figure 6b.1-1 are not affected by the phased approach to startup.

Supercell Confinement

The IXP system equipment is not installed as part of Phase 1, 2, or 3. However, the IXP cell, including the confinement box and bubble tight isolation dampers, are installed. To allow for the installation of the IXP equipment within the IXP hot cell during Phases 1, 2, and 3, the IXP hot cell is isolated from the other nine cells of the supercell and is, therefore, not considered part of the supercell confinement. Isolation of interfacing process and supporting systems to IXP equipment during Phases 1, 2, and 3 is addressed in Section 4b of this appendix to the SER.

Isolation of ventilation to the IXP hot cell during Phases 1, 2, and 3 is described in Section 9a of this appendix to the SER. A complete listing of the IXP hot cell isolations is provided in SER Section 4b, "Radioisotope Production Facility." SHINE Supplement Figure 6b.2-1 provides a block diagram of the supercell confinement boundary applicable to Phases 1, 2, and 3.

Below Grade Confinement

As part of Phase 1, the below grade confinement is installed in full, as described in SHINE FSAR Subsection 6b.2.1.2, to support initial (i.e., Phase 1) operations of the SHINE facility. The below grade confinement functional block diagram, as described in SHINE FSAR Figure 6b.2-2, is not affected by the phased approach to startup.

Process Vessel Vent Isolation

As part of Phase 1, the process vessel vent isolation SSCs are installed in full, as described in SHINE FSAR Subsection 6b.2.2, to support initial (i.e., Phase 1) operations of the SHINE facility. The process vessel ventilation isolations are described in the applicable sections of this SER.

Combustible Gas Management

As part of Phase 1, the combustible gas management system is installed in full, as described in SHINE FSAR Subsection 6b.2.3, to support initial (i.e., Phase 1) operations of the SHINE facility. The RPF combustible gas management functional block diagram, as described in SHINE FSAR Figure 6b.2-3, is not affected by the phased approach to startup.

Conclusion

The NRC staff finds that the description in SHINE Supplement Chapter 6b is adequate and acceptable. Based on the above, the staff concludes that the conclusions reached in SER Section 6b are not affected by the proposed phased approach to startup. In addition, based on the above, the staff has reasonable assurance that the RPF can operate safely during all four phases and remain unimpacted by the completion of uncompleted items of construction during the four phases.

6b.3 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE's RPF ESFs as affected by the proposed phased approach to startup, as described in SHINE Supplement Chapter 6b, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

- (1) SHINE described the design of the RPF ESFs and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.
- (2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected during the phased approach to startup.

- (3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's RPF ESFs as affected by the phased approach to startup are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

7 INSTRUMENTATION AND CONTROL SYSTEMS

Section 7, “Instrumentation and Control Systems,” of this appendix to the SER provides the NRC staff’s evaluation of the impact of SHINE’s proposed phased approach to startup on the final design of the SHINE I&C systems, as presented in SHINE Supplement Chapter 7, “Instrumentation and Control Systems.”

7.1 Summary of the Supplement to the Application

In support of the phased startup operations, the SHINE Supplement Chapter 7 states that the I&C systems required for the safe operation of the process equipment in each phase are fully tested and operable. Sufficient isolation exists between operable and non-operable portions of the systems to ensure non-operable portions do not impact the safe operation of the active systems. During installation and startup of the I&C systems for subsequent phases, adequate separations and isolation is maintained such that the operable portions of the safety systems are not adversely impacted. The following I&C system/components are installed and tested in the facility control room (FCR) prior to Phase 1 operations:

- Operator workstations, NDAS workstations, supervisor workstation, and the main control board as described in Section 7.6 of the SHINE FSAR
- Cables, conduit, and raceways for the PICS monitoring and control functions are fully installed
- Normal and uninterruptible electrical power supply systems (NPSS and UPSS A & B)
- Nine TRPS cabinets (3 each for Divisions A, B, and C)
- Three ESFAS cabinets (1 each for Divisions A, B, and C)

Except for the digital I&C hardware associated with TPS trains B and C, all the PICS I&C hardware (i.e., cabinets, power supplies, controllers, programmable logic controllers [PLCs]) is installed prior to Phase 1 operations. PICS monitoring includes inputs to PICS from field instruments. PICS monitoring and controls associated with equipment that is not yet installed or not yet operable to support Phase 1 operations are tested and placed in operation as required for subsequent phases. PICS controls include outputs to field equipment to perform process control functions. All the PICS related cabling, conduit, and raceways for monitoring and control functions will be installed prior to Phase 1 operations.

Prior to Phase 1 operation, the following vendor-provided control systems are made operable:

- Building automation system
- Supercell control system
- RLWI control system
- NDAS control system; NDAS units required for a given phased operation are connected to the NDAS control system and made operational to support operation of a given phase
- Integral controllers associated with:
 - Standby generator system (SGS)
 - Facility demineralized water system (FDWS) reverse osmosis (RO) unit
 - Facility nitrogen handling system (FNHS) unit
 - Facility heating water system (FHWS) boilers
 - Facility chilled water system (FCHS)
 - Processed chilled water system (PCHS) chillers

The IXP system's monitoring and alarms, control functions, and interlocks and permissives are made available when the system is made operational to support Phase 4 operations.

PICS equipment associated with the N2PS, radiological ventilation (RV) systems, radioisotope process facility cooling water system (RPCS), FNHS, and facility chemical reagent system (FCRS) will be connected and tested as equipment is made operational to support operation of a given phase.

PICS software development and testing will be completed during each phase of startup operations. During phased startup operations, each input to PICS will be validated from the field to the cabinet as the field devices are installed and cabinet side leads terminated. Site acceptance testing is completed for the full set of equipment applicable to each phase prior to releasing the phase to operations for commissioning.

All nine TRPS cabinets installed in the FCR prior to Phase 1 operations are brought into operation as following:

For Phase 1 operations, Divisions A, B, and C TRPS cabinets associated with IUs 1 and 2 are made operational. PICS hardware, monitoring, and controls for TPS train A is installed and commissioned to serve IUs 1 and 2.

For Phase 2 operations, Divisions A, B, and C TRPS cabinets associated with IUs 3, 4, and 5, are made operational. PICS hardware, monitoring, and controls for TPS train B is installed and commissioned to serve IUs 3, 4, and 5.

For Phase 3 operations, Divisions A, B, and C TRPS cabinets associated with IUs 6, 7, and 8, are made operational. PICS hardware, monitoring, and controls for TPS train C is installed and commissioned to serve IUs 6, 7, and 8.

Manual TPS Isolation capability from both the facility master operating permissive and the manual push button are also phased such that only the installed TPS trains are isolated.

For each IU, associated NFDS, and the RVZ1e IU cell radiation monitors are brought online in the corresponding phases.

PICS monitoring and alarms, control functions, and interlocks and permissives associated with each IU will function as described in Section 7.3.1.1 of the SHINE FSAR as the associated equipment is made operable to support an individual IU in a given phase.

All the ESFAS cabinets in the FCR are installed prior to Phase 1 operation. Affected SFMs of the HIPS platform that implements ESFAS are modified to accommodate phased operation. This HIPS SFM modification allows disabling of an individual input that is not required for a given phase of facility operation. The disabling of individual inputs is required in Phases 1, 2, and 3 related to ESFAS equipment that is not yet operable. Individual inputs for each safety actuation not required to be operable in a given phase are disabled across all divisions. Information for inputs that are disabled is transmitted to the PICS and displayed to the operator as described in Section 7.6.3 of the SHINE FSAR. The disabled inputs are restored to operable status prior to entering the TS mode of applicability for the given input.

The safety functions associated with Supercell Area 10 (IXP Area) Isolation, VTS Safety Actuation, TPS Train B Isolation, TPS Train C Isolation, TPS Process Vent Actuation, IU Cell Nitrogen Purge, RCA Isolation, and IXP Alignment Actuation, as described in Subsection 7.5.3.1 of the SHINE FSAR, have inputs disabled and safety functions not utilized during the phased startup operations, as described in Tables 7.5-1 and 7.5-2 of the SHINE operating license application supplement.

The functionality of disabling inputs is tested as part of the Pre-Factory Acceptance Test (FAT) and FAT as described in Section 7.4.5.4.7, "Independent Testing" of the FSAR. All the inputs for ESFAS and TRPS are tested as a part of the Site Acceptance Test (SAT) prior to Phase 1 operation. Upon successful completion of the SAT, TRPS cabinets associated with Phases 2, 3, and 4 are removed from operation, and the ESFAS inputs associated with Phases 2, 3, and 4 are disabled. Prior to enabling the inputs to ESFAS for a given phase of operations, the MWS is used to configure the inputs such that it does not affect equipment in operation. These ESFAS inputs are then enabled, verified, and the setpoint adjusted to the design value prior to being declared for applicable phased operations.

The manual push buttons identified in Section 7.5.3.6 of the SHINE FSAR will only actuate safety functions utilized in a given phase of operation.

During Phase 1, the following local PICS control stations are functional and available for operation:

- Target solution preparation
- Radioactive liquid waste immobilization
- Supercell A
- Supercell B
- Supercell C
- TPS Train A

During Phase 2, in addition to the above local PICS control stations, the TPS Train B control station is functional and available for operation.

During Phase 3, the eighth and final local PICS control station, the TPS Train C control station, is functional and available for operation.

During the phased operations, indication is provided to the operator for components that have been disabled and for components that have not been field terminated.

Safety-related process radiation monitors required for Phase 1 are installed prior to Phase 1 operation. Safety-related process radiation monitors not required for Phase 1 operations are installed to support the phased operation of the IUs, TPS trains, and IXP system. The safety-related process radiation monitors are installed to the extent practicable given the extent of equipment installation. Radiation monitors required for the safe operation of the process equipment in each phase are fully tested and operable. Radiation monitors associated with individual IUs and TPS trains are installed during the phase associated with that IU or TPS train. Table 7.7-1 of the SHINE operating license application supplement provides a list of the safety-related process radiation monitors and the phase in which they will be installed to support operation.

All nonsafety-related process radiation monitoring and nonsafety-related radiation monitoring

systems are installed prior to Phase 1 operations.

7.2 Technical Evaluation

The staff performed an evaluation of the technical information presented in SHINE Supplement Chapter 7 using the guidance and acceptance criteria from Chapter 7, "Instrumentation and Control Systems," of the ISG augmenting NUREG-1537, Parts 1 and 2.

