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 (Agencywide Documents Access and Management System 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 (ML22027A353), as supplemented by letters dated May 23, 2022 (ML22143A814), August 1, 2022 (ML22213A049), August 31, 2022 (ML22249A125 and ML22249A143), September 19, 2022 (ML22263A027), and September 20, 2022 (ML22263A344), and September 28, 2022 (ML22271A962) (hereafter, the SHINE 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 “Group1,” “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 final safety analysis report (FSAR).

The NRC 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 50.33, "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"
- 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material"

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," dated 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," dated 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, dated November 2012.

- NUREG/CR-7126, "Human-Performance Issues Related to the Design and Operation of Small Modular Reactors," dated June 2012.

- NUREG/CR-7202, "NRC Reviewer Aid for Evaluating the Human-Performance Aspects Related to the Design and Operation of Small Modular Reactors," dated June 2015.

- NUREG-0612, "Control of Heavy Loads at Nuclear Power Plants," dated July 1980.

- NUREG-1520, Revision 2, "Standard Review Plan for Fuel Cycle Facilities License Applications," dated 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," section 5, "Cooling Systems," section 6, "Engineered Safety Features," section 7, "Instrumentation and Control Systems," and section 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 (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 SCAS, NFDS, TOGS, PCLS, LWPS, and RVZ1r, (3) the completion of the RPF and with the installation exception of the IXP and RLWI selective removal, (4) the installation of TPS train A, and (5) all auxiliary and support systems, except as noted below for the instances of PCLS, LWPS, 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 (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 (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” (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 (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 (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.

Section (b) of 10 CFR 50.57 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 28, 2022 (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,” identities 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, “Introduction.”

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 onto a in-service IU cell 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 applicable 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, "Radioisotope Production Facility Description."

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 applicable 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, facility chilled water system (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 applicable 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 Supplement chapter 6a2.

6a.1 Summary of the Supplement to the Application

SHINE Supplement section 1.1 states that the phased approach to startup 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, “Summary Description,” 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 thorough 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 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, “Tritium Confinement Boundary,” 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, “Irradiation Facility Combustible Gas Management Functional Block Diagram,” 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 applicable 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, “Radioisotope Production Facility Engineered Safety Features.”

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, “Supercell Confinement Boundary,” 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, “Summary Description,” and 6b.2, “Detailed Descriptions,” 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 applicable 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 approach to startup, 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 that the non-operable portions do not impact the safe operation of the operable portions. During installation and startup of the I&C systems for subsequent phases, adequate separation and isolation are maintained such that the operable portions of the systems are not adversely impacted. The following I&C systems/components are installed and tested in the SHINE facility control room (FCR) prior to initial (i.e., Phase 1) operations:

- Operator workstations, NDAS workstations, supervisor workstation, and the main control board as described in SHINE FSAR Section 7.6;
- Cabling, conduit, and raceways for the Process Integrated Control System (PICS) monitoring and control functions;
- Normal and uninterruptible electrical power supply systems (the normal electrical power supply system (NPSS) and uninterruptible electrical power supply system (UPSS) A and B);
- Nine TSV Reactivity Protection System (TRPS) cabinets (3 each for Divisions A, B, and C); and
- Three Engineered Safety Features Actuation System (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 of the PICS I&C hardware (i.e., cabinets, power supplies, controllers, and programmable logic controllers) is installed prior to Phase 1. 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 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, conduits, and raceways for monitoring and control functions will be installed prior to Phase 1.

Prior to initial (i.e., Phase 1) operations, the following vendor-provided control systems are made operable:

- Building automation system;
- Supercell control system;

- RWLI control system (except portions associated with selective removal);

- NDAS control system (NDAS units required for a given phase are connected to the NDAS control system and made operational to support the phase); and

- Integral controllers associated with:
  - Standby generator system (SGS);
  - FDWS reverse osmosis unit;
  - FNHS unit;
  - Facility heating water system (FHWS) boilers;
  - FCHS; and
  - 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.

PICS equipment associated with the N2PS, radiological ventilation systems, RPCS, FNHS, and FCRS will be connected and tested as equipment is made operational to support a given phase.

PICS software development and testing will be completed during each phase. During the phased approach to startup, 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 entering the phase.

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

- For Phase 1, 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 are installed to serve IUs 1 and 2.

- For Phase 2, 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 are installed to serve IUs 3, 4, and 5.

- For Phase 3, 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 are installed 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 SHINE FSAR Section 7.3.1.1 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. Affected safety function modules (SFMs) of the HIPS platform that implement ESFAS are modified to accommodate the phased approach to startup. This HIPS SFM modification allows disabling of an individual input that is not required for a given phase. 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 SHINE FSAR Section 7.6.3. 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 SHINE FSAR Section 7.5.3.1, have inputs disabled and safety functions not utilized during the phased approach to startup, as described in SHINE Supplement Tables 7.5-1, “Monitored Variable Inputs Disabled During Phases of Startup Operations,” and 7.5-2, “Safety Functions Not Utilized During Phases of Startup Operations.”