Based on the information provided in the SHINE Supplement Chapter 7, the staff finds that:

- The TRPS for each of the IU cell that is placed in operations in a given phase is capable of independently performing all the safety functions identified in Section 7.4.3.1 of the SHINE FSAR. Since all 3 divisions of the TRPS are being made operable for the applicable IU cell, the operable TRPS will continue to meet all relevant SHINE design criteria.
- In each phase, the ESFAS is capable of performing all safety functions identified in Section 7.5.3.1 of the SHINE FSAR for the systems that are operable in a given phase of operation. Monitored variable inputs to the ESFAS that are being disabled in phases 1, 2, and 3 do not adversely impact the performance of any safety function required for operable systems. Since all 3 divisions of the ESFAS are being made operable, ESFAS will continue to meet all relevant SHINE design criteria for the operable systems.
- For the IU Cells not in service during phases 1 and 2, nitrogen purge signals that are transmitted from the TRPS to the ESFAS for nitrogen purge actuation are not being disabled. Since these ESFAS input signals are not asserted by TRPS for IU cells not in operation, the nitrogen purge actuation capabilities for the IU cells in service is not impacted. Therefore, disabling/enabling of these ESFAS input signals is not necessary for phased operations.
- Status of the disabled ESFAS inputs is transmitted to the PICS and displayed to the operator consistent with human factors design criteria described in Section 7.6.2.2.7 of the SHINE FSAR.
- Except for the TPS Trains B and C local control station, all remaining PICS local control stations are functional to support Phase 1 operations. The TPS Train B local control station is made functional for Phase 2 to support IU cells 3, 4, and 5 operations. And the TPS Train B local control station is made functional for Phase 3 to support IU cells 6, 7, and 8 operations.
- The functionality of disabling inputs to ESFAS SFMs is tested as part of the pre-factory acceptance test (FAT) and FAT as described in Section 7.4.5.4.7 of the SHINE FSAR. All inputs for ESFAS and TRPS are tested as a part of the site acceptance test (SAT) as described in Section 7.4.5.4.2.6 of the SHINE FSAR prior to Phase 1 of operations. Upon successful completion of the SAT, TRPS cabinets associated with Phases 2, 3, and 4 are removed from operation, and the ESFAS inputs associated with Phases 2, 3, and 4 are disabled.
- Prior to enabling inputs to ESFAS for subsequent phases of operation, MWS is used to configure these inputs such that they do not affect equipment in operation. Each input is then enabled, verified, and the setpoint is adjusted to the design value prior to process equipment operation.
- All required safety-related process radiation monitors are made functional for each phase of operation and provide inputs to TRPS and ESFAS for IU cell safety actuation and isolation functions.

Based on the above technical evaluation, the staff finds that during phased operations the SHINE I&C systems described in Chapter 7 of the SHINE FSAR will continue to meet all applicable SHINE design criteria and are capable of performing the required safety functions during each phase of operation.

7.3 Human Factors Engineering

SHINE is required by 10 CFR 50.34(a)(3) to establish Principal Design Criteria (PDC) for its facility. In FSAR Table 3.1-3, "SHINE Design Criteria," SHINE establishes the following PDC that is within the scope of a human factors engineering review:

PDC 6 – Control Room

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

The staff evaluated whether the proposed design meets the HFE-related aspects of PDC #6 in section 7.4.9 of this SER. The staff also evaluated in SER section 7.4.9 whether the proposed design provides HFE support for administrative controls within the specific context of the operator role in safety at SHINE. In reviewing the SHINE phased startup operations application supplement, the staff determined that it was necessary to determine whether these evaluations remained adequate in light of phased startup operations.

In reviewing the SHINE phased startup operations application supplement, the staff noted that HFE-related review guidance to address a phased startup approach does not exist within the relevant NUREG-1537 or the associated Interim Staff Guidance (ISG). However, the staff noted that SHINE's described phased startup operations approach involving, in part, the sequential installation of additional IUs after earlier units have already begun operation is conceptually similar to installing additional small modular reactor units at an operating power reactor facility. Based upon this general similarity, the staff determined that was appropriate to draw upon a similar set of considerations to inform the review. The relevant considerations identified by the staff included the following:

- NUREG/CR-7126, Section 6, identifies potential human-performance issues to consider in regulatory reviews. One of the issues identified for consideration is the potential for ongoing construction activities to distract facility operators.
- NUREG/CR-7202 supplements the content of NUREG/CR-7126 by identifying specific questions for use by reviewers. This report discusses that, in the absence of additional guidance, NRC technical staff can use information about potential human-performance issues to support safety evaluations. For the human performance issue of "impact of adding new units while other units as operating," the NUREG-0711 elements impacted are noted to be Human-System Interface (HSI) Design and Procedure Development. It is suggested that issues within these two elements be considered using the following questions:
 - For the HSI Design element:
 - Will any changes to HSIs be needed during the time period when new units are added to the plant?

- How will a new unit's HSIs be added to an existing workstation that is being used to monitor and control current units?
- How will new workstations that support the operation of new units be introduced in a manner that does not distract or disrupt the monitoring and control of existing units?
- For the Procedure Development element:
 - How will the installation of new units impact procedures? Will special procedures be used during this time?

The staff applied engineering judgement to adapt these considerations in evaluating the HFE implications of SHINE's phased startup operations. The evaluation of each area detailed in the following sections.

7.3.1 Changes to Human-System Interfaces

The staff considered whether any changes to HSIs would be needed during SHINE phased startup operations, whether HSIs would be added to existing workstations that are already in use, and whether the HFE evaluation previously conducted by the staff under section 7.4.9 of this SER remains adequate.

SHINE states in Chapter 3 of the phased startup operations application supplement that the design of structures, systems, and components described in Chapter 3 of the FSAR is not affected by the phased startup operations and that the design criteria and systems and components descriptions provided in Sections 3.1 and 3.5 of the FSAR, respectively, are applied to phased startup operations. The staff noted that the design criteria of FSAR Section 3.1 include including PDC #6 for the control room.

SHINE states in Chapter 7 of the phased startup operations application supplement that the descriptions of the main control board, operator workstations, supervisor workstation, maintenance workstations, and other control room interface equipment provided in Subsections 7.6.1.1 through 7.6.1.5 of the FSAR, respectively, are not affected by phased startup operations. SHINE also states in Chapter 7 of the phased startup operations application supplement that, during phased startup operations, I&C systems required for the safe operation of the process equipment in each phase are fully tested and operable. The Process Integrated Control System (PICS) monitoring and controls associated with equipment that is not yet installed, or not yet operable, is described as being tested and placed in operation as required for a given phase. Each input to PICS is described as being validated as field devices are installed, with acceptance testing being completed for the equipment applicable to each phase prior to releasing the phase to operations. Additionally, the Neutron Driver Assembly System (NDAS) control system control stations are described as being installed and operational prior to Phase 1 operations, with NDAS units being connected to the NDAS control system as they are installed to support operation of a given phase.

SHINE states in section 7.4 of the phased startup operations application supplement that the Target Solution Vessel Reactivity Protection System (TRPS) description provided in Section 7.4.1 of the FSAR is not affected by phased startup operations and that each IU is supported by a unit specific instance of the TRPS. SHINE further states that the description of human factors provided in Subsection 7.4.3.7 of the FSAR is not affected by phased startup operations, with the exception of the implementation of the manual Tritium Purification System (TPS) Isolation push button. Manual TPS Isolation from both the facility master operating permissive and the

manual push button are only tied to instances of TRPS for the installed TPS trains during each phase of operation; the same actuation push button is provided to the operator to initiate the manual TPS isolation, and only equipment applicable to the particular phase is actuated when the button is depressed.

SHINE states in section 7.5 of the phased startup operations application supplement that the Engineered Safety Features Actuation System (ESFAS) description provided in Subsection 7.5.1 of the FSAR remains accurate during phased startup operations relative to the capabilities of the ESFAS. During phased startup operations, inputs to the ESFAS for equipment that is not required to be operable are disabled and are restored and verified to be operable prior to entering the TS mode of applicability associated with the given input. SHINE further states that the manual push buttons identified in Subsection 7.5.3.6 of the FSAR will only actuate safety functions utilized in a given phase of operation.

The staff also conducted an audit on August 25, 2022 to clarify and confirm the information described above. The observations from this audit are documented in an audit report (ADAMS Accession No. MLXXXXXXXXX). During the audit discussion, SHINE clarified how it will be ensured that operators maintain a current understanding of system configuration and expected response during successive stages of phased construction. 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.

The staff finds that the applicant has described the changes to HSIs that will be needed during SHINE phased startup operations. The changes do not involve the physical installation of new HSIs during successive phases; rather, existing HSIs that have already been installed will be modified during facility operations. The HSIs needed to support the equipment associated with a given phase will be placed in service and tested in conjunction with completing successive phases. This is supported by operator training to assist operators in maintaining an awareness of facility status. Based upon the described changes, the staff concludes that the modification of existing HSIs will be adequately managed and that the HFE evaluation of PDC #6 previously conducted by the staff in SER section 7.4.9 remains adequate.

7.3.2 Management of Distractions

The staff considered whether HSIs associated with new facility equipment will be introduced in a manner that does not distract or disrupt the monitoring and control of existing facility equipment and whether the related HFE evaluation previously conducted by the staff under section 7.4.9 remains adequate. SHINE states in Chapter 7 of the phased startup operations application supplement that control consoles and displays associated with equipment to be installed in later phases will have the capability to have their displays secured or their signals removed to avoid distracting the operators. SHINE also states that the description of the design basis provided in Subsection 7.6.3 of the FSAR is not affected by phased startup operations. The staff noted that this is inclusive of FSAR section 7.6.3.3 which addresses the application of human factors engineering principles. SHINE further states that indication will be provided to the operator for components that have been disabled and for components that have not been field terminated. The staff conducted an audit on August 25, 2022 to clarify and confirm the information described above. The observations from this audit are documented in an audit report (ADAMS Accession No. MLXXXXXXXXX). During the audit discussion, SHINE clarified how displays

associated with the equipment that has not yet been installed will be managed to avoid creating operator distractions. 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. SHINE also clarified how indications will be provided via PICS for components that are disabled or disconnected. 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.

The staff finds that the applicant has described how the HSIs associated with new facility equipment will be introduced in a manner that does not distract or disrupt the monitoring and control of existing facility equipment. Displays that are not needed during a given phase will remain off and, where displays that are turned on contain indications for components that are not yet fully installed, those indications will be annotated accordingly. This is also supported by the use of an operator aid to address indications that may display unreliable values based on the current state of installation and testing activities. Based upon the described changes, the staff concludes that operator distractions and disruptions will be adequately managed and that the HFE evaluation of PDC #6 previously conducted by the staff in SER section 7.4.9 remains adequate.

7.3.3 Procedure Changes

The staff considered whether the installation of new facility equipment will impact procedures used during SHINE phased startup operations and whether the related HFE evaluation previously conducted by the staff under section 7.4.9 remains adequate. SHINE states in Chapter 12 of the phased startup operations application supplement that the conduct of operations described in Chapter 12 of the FSAR is not affected by phased startup operations and that the organizational and programmatic descriptions provided in Chapter 12 of the FSAR will be implemented to support Phase 1 operations. The staff noted that FSAR Chapter 12 includes the SHINE procedure management program and, furthermore, that procedure change control is a component of this program.

In Chapters 13a2 and 13b of the SHINE Supplement, SHINE describes that new or different accident scenarios that were identified as part of phased startup operations resulted in several new specific administrative controls being credited. The staff noted that the HFE-related management measures used to support the reliability of SHINE's specific administrative controls continue to generally consist of training and procedures. Based upon this, the staff further considered whether the reliability of the new administrative controls would be adequately supported by these management measures.

The staff conducted an audit on August 25, 2022 to clarify and confirm the information described above. The observations from this audit are documented in an audit report (ADAMS Accession No. MLXXXXXXXXXX). During the audit discussion, SHINE clarified how it be ensured that crane operators are trained to implement crane-related administrative controls. SHINE indicated that crane operators will consist of either maintenance or operations personnel and that their qualification program will include coverage of Specific Administrative Controls (SACs).

In response to Request for Confirmatory of Information (RCI) HFE-1 (ADAMS Accession No. ML22263A027), SHINE confirmed 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.

The staff finds that the applicant has described how the installation of new facility equipment will impact procedures used during SHINE phased startup operations. The procedure management program includes measures to address procedure changes. Administrative controls that are credited are supported by HFE-related management measures in the areas of training and procedures, including those associated with crane operations. Based upon the described changes, the staff concludes that the evaluation of the applicant's procedure management program support for the implementation of administrative controls previously conducted by the staff in SER section 7.4.9 remains adequate.

7.3.4 Conclusions

The NRC staff finds that the applicant described the changes to HSIs that will be needed during the proposed phased approach to startup and demonstrated that the changes will not adversely impact the monitoring and control of existing facility equipment. Therefore, the staff concludes that the requirement of 10 CFR 50.34(b) for an operating license application to include a description and analysis of the SSCs of the facility and the evaluations required to show that safety functions will be accomplished is still met within the context of the HFE-related aspects of SHINE Design Criteria 6 under the phased approach to startup.

The NRC staff finds that the applicant demonstrated that impacts to facility procedures due to the completion of uncompleted items of construction during the phased approach to startup will be adequately addressed. Therefore, the staff concludes that the requirement of 10 CFR 50.57(a)(3) for reasonable assurance that activities authorized by the operating license will not endanger the health and safety of the public is still supported by the application of HFE measures within the context of administrative controls.

7.4 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE's I&C systems as affected by the proposed phased approach to startup, as described in SHINE Supplement Chapter 7, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

- (1) SHINE described the design of the I&C systems and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.
- (2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected during the phased approach to startup.
- (3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's I&C systems as affected by the phased approach to startup are sufficient and meet the

applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

8 ELECTRICAL POWER SYSTEMS

Section 8, “Electrical Power Systems,” of this appendix to the SER provides the NRC staff’s evaluation of the impact of SHINE’s proposed phased approach to startup on the final design of the SHINE electrical power systems, as presented in SHINE Supplement Chapter 8a2, “Irradiation Facility Electrical Power Systems,” and Chapter 8b, “Radioisotope Production Facility Electrical Power Systems.”

8a Irradiation Facility Electrical Power Systems

Section 8a, “Irradiation Facility Electrical Power Systems,” of this appendix to the SER provides the NRC staff’s evaluation of the final design of the SHINE IF electrical power systems as affected by the proposed phased approach to startup, as presented in SHINE Supplement Chapter 8a2.

8a.1 Summary of the Supplement to the Application

SHINE Supplement 8a2 provides SHINE’s phased approach to construction related to the Electrical Power System of the Irradiation Facility.

SHINE Supplement Section 8a2.1, “Normal Electrical Power Supply System,” describes the normal electrical power system. In Section 8a.2.1, SHINE provided the following summary:

The Electrical Power Systems are not affected by the phase startup operations and the NPSS will be installed in full to support the Phase 1 operations. Sufficient isolation exists between operable and not yet installed or not yet operable equipment to ensure that not yet installed or not yet operable equipment loads do not impact the NPSS. The NPSS will meet all codes and Standards described in Subsections 8a2.1.1, 8a2.1.3, 8a2.1.4, and 8a2.1.5 of the FSAR. All raceway and cable routing will be installed in full to support Phase 1 operations.

SHINE Supplement Section 8a2.2, “Emergency Electrical Power Systems,” provides SHINE’s phased approach for the emergency electrical power systems. In Section 8a2.2, SHINE provided the following summary:

The emergency electrical power systems are not affected by the phase approach construction. All the emergency electrical power systems will be installed during Phase 1 of the construction, including the uninterruptible electrical power supply system (UPSS), the nonsafety-related standby generator system (SGS), and nonsafety-related local power supplies and unit batteries. Sufficient isolation exists between operable and not yet installed or not yet operable equipment to ensure that not yet installed or not yet operable equipment loads do not impact the UPSS. Subsections 8a2.2.1, 8a2.2.2, 8a2.2.3, 8a2.2.7, and 8a2.2.8 of the FSAR are not impacted by isolating loads that are not yet installed or not yet operable. The UPSS continues to satisfy codes and standards as described in Subsections 8a2.2.2 and 8a2.2.3 of the FSAR.

8a.2 Technical Evaluation

The staff performed an evaluation of the technical information presented in SHINE Supplement Section 8a2 using the guidance and acceptance criteria from Section 8a2, "Aqueous Homogeneous Reactor Electrical Power Systems," of the ISG augmenting NUREG-1537, Parts 1 and 2.

The staff performed an evaluation of the technical information presented in SHINE Supplement Section 8a2 using the guidance and acceptance criteria from Section 8a2, "Aqueous Homogeneous Reactor Electrical Power Systems," of the ISG augmenting NUREG-1537, Parts 1 and 2.

The staff reviewed the proposed phase construction approach for the Irradiation Facility Electrical Power Systems. All the electrical systems, including the NPSS and the emergency electrical power systems will be installed during Phase 1 of the phase construction approach proposed by SHINE. Therefore, the Electrical Power Systems are not affected by the phase approach and the Electrical Power Systems will continue to meet all applicable portions of codes and standards described in Chapter 8 of the FSAR. SHINE used the guidance in Sections 6.1.2.1, 6.1.2.2, and 6.1.2.3 of IEEE Standard (Std.) 384-2008, "IEEE Standard Criteria for Independence of Class 1E Equipment and Circuits," for isolation of the electrical systems, as described in Subsection 8a2.1.1, "Design Basis," of the FSAR. SHINE's conformance with applicable portions of IEEE Std. 384-2008 provides reasonable assurance that equipment not yet operable or not installed during Phase 1 of the phase construction approach will be isolated from the NPSS and the emergency electrical power system. The staff has evaluated Chapter 8 of the FSAR and found that SHINE's electrical system is acceptable, as documented in the SER.

Based on the above, the NRC staff finds that the electrical power systems described in SHINE FSAR Chapter 8 are not affected by the phased approach to startup. Therefore, the staff technical evaluation provided in SER Chapter 8, "Electrical Power Systems," is applicable to the phased approach to startup without further supplementation.

8a.3 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE's electrical power systems as affected by the proposed phased approach to startup, as described in SHINE Supplement Chapter 8a2, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

- (1) SHINE described the design of the electrical power systems and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.
- (2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected during the phased approach to startup.
- (3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's electrical power systems as affected by the phased approach to startup are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

8b Radioisotopes Production Facility Electrical Power Systems

SHINE Supplement Chapter 8b states that the SHINE facility has one common normal electrical power system and one common emergency electrical power system. Therefore, the summary of the supplement to the application, technical evaluation, and review findings provided in Section 8a of this appendix to the SER are applicable to both the IF and the RPF.

9 AUXILIARY SYSTEMS

Section 9, "Auxiliary Systems," of this appendix to the SER provides the NRC staff's evaluation of the impact of SHINE's proposed phased approach to startup on the final design of the SHINE auxiliary systems, as presented in SHINE Supplement Chapter 9a2, "Irradiation Facility Auxiliary Systems," and Chapter 9b, "Radioisotope Production Facility Auxiliary Systems."

9a Irradiation Facility Auxiliary Systems

Section 9a, "Irradiation Facility Auxiliary Systems," of this appendix to the SER provides the NRC staff's evaluation of the final design of the SHINE IF auxiliary systems as affected by the proposed phased approach to startup, as presented in SHINE Supplement Chapter 9a2.

9a.1 Summary of the Supplement to the Application

SHINE supplement Section 1.1 states the phased approach has been developed to minimize the complexities of maintaining process isolation and confinement requirements and to limit the number of physical locations where remaining equipment installation is occurring during different phases to minimize impacts on the operating portions of the facility. Each IU has a dedicated IU cell, TOGS cell, and primary cooling room. This design results in an installation area of the nonoperating IUs that is physically separate from operating IU units. The IU cells and primary cooling rooms are designed to allow access for maintenance or other operational needs while adjacent units are operating, including irradiation cell biological shield (ICBS) design, sufficient to minimize dose rates consistent with as low as reasonably achievable (ALARA) principles at the facility.

The phased approach to startup is separated into four phases. The first three phases bring the eight IUs and Mo-99 production capability online. During Phase 1, the equipment necessary to support operation of IUs 1 and 2 are functional and available for operation. During Phase 2, the equipment necessary to support operation of IUs 1 through 5 are functional and available for operation. During Phases 3, the equipment necessary to support operation of all IUs (i.e., IUs 1 through 8) are functional and available for operation. Phase 4 adds iodine and xenon production capability. The SHINE supplement describes the sequence in which the IUs will become operational during phased startup, the configuration of the radiological and non-radiological ventilation systems during different phases of startup, including the design features employed to isolate the ventilation systems that are supporting the operation of the active IUs and the Mo-99 production facility from other areas of the facility that are undergoing phased construction and startup activities.

9a.2 Technical Evaluation

The staff performed an evaluation of the technical information presented in SHINE Supplement Section 9a2 using the guidance and acceptance criteria from Section 9a2, "Aqueous Homogeneous Reactor Auxiliary Systems," of the ISG augmenting NUREG-1537, Parts 1 and 2.

In its evaluation, the staff reviewed the pertinent information associated with the phased startup and the system isolations necessary for safe operation of the facility described in Section 9.2 of SHINE supplement during the various phases.

The radiological ventilation (RV) system descriptions provided in Subsection 9a2.1.1 of the FSAR are not affected by phased startup operations, except for the following:

- The ventilation system zone designations identified in Figure 9a2.1-1 of the FSAR are not applicable for certain areas of the facility because they do not contain operational equipment during phased startup operation. During the phased startup, IU specific instances of RVZ1r and RVZ1e for IUs 1 and 2 are operational. The irradiation cell biological shield (ICBS) cover plugs for cooling rooms, TOGS cell, and IU cell are also installed during phase 1 operations. Once the cover plugs are installed during phase 1, the IU cells, the TOGS cells and RVZ1r for IUs 1 and 2 becomes part of ventilation zone 1. A similar sequencing would follow for IUs 3, 4, and 5 during Phase 2, and IUs 6, 7, and 8 during Phase 3 to become part of ventilation zone 1.
- RV interfaces with tritium purification system (TPS) Train A is operational in Phase 1, with TPS Train B and TPS Train C isolated during Phase 1. TPS Train B becomes operational in Phase 2 and TPS Train C becomes operational in Phase 3. RV interfaces with TPS Train C are isolated during Phase 2, and RV interfaces with the IXP system are isolated during Phase 1 through Phase 3.
- The non-operating IUs during Phases 2 and 3 will be part of ventilation zone 2, becoming part of ventilation zone 1 after their installation work is complete and their ICBS cover plugs are installed.

SHINE Supplement further states that IU specific instances of RV systems are installed to support phased startup operation and RV system interface points are isolated as needed to support phase startup operation for each RV system.

Radiological Ventilation Zone 1

Since there are no common components or connections between the unit specific instances of RVZ1r or between RVZ1r and other RV systems, there is no need to isolate RVZ1r for the IU specific instances that are not yet operational during phased startup.

The RVZ1e system interfaces with IU specific instances of the primary closed loop cooling system (PCLS) within the IU cells (i.e., PCLS expansion tank exhaust). IU specific portions of RVZ1e within the cooling rooms and IU cells are installed to support phased startup operation in the same sequence as RVZ1r units. The RVZ1e system interface points for the IUs that are not yet operational are isolated outside of the cooling rooms and IU cells by a manual isolation valve and a blind flange or cap to support phased startup operation.

The RVZ1 interfaces with train specific instances of the TPS process exhaust are isolated to support phased startup operation. RVZ1 interface with TPS Train A is operational with TPS Train B and TPS Train C isolated during Phase 1 operation. The isolations of TPS Trains in Phases 1 and Phase 2 are achieved by a manual isolation valve and a blind flange or cap.

The RVZ1 system interfaces with the IXP hot cell exhaust. During Phase 1 through Phase 3, the RVZ1 system interface points with the IXP hot cell are isolated to support phased startup operation via two bubble-tight dampers. The RVZ1 system also interfaces with the IXP system processes cryotrap. During Phase 1 through Phase 3, the RVZ1 system interface point with the IXP system is isolated via a manual isolation valve and a blind flange or cap. During Phase 4, all RVZ1 interfaces with IXP system exhaust become operational.

Radiological Ventilation Zone 2

The RVZ2 system interfaces with train specific instances of TPS nitrogen exhaust isolated to support phased startup operation. RVZ2 interfaces with TPS Train A and Train B are open during Phase 2, with TPS Train C remaining isolated. TPS Train C will be operational during Phase 3 operation. All isolations during Phase 1 and Phase 2 are achieved via a manual isolation valve and a blind flange or cap.

The RVZ2 system interfaces with the IXP system to supply air for tanks ventilated by the PVVS. During Phase 1 through Phase 3, the RVZ2 system interface point with the IXP system is isolated to support phased startup operation via a manual isolation valve and a blind flange or cap.

The radiological ventilation zone 2 recirculation subsystem (RVZ2r) interfaces with the IXP hot cell to supply air. During Phase 1 through Phase 3, the RVZ2r interface points with the IXP hot cell are isolated to support phased startup operation via two bubble-tight dampers.

Radiological Ventilation Zone 3

The phased startup operations have no impact on RVZ3 description provided in Subsection 9a2.1.1 of the FSAR.

Conclusion

Based on the ventilation system phased startup descriptions in Section 9a2.1.1 of the SHINE supplement, the main ventilation units located in the mezzanine levels of ventilation zones 2 and 4 will be installed and operational during phase 1. They are the RVZ2 supply subsystem (RVZ2s) air handling units (AHUs) located in ventilation zone 4, and the Radiological Ventilation Zones 1 and 2 exhaust subsystems filter trains (RVZ1e and RVZ2e, respectively) located in ventilation zone 2. The AHUs and the filter trains will be installed during phase 1, complete with the system automatic isolation provisions (bubble tight dampers and tornado dampers) with the adjacent radiological and non-radiological ventilation zones, as designed for the facility operation, as these isolations are required regardless of the number of IUs in operation.

The ventilation systems are described in adequate detail to describe the interim configuration of the ventilation systems in each of Phases 1, 2, 3, and 4, including the isolations provided for equipment in the interim configuration during different phases of startup. The staff has determined that at the conclusion of Phase 4, the SHINE facility ventilation systems will be in full conformance with the SHINE FSAR.

The isolation features and the locations of the portions of the ventilation systems that would not be required in each of Phases 1, 2, 3, and 4 are described in sufficient detail.

The staff reviewed the radiological ventilation systems information in Chapter 7, "Instrumentation and Control Systems," Table 7.5-1 "Monitored Variable Inputs Disabled During Phases of Startup Operations," Table 7.5-2, "Safety Functions Not Utilized During Phases of Startup Operations," and Table 7.7-1, "Safety-Related Process Radiation Monitor Phasing" and conclude that they are consistent with the description of the radiological controlled area ventilation in Section 9a2.1.1 of the SHINE Supplement.

Based on the passive and active isolation features described in the SHINE supplement, the staff finds that the operation of SHINE facility ventilation systems during the different phases of startup is similar to the description provided in the SHINE FSAR, in terms of equipment required for responding to mitigation of potential accidents/events analyzed in the SHINE FSAR, Chapter 13.

Non-Radiological Ventilation and Support Systems

The non-radiological area ventilation system, the facility chilled water system (FCHS), the facility heating water system (FHWS), handling and storage of target solution, communication systems, and the neutron driver assembly system service cell are not affected by phased startup operations.

Tritium Purification System

SHINE Supplement Section 9a2.7.1, "Tritium Purification System," states that the TPS has three independent trains (Trains A, B, and C) that support operation of the NDAS in the IUs. TPS train A supports IUs 1 and 2. Train B supports IUs 3, 4, and 5. Train C supports IUs 6, 7, and 8. In phase 1, IUs 1 and 2 are operational and Train A of the TPS is operational. Phase 2 adds IUs 3, 4, and 5 and Train B of the TPS for a total of 5 operating IUs and 2 TPS trains. Phase 3 adds IUs 6, 7, and 8 and Train C of the TPS so all 8 IUs and all 3 trains of the TPS are operating. The IF and TPS will be running at its full capacity of 8 IUs and 3 TPS trains for phases 3 and 4.

SHINE Supplement Section 9a2.7.1 states that each TPS train is designed to operate independently from the other trains and contains its own instances of the isotope separation system using the Thermal Cycling Adsorption Process (TCAP), TPS-NDAS interface lines, secondary enclosure cleanup (SEC), vacuum/impurity treatment subsystem (Vac/ITS), NDAS SEC, and TPS glovebox. Each TPS train has its own tritium confinement boundary and is not impacted by installation and testing of the other trains. The interface points of uncompleted trains are isolated by manual valves, blind flanges, or caps, so that installation of the new trains does not impact the operating trains.

SHINE Supplement Section 9a2.7.1 states that the process exhaust to facility ventilation RVZ1e connections to TPS trains are isolated with manual valves and blind flanges or caps. The liquid nitrogen exhaust to facility ventilation RVZ2e connections to TPS trains are isolated with manual valves and blind flanges or caps. The pneumatic equipment gas line connections to TPS trains are isolated with manual valves. The liquid nitrogen supply connections to TPS trains are isolated with manual valves. The deuterium supply connections to TPS trains are isolated with manual valves. The inert flush gas connections to TPS trains are isolated with manual valves.

SHINE Supplement Section 13a2 identifies a new accident sequence related to the phased approach to construction and operation in the TPS and increases the likelihood of an existing scenario. The new sequence is damage to an installed TPS train during the installation of a new TPS train. The modified sequence with an increased likelihood is a heavy load drop on the TPS. These are discussed in Chapter 13 of this SER Appendix.

Based on its review, the NRC staff finds that each TPS train is capable of operating independently of the other TPS trains and that uncompleted items of construction related to TPS trains can be completed without impacting operating IUs. The staff also finds that the isolation

of systems that interface with the uncompleted TPS trains is adequate to allow the completion of uncompleted items of construction during the phased approach to startup.

9a.3 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE's IF auxiliary systems as affected by the proposed phased approach to startup, as described in SHINE Supplement Chapter 9a2, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

- (1) SHINE described the design of the IF auxiliary systems and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.
- (2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected during the phased approach to startup.
- (3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's IF auxiliary systems as affected by the phased approach to startup are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

9b Radioisotope Production Facility Auxiliary Systems

Section 9b, "Radioisotope Production Facility Auxiliary Systems," of this appendix to the SER provides the NRC staff evaluation of the final design of the SHINE RPF auxiliary systems as affected by the proposed phased approach to startup, as presented in SHINE Supplement Chapter 9b.

9b.1 Summary of the Supplement to the Application

SHINE Supplement Sections 9b.6.1 and 9b.6.2 provide a discussion of the impact of the phased startup on FSAR Sections 9b.6, "Cover Gas Control in Closed Primary Coolant Systems," specifically FSAR Sections and 9b.6.1 "Process Vessel Vent System" and 9b.6.2 "Nitrogen Purge System." The PVVS collects and treats the off-gases from process vessels in the SHINE facility. The PVVS collects off-gases from each RPF tank containing irradiated solutions, from the VTS vacuum pump discharge, and periodically from the TOGS. The treatment part of the PVVS consists of acid absorbers, carbon filters, HEPA filters, condensers, reheaters, carbon beds, and blowers. N2PS provides a backup supply of sweep gas (nitrogen) to IU and all tanks normally supplied by PVVS during a loss of normal sweep gas or a loss of normal power. The off-gas resulting from the nitrogen purge is treated by the same passive filtration equipment of PVVS discussed above before discharging to the stack.

SHINE Supplement Section 9b.7.2 states the MHS description provided in Subsection 9b.7.2 of the FSAR is not affected by phased startup operations. SHINE FSAR implements the material handling program in accordance with NUREG-0612, which is applicable during the phased approach for construction and startup. The IF and RPF overhead cranes will be installed during Phase 1 to support operations.

SHINE Supplement Section 9b.7.3 states the RLWI solidification equipment is available in Phase 1. Therefore, the RLWI equipment is available to receive and solidify blended liquid waste from the RLWS. SHINE also indicates the RLWI description provided in Subsection 9b.7.3 of the FSAR is not affected by phased startup operations, except that the selective removal process is not available during Phase 1 and 2 and isolated with a valve and a blind flange or cap.

SHINE Supplement section 9b.7.4 states that the RLWS description provided in Subsection 9b.7.4 of the FSAR is not affected by phased startup operations, except that IXP is not available during Phase 1 through Phase 3. SHINE Supplement Figure 6b.3-1 provides an overview of RLWS connections applicable to Phase 1, 2, and 3, which is consistent with Figure 6b.2-2 of the FSAR without IXP connection. During Phase 1 through Phase 3 operations, interfacing RLWS connections to the IXP system are isolated with a manual valve and a blind flange or cap. Chapter 4b of SHINE supplement indicates that the RLWS does not collect liquid wastes from the IXP system, as described in Subsection 4b.1.3.7.2 of the FSAR, during Phase 1 through Phase 3, and waste from the IXP system will not be generated in Phases 1 through 3.

SHINE Supplement Section 9b.7.5 states the SRWP 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 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 RPF. As indicated in Section 9b.2.8, solid wastes generated during Phase 1 and Phase 2 are stored in the radiologically controlled area (RCA) within the main production facility prior to shipment off site to a designated disposal site. Solid wastes are characterized and staged for shipment in the main production facility in accordance with the radioactive waste management program.

SHINE Supplement Section 9b.7.6 states the RDS description provided in Subsection 9b.7.6 of the FSAR is not affected by phased startup operations, except that IXP is not available during Phase 1 through Phase 3. During Phase 1 through Phase 3, the IXP hot cell is not operational. As indicated in Section 4b.1 of the application, the supercell confinement boundary is isolated from the IXP hot cell, and the IXP hot cell drain to RDS is plugged during Phase 1 through Phase 3.

SHINE Supplement Section 9b.7.7 states the FPWS is not affected by the phased approach.

SHINE Supplement Section 9b.7.8 indicates, the FNHS is not affected by phased startup operation and will be available for operation in Phase 1. SHINE described isolation of the interfaces to important individual IU systems, TPS trains, and the IXP system as not affecting the capability of the FNHS to perform its functions for other system interfaces.

SHINE Supplement Section 9b.7.9 indicates that FSDS is not affected by the phased approach. The system is non safety and functions normally during phased approach operation.

SHINE Supplement Section 9b.7.10 states that FCRS is not affected by the phased approach and the FCRS is available in Phase 1.

9b.2 Technical Evaluation

The staff performed an evaluation of the technical information presented in SHINE Supplement Section 9a2 using the guidance and acceptance criteria from Section 9b, "Radioisotope Production Facility Auxiliary Systems," of the ISG augmenting NUREG-1537, Parts 1 and 2.

Handling and Storage of Target Material

The SHINE FSAR Supplement for Phased Startup Operations, Section 9b.2, "Handling and Storage of Target Solution," describes the impacts of phased startup operations to systems used in the handling and storage of target material. SHINE FSAR Supplement Section 9b.2.1, "Target Solution Lifecycle," states, in part, that the IXP system is not installed, IXP connections are isolated, and the IXP hotcell is isolated during Phase 1 through 3. In Section 4b2.3 of this appendix, the NRC staff evaluated the isolations to the IXP system and determined the isolations are acceptable.

In Section 9b.2 of the SHINE FSAR Supplement, SHINE states that the receipt and storage of unirradiated SNM, target solution preparation, target solution staging system, and criticality control are not impacted by phase startup operations. The NRC staff reviewed FSAR Sections 9b.2.2, 9b.2.3, 9b.2.4, and 9b.2.9 of the supplement and did not identify any potential safety impacts to these systems and processes as a result of phased startup operations.

In Section 9b.2.5 of the SHINE FSAR Supplement, SHINE states that the vacuum transfer system (VTS) is not affected by phase startup operations. During Phase 1 startup operations, the VTS interfaces to the IUs 3 through 8 and IU system components will be isolated as described in in the FSAR supplement Section 4b.3. In Section 4a.2 of this appendix, the NRC staff evaluated the isolations of VTS and determined the isolations are acceptable for phased startup operations.

The NRC staff evaluated the impact of phased startup operations to the radioactive liquid waste (RWLI) immobilization system in Section 9b.7.3 and the solid radioactive waste packaging (SRWP) system in Section 9b.7.5 of this appendix. SHINE FSAR Supplement, Section 1.1, "Introduction," states, in part, that the full capability of the RLWI system and waste staging is included in Phase 3 operations. In Section 9b.7.3 and 9b.7.5 of this appendix, the NRC found that the RWLI system and SRWP are available for Phase 1 and 2 operations and are not affected by phased startup operations.

Process Vessel Vent System

The PVVS description provided in Subsection 9b.6.1 of the SHINE FSAR is not affected by phased startup operations because PVVS is available for operation in Phase 1. However, isolation of PVVS connections to non-operating IU cells and IXP system are required during the phased startup, as described in Sections 4a2.1 and 4b.3 of SHINE Supplement.

During Phase 1 and Phase 2, interfacing PVVS connections to IU specific instances of IU systems (i.e., TOGS) are isolated within the IU cell (i.e., interfaces with IUs 3 through 8 are isolated during Phase 1, interfaces with IUs 6 through 8 are isolated during Phase 2). The isolation is achieved by means of a locked closed isolation valve in the PVVS line that exits non-

operating IU units.

During Phase 1 through Phase 3, interfacing PVVS connections to the IXP system are isolated with a manual Isolation valve and a blind flange.

The staff concludes that the isolation provisions provided in the PVVS lines for the phased startup are adequately described and acceptable, and that the isolations will not impact the capability of PVVS to perform its functions for other system interfaces.

Nitrogen Purge System

The N2PS description provided in Subsection 9b.6.2 of the SHINE FSAR is not affected by phased startup operations, because N2PS is available for operation in Phase 1. However, isolation of N2PS connections to non-operating IU cells and IXP system are required during the phased startup as described in Section 4a2.1 and 4b.3 of the SHINE supplement.

During Phase 1 and Phase 2, interfacing N2PS connections to IU systems and components (i.e., TSV, TSV dump tank, and TOGS) are isolated within the IU cell (i.e., interfaces with IUs 3 through 8 are isolated during Phase 1, interfaces with IUs 6 through 8 are isolated during Phase 2). The isolation is achieved by means of one isolation valve and a blind flange and cap.

During Phase 1 through Phase 3, interfacing N2PS connections to the IXP system are isolated with a manual Isolation valve and a blind flange. The ventilation Zone 2 air to the IXP elute hold tank, also served by N2PS supply, is isolated with a manual valve and blind flange or cap.

The staff concludes that the isolation provisions provided in the N2PS lines for the phased startup are adequately described and acceptable, and that the isolations will not impact the capability of N2PS to perform its functions for other system interfaces. The staff concludes that the isolation provisions provided in the N2PS lines for the phased startup are adequately described and acceptable.

Molybdenum Isotope Product Packing System

The SHINE FSAR Supplement for Phased Startup Operations, Section 9b.7.1, "Molybdenum Isotope Product Packing System," states, in part, that the MIPS is not affected by phased startup operations with the exception that the IXP system is not available during Phase 1 through Phase 3 and that MIPS is isolated from IXP system. In Section 4b2.3 of this appendix, the NRC staff evaluated the isolations to the IXP system and determined the isolations are acceptable.

Material Handling System

The material handling system (MHS) includes overhead cranes and hoists that are used to move or manipulate radioactive material in the radiologically controlled area (RCA). The MHS design is evaluated for loads associated with two overhead bridge cranes, one servicing the IF area and one servicing the RPF area. The IF overhead crane is a 40-ton, double girder, bridge style crane designed to span the width and travel the length of the IF. The RPF overhead crane is a 15-ton, double girder, bridge style crane designed for the handling of shield cover plugs and equipment within the RPF.

For the IF overhead crane, the use of a single-failure-proof crane with rigging and procedures that implement the guidance of NUREG-0612 assure that the potential for a heavy load drop during construction is small. As described in FSAR section 9b.7.2, the RPF overhead crane is a non-single failure proof crane that employs the use of mechanical stops, electrical-interlocks, and predetermined safe load paths to minimize the movement of loads in proximity to redundant or dual safe shutdown equipment. For cranes operating in the vicinity of safety-related SSCs, SHINE has applied guidance from Section 5.1.1 of NUREG-0612

Areas of concern are the RLWI shielded enclosure or supercell during phased startup since these systems will not be complete during Phase 1 & 2 and ongoing work may be in process. Section 13b.1.2.3 of the FSAR discusses potential accidents involving heavy load handling near the RLWI shielded enclosure or supercell during phased startup operations to account for an increased likelihood of the initiating event because of on-going installation activities. A crane failure or operator error resulting in a heavy load drop on the RLWI shielded enclosure or the supercell causes damage to the affected structure and internal equipment. To prevent a heavy load drop on the enclosure or the supercell, crane operation procedures include safe load paths to avoid the RLWI enclosure and supercell, and require suspension of supercell and RLWI activities during a heavy lift.

While SHINE Supplement Section 9b.7.2 indicates the MHS description provided in Section 9b.7.2 of the FSAR is not affected by phased startup operations, it was unclear whether NUREG-0612 controls will be applied during the phased approach. During an audit dated May 24, 2022, SHINE verified 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 will be applied during phased startup activities.

In SHINE FSAR Supplement Section 13b.1.2.3, SHINE describes their modification of evaluation related to heavy load drop onto the RLWI shielded enclosure or supercell during phased startup operations to account for an increased likelihood of the initiating event because of on-going installation activities. SHINE indicates this increase is small in comparison to the total planned lifts during normal operations and does not result in an increase in the likelihood index for the initiating event.

Because MHS controls and safety features defined in FSAR section 9b.7.2 and NUREG-0612 will be applied, potential accident conditions with use of IF and RPF cranes are minimized. Conclusions reached in Section 9b 7.2 of the initial SER are not affected by the phased approach to construction and operation.

Radioactive Liquid Waste Immobilization System

The RLWI system solidifies blended liquid waste to a form suitable for shipping and disposal. The RLWI system removes selected isotopes, as needed, from the blended liquid waste and then immobilizes the wastes for ultimate disposal. The immobilization feed tank, liquid waste drum fill pumps, and valves are in a shielded enclosure. Selective isotope removal and waste drum filling and mixing are also performed within the shielded enclosure.

The RLWI selective removal process is described in Subsection 4b.1.3.8.2 of the FSAR. Using the selective removal, wastes can be recirculated in the RLWI system through a set of adsorption columns to remove isotopes that impact dose and classification of the waste package. As a result of unavailability, waste solidified during Phase 1 and Phase 2 may have higher dose rates and higher waste classifications than wastes solidified during Phase 3 and

Phase 4. During Phase 1 and Phase 2, liquid waste is stored in the subgrade RLWS tanks prior to transfer to RLWI to maximize the decay time and limit the volume of solidified waste requiring disposal. Estimated waste streams during phased startup operations are described in Section 11.2 of the supplement.

Because RLWI is available to support operation, with exception of isolated selective removal processes, the RLWI system is available and not affected by the phased startup approach and operation. SHINE will also maximize decay time and limit volume of solidified waste requiring disposal during phase 1 & 2 when MATB is unavailable.

Radioactive Liquid Waste Storage System

The RLWS system collects, stores, blends, conditions, and stages liquid wastes upstream of the RLWI system for solidification. The RLWS is a set of below grade tanks used to provide storage for radioactive liquid wastes prior to immobilization. Liquid wastes from other processes are collected separately.

Liquid wastes from the isotope production processes may contain SNM. These liquids are drained from the hot cells to the first favorable geometry uranium waste tank in the RLWS system. Once the liquid waste is verified to be below administrative limits, it is transferred to the second uranium waste tank where it is sampled again prior to sending to the liquid waste blending tanks for additional storage time. Target solution batches are disposed of through the RLWS system. Once a batch is designated for disposal, it is transferred to the RLWS system to be blended with other wastes.

Because RLWS is installed for Phase 1, with exception of IXP which is isolated during Phase 1 through Phase 3, the system is available to receive liquid waste. Conclusions reached in Section 9b 7.4 of the initial SER are not affected by the phased approach to construction and operation.

Solid Radioactive Waste Packaging System

The SRWP system consists of equipment designed and specified to collect, segregate, process (i.e. encapsulate) and stage for shipment, solid radioactive waste from systems throughout the IF and RPF without limiting the normal operation or availability of the facilities. Solid waste may include dry active waste, spent ion exchange resin, and filters and filtration media. The SRWP system also inventories materials entering and exiting the facility structure storage bore holes as the supercell imports and exports them. Solid radioactive waste is collected in segregated containers. Containers may be sorted for potentially non-contaminated waste. Contaminated waste is sealed, labeled, and transported to the MATB for characterization, documentation, and staging for shipment.

SHINE Supplement, Section 9b.7.5, indicates there is adequate bore hole storage space for waste streams that may require encapsulation processing until the MATB is available during Phase 3.

Because SRWP is available to handle solid waste, with exception of MATB which is not available during Phase 1 and 2, conclusions reached in Section 9b 7.5 of the initial SER are not affected by the phased approach to construction and operation.

Radioactive Drain System

The RDS is comprised of drip pans, piping, and collection tanks. The collection tanks are normally maintained empty and are equipped with instrumentation to alert personnel of an abnormal condition. The system operates by gravity drain, where overflows and leakage flow through installed piping drains directly to the RDS hold tanks.

Based on RDS being functional and isolated from collection of nonoperational IXP process liquids or overpressure protection for IXP during Phase 1 through Phase 3, the RDS retains ability to perform its function and staff conclusions reached in Section 9b.7.6 of the initial SER are not affected by the phased approach to construction and operation.

Facility Potable Water System

The potable water supply to the SHINE facility is connected to the City of Janesville water supply. The FPWS ends at the backflow prevention device interfacing with both the facility demineralized water system (FDWS) and facility heating water system (FHWS). Because the FPWS interfaces contain backflow preventors to prevent inadvertent contamination from interfacing systems, conclusions reached in Section 9b.7.7 of the initial SER are not affected by the phased approach to construction and operation.

Facility Nitrogen Handling System

The facility nitrogen handling system (FNHS) is designed to supply liquid and compressed gaseous nitrogen to systems inside the RCA. As described in Section 9b.7.8 of the FSAR, the FNHS is not relied upon to prevent accidents that could cause undue risk to the health and safety of the workers and the public or to control or mitigate the consequences of such accidents. Supplement Section 9b.7.8 summarizes these isolated interfaces as follows:

- During Phase 1 and Phase 2, interfacing FNHS connections to IU specific instances of IU systems (i.e., TOGS) are isolated outside the IU cell as described in Section 4a2.1 (i.e., interfaces with IUs 3 through 8 are isolated during Phase 1, interfaces with IUs 6 through 8 are isolated during Phase 2).
- During Phase 1 and Phase 2, interfacing FNHS connections to tritium purification system (TPS) trains are isolated as described in Section 9a2.7 (i.e., interfaces with TPS Train B and Train C are isolated during Phase 1, interfaces with TPS Train C are isolated during Phase 2).
- During Phase 1 through Phase 3, interfacing FNHS connections to the IXP system are isolated as described in Section 4b.3.

Based on FNHS Phase 1 availability and isolation from the phase dependent interfacing systems, the staff finds FNHS retains ability to support its function and not affected by the phased approach to construction and operation.

Facility Sanitary Drain System

The facility sanitary drain system (FSDS) collects domestic sanitary waste and wastewater outside RCA, discharging it to a city sewer main. SHINE FSAR Section 9b.7.9, "Facility Sanitary Drain System," states that the FSDS removes domestic sanitary waste and wastewater from the areas of the main production facility (outside the RCA), the storage building, and the resource

building; and discharges sanitary waste and wastewater to the City of Janesville public sewer main. Because the FSDS interfaces only with systems outside the RCA and contains backflow preventors to prevent inadvertent contamination with interfacing systems, conclusions reached in Section 9b.7.9 of the initial SER are not affected by the phased approach to construction and operation.

Facility Chemical Reagent System

The facility chemical reagent system (FCRS) provides storage and equipment for non-radioactive chemical reagents used in the SHINE processes. The supplement described that in Phase 1 and Phase 2, interfacing FCRS connections to IU-specific systems (i.e., TOGS) are isolated as described in Section 4a2.1 (i.e., interfaces with IUs 3 through 8 are isolated during Phase 1, interfaces with IUs 6 through 8 are isolated during Phase 2). During Phase 1 through Phase 3, interfacing FCRS connections to the IXP system are isolated. Isolating the interfaces to individual IUs and the IXP system does not affect the capability of the FCRS to perform its functions for other system interfaces.

Additionally, FCRS reagents transported in portable containers are not connected to process tie-in locations until the respective equipment is installed.

Based on FNHS availability in Phase 1 to perform its function and isolation from interfacing systems, the staff finds FCRS retains ability to support its function and not impacted by the phased approach to construction and operation.

9b.3 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE's RPF auxiliary systems as affected by the proposed phased approach to startup, as described in SHINE Supplement Chapter 9b, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

- (1) SHINE described the design of the RPF auxiliary systems and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.
- (2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected during the phased approach to startup.
- (3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's RPF auxiliary systems as affected by the phased approach to startup are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

10 EXPERIMENTAL FACILITIES

Section 10, "Experimental Facilities," of this appendix to the SER provides the NRC staff's evaluation of the impact of SHINE's proposed phased approach to startup on the SHINE experimental facilities, as presented in SHINE Supplement Chapter 10, "Experimental Facilities."

SHINE Supplement Chapter 10 states that the SHINE facility does not contain experimental facilities as described in NUREG-1537 and the ISG augmenting NUREG-1537.

The NRC staff evaluated the sufficiency of SHINE's description of experimental facilities using the guidance and acceptance criteria from Chapter 10, "Experimental Facilities and Utilization," of NUREG-1537, Parts 1 and 2, and Chapter 10, "Experimental Facilities," of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff determined that the information provided in SHINE FSAR Chapter 10 is not affected by the phased approach to startup. Therefore, the staff evaluation provided in SER Chapter 10, "Experimental Facilities," is applicable to the phased approach to startup without further supplementation.

11 RADIATION PROTECTION PROGRAM AND WASTE MANAGEMENT

Section 11, "Radiation Protection Program and Waste Management," of this appendix to the SER provides the NRC staff evaluation of the impact of SHINE's proposed phased approach to startup on the final design of the SHINE radiation protection program and waste management, as presented in SHINE Supplement Chapter 11, "Radiation Protection Program and Waste Management."

11.1 Summary of the Supplement to the Application

The SHINE Supplement provides information on the areas that workers are expected to be in during the proposed phased approach to startup. The radiation sources previously described in the SHINE FSAR are applicable and bounding for the dose analysis that would be used for the phased approach to startup.

During Phase 1, with IU cells 1 and 2 operating a worker could be in an adjacent IU and Target Solution Vessel (TSV) off-gas system (TOGS) cell 3. During Phase 2, with IU cells 1 through 5 operating a worker could be in an adjacent IU and TOGS cell 6. In addition, the applicant provides information on the IXP hot cell dose rates for Phases 1 through 3. During Phases 3 and 4 for the IU and TOGS cells, and Phase 4 for the IXP hot cell, the occupational doses are expected to match the information in FSAR Figure 11.1-1 for normal operations.

For radioactive waste controls, the MATB will not be used for interim storage of waste until it is operational during Phase 3. Any solidified waste generated during Phase 1 and 2 will be stored in bore holes as discussed in FSAR Chapter 9b.

Radioactive waste streams expected to be produced during phased operations are provided in supplement Table 11.2-1. The radioactive waste streams expected to be disposed of during phased operations are provided in supplement Table 11.2-2.

Releases of radioactive wastes are not affected by phased startup operations, except that the radioactive liquid waste immobilization (RLWI) selective removal process is not available during Phase 1 and Phase 2, and the IXP system is not available during Phases 1 through 3. The phased approach also states that waste solidified during Phase 1 and Phase 2 may have higher dose rates and higher waste classifications than wastes solidified during Phase 3 and Phase 4. During Phase 1 and Phase 2, liquid waste is stored in the subgrade radioactive liquid waste storage (RLWS) tanks prior to transfer to RLWI in order to maximize the decay time and limit the volume of solidified waste requiring disposal.

11.2 Technical Evaluation

The staff performed an evaluation of the technical information presented in SHINE Supplement Chapter 11 using the guidance and acceptance criteria from Chapter 11, "Radiation Protection Program and Waste Management," of the ISG augmenting NUREG-1537, Parts 1 and 2.

In review of the SHINE Phase Approach supplement, the NRC staff evaluated the impacts of radiation exposures on workers what would work in adjacent cells. In review of the information available on the reading room, the NRC staff observed dose rates specified by the applicant and confirmed those results from the calculation files available during the audit. In a request for

confirmation of information (RCI) submitted to SHINE (ADAMS Accession No. ML22206A208), the applicant confirmed the following information:

- The average dose rate in an empty IU cell adjacent to an operating IU cell is approximately 15 millirem per hour (mrem/hr) below the normal light water pool height and less than 5 mrem/hr above the light water pool height. The dose rate in the empty IU cell is approximately 60 mrem/hr at the height of the target solution vessel near the south wall.
- The maximum dose rate in an adjacent target solution vessel (TSV) off-gas system (TOGS) cell is expected to be approximately 60 mrem/hr.
- The maximum dose rate in an adjacent primary cooling room is expected to be approximately 5 mrem/hr.
- During installation of the iodine and xenon purification and packaging (IXP) system components, the adjacent cell can be operating, and the dose rate is expected to be approximately 5 mrem/hr.
- Radiation protection surveys, and ALARA work planning practices will be implemented to maintain occupational doses ALARA.

With the information confirmed in the RCI, the NRC staff finds that SHINE has an appropriate level of understanding around those areas that could be a concern for occupational exposures. Through this confirmation the applicant has confirmed varying dose rates and has also acknowledged the use of radiation protection and ALARA work planning before entering these areas. Given this information and the commitments made in the FSAR, the SHINE facility will meet the ALARA guidelines in accordance with 10 CFR 20.1101(b).

Staff review of the expected waste streams both produced and disposed of during phase startup operations determined that the information in the phased approach tables is consistent with the information provided in FSAR Table 11.2-1. This information is consistent since as more units come online you see the waste generation and disposal rates approach the values provided in FSAR Table 11.2-1. The information provided in this phased approach table identifies the amounts of radioactive material that is expected and supports the conclusions established in the FSAR to show that exposures and releases of radioactive material are bounded by the FSAR analysis. The applicant states in phased approach section 11.2.3 that during Phase 1 and 2 the solidified waste generated may have higher dose rates and waste classifications than would be observed in Phases 3 and 4 because there is no RLWI selective removal process available. As a result, the applicant plans to maximize decay times using the below grade radioactive liquid waste storage system (RLWS) tanks prior to transfer to the RWLI.

Given that the MATB will not be used for interim storage of waste until it is operational during Phase 3, the applicant states that the subgrade bore holes in the radioisotope production facility (RPF) will ensure dose rates with the RFP remain ALARA. The applicant's proposed radiation protection and ALARA programs will ensure that doses will be ALARA around these storage areas. The NRC staff find this to be acceptable since the bore holes are intended to be used for interim storage prior to disposals or movement into the MATB.

As a result of the SHINE Phase Approach, FSAR Chapter 11 is not affected by the phase startup operations except for those areas discussed. The applicant will continue to implement the Radiation Protection Program, the ALARA Program, the Radiation Monitoring and Surveying

Program, Radiation Exposure Control and Dosimetry, Contamination Control, Environmental Monitoring and Radioactive Waste Management programs consistent with the information previously described in the SHINE FSAR. The applicant confirms the expected dose rates and waste storage options while the facility is finishing construction and installation of components. NRC staff review of the phase approach supplement finds that the applicant has appropriately addressed those areas where the phased approach could be a concern for the Radiation Protection Program and Waste Management topic areas.

11.3 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE's radiation protection program and waste management as affected by the proposed phased approach to startup, as described in SHINE Supplement Chapter 11, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

- (1) SHINE described the radiation protection program and waste management and the respiratory protection program and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.
- (2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the regulations in 10 CFR Part 19, 10 CFR Part 20, 10 CFR Part 50, 10 CFR Part 61, 10 CFR Part 71, 40 CFR, Chapter I, and 49 CFR, Chapter I, and that the health and safety of the public will be protected during the phased approach to startup.
- (3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's radiation protection program and waste management as affected by the phased approach to startup are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

12 CONDUCT OF OPERATIONS

Section 12, "Conduct of Operations," of this appendix to the SER provides the NRC staff's evaluation of the impact of SHINE's proposed phased approach to startup on the SHINE conduct of operations, as presented in SHINE Supplement Chapter 12, "Conduct of Operations."

SHINE Supplement Chapter 12 states that the information provided in the SHINE FSAR is not affected by the phased approach to startup.

The NRC staff evaluated the sufficiency of SHINE's description of the conduct of operations using the guidance and acceptance criteria from Chapter 12, "Conduct of Operations," of NUREG-1537, Parts 1 and 2, and Chapter 12, "Conduct of Operations," of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff determined that the information provided in SHINE FSAR Chapter 12 is not affected by the phased approach to startup. Therefore, the staff technical evaluation provided in SER Chapter 12, "Conduct of Operations," is applicable to the phased approach to startup without further supplementation.

13 ACCIDENT ANALYSES

Section 13, "Accident Analyses," of this appendix to the SER provides the NRC staff's evaluation of the impact of SHINE's proposed phased approach to startup on the SHINE accident analyses, as presented in SHINE Supplement Chapter 13a2, "Irradiation Facility Accident Analysis," and Chapter 13b, "Radioisotope Production Facility Accident Analysis."

13.1 Irradiation Facility and Radioisotope Production Facility Accident Analyses

Section 13.1, "Irradiation Facility and Radioisotope Production Facility Accident Analyses," of this appendix to the SER provides the NRC staff's evaluation of the SHINE IF and RPF accident analyses as affected by the proposed phased approach to startup, as presented in SHINE Supplement Chapter 13a2 and Chapter 13b.

13.2 Summary of the Supplement to the Application

The startup phasing of the SHINE facility has been developed to minimize the complexities of maintaining process isolation and confinement requirements and to limit the number of physical locations where remaining equipment installation is occurring during operation to minimize impacts on the operating portions of the facility. The phased approach to operation is separated into four phases. The first three phases bring the eight IUs and Mo-99 production capability online, while Phase 4 adds iodine and xenon production capability.

The SHINE Safety Analysis (SSA) methodology described in Chapter 13 of the SHINE FSAR has been used to evaluate whether any new or different hazards are introduced by phased startup operations. Additional details on the safety analysis evaluation specific to phased startup operations is provided in SHINE FSAR Supplement Section 13a2 and Section 13b. The results of this evaluation concluded phased startup operations do not result in new accident categories, but the following new accident sequences within the IF were identified:

- Improper target solution routing to an uninstalled IU cell.
- Damage to an installed TPS train during the installation of another TPS train.
- Damage to a PVVS to TSV off-gas system (TOGS) interface line during installation of the subcritical assembly system (SCAS).

Accident sequences within the IF were modified based on increased likelihood include:

- Heavy load drop on the TPS.
- Heavy load drop on an in-service IU or TOGS cell.
- Fire in the IF general area.

Within the radioisotope production facility, phased startup operations do not result in new accident categories, but the following new accident sequences were identified:

- Improper target solution routing to the iodine and xenon purification and packaging cell, prior to Phase 4 operation.
- Backflow of target solution to the IXP cell prior to Phase 4 operations.

Accident sequences within the radioisotope production facility that are modified based on an increased likelihood are:

- Heavy load drop onto the radioactive liquid waste immobilization (RLWI) shielded enclosure or supercell
- Fire in the RPF general area

13.3 Technical Evaluation

The NRC staff performed an evaluation of the technical information presented in SHINE Supplement Section 13a2 using the guidance and acceptance criteria from Section 13a2, "Aqueous Homogeneous Reactor Accident Analyses," of the ISG augmenting NUREG-1537, Parts 1 and 2.

IU systems are designed and operated at the unit level. The design criteria for each system, both general and system specific, are met during all phases of operation for the systems in operation. During each phase of construction, the equipment necessary to support operation of IUs is functional and available for operation. As such, the engineered safety features required to mitigate the design basis accidents, are not affected by phased startup operations. Additionally, support systems and auxiliary systems are installed prior to Phase 1 operations. Support system and process line interfaces with the IUs are isolated to support phased startup operation.

Isolations at interface points with uninstalled systems are described throughout the supplement and generally consist of one or more valves and blind flanges or caps. The blind flanges and caps described are not credited controls and are not necessary to meet design criteria for the systems. As system installation progresses in preparation for the next phase of operation, the blind flanges and caps are removed, and the appropriate process connections are made. Confinement boundaries for operating systems are not impacted by installation activities. During Phase 1, the primary confinement boundaries for IUs 1 and 2 are operable. During Phase 2, the primary confinement boundaries for IUs 1 through 5 are operable. The primary confinement boundaries for all 8 IUs are operable during Phases 3 and 4. For the primary confinement boundaries that are not operable in Phases 1 and 2, system isolations are in place to prevent release of radiological or chemical hazards into the uninstalled IU. For Phase 1 operations, only Train A of the TPS is installed, and supports the operation of IUs 1 and 2. For Phase 2 operations, Trains A and B of the TPS are installed. Train A of the TPS supports the units installed as part of Phase 1 and Train B supports operation of IUs 3 through 5. For Phase 3 and 4 operations, the TPS and IUs are installed in full.

Within the IF, the following isolation points are provided inside IU cells 3 through 8 during Phase 1 and inside IU cells 6 through 8 during Phase 2:

- The vacuum transfer system (VTS) line to fill the TSV includes two isolation valves.
- The VTS line to the TSV dump tank includes one isolation valve inside the IU cell and an additional isolation valve outside of the IU cell.
- The VTS line to the TOGS vacuum tank includes two isolation valves.
- The PVVS line which exits the IU cell includes one locked closed isolation valve.

The following isolation points are provided outside IU cells 3 through 8 or TOGS cells 3 through 8 during Phase 1 and outside IU cells 6 through 8 or TOGS cells 6 through 8 during Phase 2:

- Radioisotope process facility cooling system supply and return lines.
- Facility nitrogen handling system supply lines include one isolation valve.
- Facility chemical reagent system supply lines include one isolation valve.
- N2PS purge lines include one isolation valve and a blind flange or cap.
- RVZ1 exhaust lines.

Mishandling or Malfunction of Target Solution

In SHINE Supplement Section 13a2.1.4, the applicant identified and evaluated an additional mishandling and malfunction of target solution scenario of improper target solution routing to an uninstalled IU cell. The initiating event in this scenario is a failure of the VTS lower lift tank target solution valve. In the uncontrolled sequence, failure of the valve would cause leakage of target solution into an uninstalled IU cell. This scenario is prevented by the dump tank drain isolation valve, which is installed as part of Phase 1 operation and maintained disconnected from power until the remaining IU equipment is installed and ready for hot commissioning. Since this scenario has preventative measures in place, there are no radiological consequences. The staff reviewed the information provided in Section 13a2.1.4 of the FSAR and find the staff's findings remain valid for phased startup operations.

System Interaction Events

In SHINE Supplement Section 13a2.1.11, the applicant identified and evaluated an additional system interaction event of damage to a PVVS to TOGS interface line during installation of the SCAS during phased operations. The accident scenario of fire in the IF general area leading to damage of cooling room equipment was also modified and evaluated for increased initiating event likelihood during phased startup operations. Errors during installation of SCAS equipment in an IU cell during Phase 1 or Phase 2 operations may result in damage to the PVVS to TOGS interface line that extends into the IU cell. Damage to this line could create a preferred flow path for PVVS gas to bypass process tanks, leading to deflagration and radiological dose. This scenario is prevented through the application of a new passive engineered control of a physical barrier installed over vulnerable portions of the PVVS to TOGS interface line and a specific administrative control to limit crane hoist speed during SCAS installation. The accident sequence of a fire in the IF general area leading to damage of cooling room equipment resulting in a complete loss of primary closed loop cooling system cooling in one or more IU cells or TOGS cells is modified during phased startup operations to account for an increased likelihood of the initiating event as a result of on-going installation activities. Radiological release due to this scenario is prevented by the credited controls currently in place. Since these have preventative measures in place, there are no radiological consequences. The staff reviewed the information provided in Subsection 13a2.2.11 of the FSAR and find the staff's findings remain valid for phased startup operations.

Facility-Specific Events

In SHINE Supplement Section 13a2.1.12, The applicant identified an additional facility-specific event of damage to an operating TPS train during the installation of another TPS train was identified and evaluated. The accident scenarios of a heavy load drop onto an in-service IU cell or TOGS cell and a heavy load drop onto TPS equipment were also modified and

evaluated for increased initiating event likelihood during phased startup operations. Errors during installation of TPS trains B or C during Phase 1 or Phase 2 operations, respectively, may result in damage to an operating TPS train. In the uncontrolled scenario, mechanical damage to an installed TPS train leads to release of tritium and radiological dose to workers and the public. The physical distance separating the TPS train installation locations reduces the likelihood of the initiating event. The scenario is prevented through the application of a new specific administrative control for operators to install physical barriers (e.g., roping or stanchions) around installed TPS trains to limit access to areas where mechanical damage to an installed TPS train is possible. The accident sequences of a heavy load drop onto an in-service IU cell or TOGS cell and a heavy load drop onto TPS equipment are modified during phased startup operations for increased likelihood of the initiating event as a result of on-going installation activities. These scenarios are prevented by a credited control currently in place (i.e., single failure proof crane in the IF). Since these events have preventative measures in place, there are no radiological consequences. The staff reviewed the information provided in Subsection 13a2.2.12 of the FSAR and find the staff's findings remain valid for phased startup operations.

Radioisotope Production Facility Critical Equipment Malfunction

In SHINE Supplement Section 13b.1.2.3, the applicant identified two additional RPF critical equipment malfunction scenarios of a target solution leak into the IXP cell was identified and evaluated. The initiating event in the first scenario is the failure of a locked closed valve between the MEPS and the IXP system, located in the MEPS cell. In the uncontrolled sequence, failure of the valve causes leakage of target solution into the IXP cell, resulting in dose consequences to the worker and the public. This scenario is prevented by a second locked closed manual valve between MEPS and IXP, located in the IXP cell. The initiating event in the second RPF critical equipment malfunction scenario is the backflow of solution from the target solution staging system (TSSS) to the IXP due to failure of a TSSS tank isolation valve. In the uncontrolled sequence, failure of the TSSS tank isolation valve during molybdenum extraction causes a backflow of target solution into the IXP cell through the MEPS drain line, resulting in dose consequences to the worker and the public. This scenario is prevented by the locked closed isolation valve between MEPS and IXP, located inside the IXP cell, as well as the cap on the pipe entering the IXP cell. The accident sequence of a heavy load drop onto the RLWI shielded enclosure or supercell is modified during phased startup operations to account for an increased likelihood of the initiating event as a result of on-going installation activities. This increase was small in comparison to the total planned lifts during normal operations and did not result in an increase in the likelihood index for the initiating event. This scenario is prevented by the credited controls currently in place, including the application of applicable guidance from NUREG-0612, Control of Heavy Loads at Nuclear Power Plants (USNRC, 1980), for control of heavy loads in the SHINE facility. Since these scenarios have preventative measures in place, there are no radiological consequences. The staff reviewed the information provided in Subsection 13b.1.2.3 of the FSAR remains valid for phased startup operations.

Radioisotope Production Facility Fire

In SHINE Supplement Section 13b.1.2.5, the applicant identified an increase in the initiating event likelihood for a fire in the RPF general area for phased startup operations which resulted in an increase in the likelihood index for the initiating event. A new specific administrative control of suspension of radiological material processing in the adjacent cell during hot work is applied in addition to the existing RPF fire controls. Because this scenario has preventative measures in place, there are no radiological consequences. The staff reviewed the information provided in Subsection 13b.1.2.5 of the FSAR remains valid for phased startup operations.

13.4 Review Findings

The NRC staff reviewed the descriptions and discussion of SHINE's IF and RPF accident analyses as affected by the proposed phased approach to startup, as described in SHINE Supplement Chapter 13a2 and Chapter 13b, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. Based on its review of the information in the SHINE Supplement and independent confirmatory review, as appropriate, the staff determined that:

- (2) SHINE described the IF and RPF accident analyses and identified the major features or components incorporated therein as affected by the proposed phased approach to startup for the protection of the health and safety of the public.
- (2) The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected during the phased approach to startup.
- (3) The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of SHINE's IF and RPF accident analyses as affected by the phased approach to startup are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.

13.5 SHINE Safety Analysis

13.5.1 Summary of the Supplement

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13.5.2 Technical Evaluation

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13.5.3 Consistency with FSAR, Phased Operations Impacts and Safety-Related Controls

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13.5.4 SSA Method Implementation

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13.5.5 SSA Implementation

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13.5.6 Review Findings

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14 TECHNICAL SPECIFICATIONS

Section 14, "Technical Specifications," of this appendix to the SER provides the NRC staff's evaluation of the impact of SHINE's proposed phased approach to startup on the TSs of the SHINE facility, as presented in the SHINE Supplement Chapter 14, "Technical Specifications."

SHINE Supplement Chapter 14 states that the information provided in the SHINE FSAR is not affected by the phased approach to startup.

The NRC staff evaluated the sufficiency of SHINE's TSs using the guidance and acceptance criteria from Chapter 14, "Technical Specifications," of NUREG-1537, Parts 1 and 2, and Chapter 14, "Technical Specifications," of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff determined that the information provided in SHINE FSAR Chapter 14 is not affected by the phased approach to startup. Therefore, the staff technical evaluation provided in SER Chapter 14, "Technical Specifications," is applicable to the phased approach to startup without further supplementation.

15 FINANCIAL QUALIFICATIONS

Section 15, "Financial Qualifications," of this appendix to the SER provides the NRC staff's evaluation of the impact of SHINE's proposed phased approach to startup on the financial qualifications of SHINE, as presented in SHINE Supplement Chapter 15, "Financial Qualifications."

SHINE Supplement Chapter 15 states that the information provided in the SHINE FSAR is not materially affected by the phased approach to startup. SHINE stated that the decommissioning cost estimate for the facility remains bounding for the phased approach to startup.

The NRC staff evaluated the sufficiency of SHINE's financial qualifications using the guidance and acceptance criteria from Chapter 15, "Financial Qualifications," of NUREG-1537, Parts 1 and 2, and Chapter 15, "Financial Qualifications," of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff determined that the information provided in SHINE FSAR Chapter 15 is not materially affected by the phased approach to startup and that the decommissioning cost estimate remains bounding for the facility with the phased approach to startup. Therefore, the staff technical evaluation provided in SER Chapter 15, "Financial Qualifications," is applicable to the phased approach to startup without further supplementation.

16 OTHER LICENSE CONSIDERATIONS

Section 16, "Other License Considerations," of this appendix to the SER provides the NRC staff's evaluation of the impact of SHINE's proposed phased approach to startup on the issue of other license considerations, as presented in SHINE Supplement Chapter 16, "Other License Considerations."

SHINE Supplement Chapter 16 states that the SHINE facility utilizes new components and systems and, therefore, discussions regarding used components and systems are not applicable to the SHINE facility. SHINE also stated that the facility does not contain equipment or facilities associated with direct medical administration of radioisotopes or other radiation-based therapies and, therefore, discussions regarding medical use of the SHINE facility are not applicable.

The NRC staff evaluated the sufficiency of SHINE's discussion regarding other license conditions using the guidance and acceptance criteria from Chapter 16, "Other License Considerations," of NUREG-1537, Parts 1 and 2, and Chapter 16, "Other License Considerations," of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff determined that the information provided in SHINE FSAR Chapter 16 is not affected by the phased approach to startup. Therefore, the staff evaluation provided in SER Chapter 16, "Other License Considerations," is applicable to the phased approach to startup without further supplementation.

17 DECOMMISSIONING AND POSSESSION-ONLY LICENSE AMENDMENTS

Section 17, "Decommissioning and Possession-only License Amendments," of this appendix to the SER provides the NRC staff's evaluation of the impact of SHINE's proposed phased approach to startup on the issue of decommissioning and possession-only license amendments, as presented in SHINE Supplement Chapter 17, "Decommissioning and Possession-only License Amendments."

SHINE Supplement Chapter 17 states that a decommissioning report is provided in SHINE FSAR Section 15.3, "Financial Ability to Decommission the SHINE Facility." SHINE also stated that a possession-only license is not applicable to the SHINE facility.

The NRC staff evaluated the sufficiency of SHINE's discussion regarding decommissioning and possession-only license amendments using the guidance and acceptance criteria from Chapter 17, "Decommissioning and Possession-only License Amendments," of NUREG-1537, Parts 1 and 2, and Chapter 17, "Decommissioning and Possession-only License Amendments," of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff determined that the information provided in SHINE FSAR Chapter 17 is not affected by the phased approach to startup. Therefore, the staff evaluation provided in SER Chapter 17, "Decommissioning and Possession-only License Amendments," is applicable to the phased approach to startup without further supplementation.

18 HIGHLY ENRICHED TO LOW ENRICHED URANIUM CONVERSIONS

Section 18, "Highly Enriched to Low Enriched Uranium Conversions," of this appendix to the SER provides the NRC staff's evaluation of the impact of SHINE's proposed phased approach to startup on the issue of highly enriched to low enriched uranium conversions, as presented in SHINE Supplement Chapter 18, "Highly Enriched to Low Enriched Uranium Conversion."

SHINE Supplement Chapter 18 states that the SHINE facility is a new facility that uses low enriched uranium and, therefore, discussions of highly enriched to low enriched uranium conversions are not applicable.

The NRC staff evaluated the sufficiency of SHINE's discussion regarding highly enriched to low enriched uranium conversions using the guidance and acceptance criteria from Chapter 18, "Highly Enriched to Low Enriched Uranium Conversions," of NUREG-1537, Parts 1 and 2, and Chapter 18, "Highly Enriched to Low Enriched Uranium Conversions," of the ISG augmenting NUREG-1537, Parts 1 and 2. The staff determined that the information provided in SHINE FSAR Chapter 18 is not affected by the phased approach to startup. Therefore, the staff evaluation provided in SER Chapter 18, "Highly Enriched to Low Enriched Uranium Conversion," is applicable to the phased approach to startup without further supplementation.