The functionality of disabling inputs is tested as part of the pre-factory acceptance test and the factory acceptance test, as described in SHINE FSAR Section 7.4.5.4.7, “Independent Testing.” All of the inputs for ESFAS and TRPS are tested as part of the site acceptance test prior to Phase 1. Upon successful completion of the site acceptance test, 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 subsequent phase, the maintenance workstation 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 SHINE FSAR Section 7.5.3.6 will only actuate safety functions utilized in a given phase.

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; and
- 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 approach to startup, 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. Safety-related process radiation monitors not required for Phase 1 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 before that phase. Radiation monitors associated with individual IUs and TPS trains are installed for the phase associated with that IU or TPS train. SHINE Supplement table 7.7-1, "Safety-Related Process Radiation Monitor Phasing," provides a list of the safety-related process radiation monitors and the phase in which they will be operable to support operation.

All nonsafety-related process radiation monitoring and nonsafety-related radiation monitoring systems are installed prior to Phase 1.

7.2 Technical Evaluation

The NRC 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 SHINE Supplement Chapter 7, the NRC staff finds that:

- The TRPS for each IU cell that is in operation in a given phase is capable of independently performing all the safety functions identified in SHINE FSAR section 7.4.3.1. Since all 3 divisions of the TPRS are 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 SHINE FSAR Section 7.5.3.1 for the systems that are operable in that phase. Monitored variable inputs to the ESFAS that are 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 operable, ESFAS will continue to meet all relevant SHINE design criteria for the operable systems.

- For the IU cells that are 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 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 that are in service is not impacted. Therefore, disabling/enabling these ESFAS input signals is not necessary for the phased approach to startup.

- The status of the disabled ESFAS inputs is transmitted to the PICS and displayed to the operator consistent with human factors design criteria described in SHINE FSAR section 7.6.2.2.7.

- Except for the TPS Trains B and C local control stations, all the PICS local control stations are functional to support Phase 1. 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 C 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 and the factory acceptance test, as described in SHINE FSAR Section 7.4.5.4.7. All of the inputs for ESFAS and TRPS are tested as part of the site acceptance test, as described in SHINE FSAR section 7.4.5.4.2.6, prior to Phase 1. Upon successful completion of the site acceptance test, 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 subsequent phases, the maintenance workstation is used to configure the inputs such that they do not affect equipment in operation. Each input is then enabled, verified, and the setpoint 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 NRC staff finds that during the phased approach to startup the SHINE I&C systems, as described in SHINE FSAR Chapter 7, will continue to meet all applicable SHINE design criteria and are capable of performing the required safety functions during each phase such that the uncompleted items of construction can be completed without impacting the operating systems.

7.3 Human Factors Engineering

The SHINE design criteria are provided in SHINE FSAR section 3.1, “Design Criteria,” table 3.1-3, “SHINE Design Criteria.” The following design criterion is applicable to the human factors engineering (HFE) review:

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

The NRC staff evaluates whether the SHINE facility meets the HFE-related aspects of SHINE Design Criterion 6 in Section 7.4.9 of this SER. The staff also evaluates in section 7.4.9 of this SER whether the SHINE facility provides HFE support for administrative controls within the specific context of the operator role in safety at the facility. As part of its review of the SHINE

Supplement, the staff determined that it was necessary to ascertain whether these evaluations remain valid in light of the proposed phased approach to startup.

Although NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2, do not contain guidance and acceptance criteria related to HFE with respect to a phased approach to startup, the NRC staff notes that SHINE's proposed phased approach to startup involving, in part, the sequential installation of additional, independent IUs after previously installed IUs have already begun operation is conceptually similar to installing additional small modular reactor units at an operating power reactor facility. Therefore, the staff determined that it was appropriate to draw upon a similar set of considerations from the following guidance documents to inform its HFE review of the SHINE Supplement:

- NUREG/CR-7126, Section 6, which 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, which supplements NUREG/CR-7126 by identifying specific questions for use by reviewers. This guidance discusses that, in the absence of additional guidance, the NRC staff can use information about potential human-performance issues to support safety evaluations. It provides that for the human-performance issue of "impact of adding new units while other units are operating," the NUREG-0711 elements impacted are "Human-System Interface Design" and "Procedure Development." The guidance suggests that issues within these two elements be considered using the following questions:

  - For the Human-System Interface (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 NRC staff applied its technical judgement to adapt these considerations to its evaluation of the HFE implications of SHINE's proposed phased approach to startup. The evaluation of each applicable area is detailed in the following sections.

7.3.1 Changes to Human-System Interfaces

The NRC staff considered whether any changes to HSIs would be needed during SHINE's proposed phased approach to startup, whether HSIs would be added to existing workstations that would already be in use, and whether the HFE evaluation previously conducted by the staff in Section 7.4.9 of this SER remains valid.

SHINE Supplement chapter 3 states that the design of SSCs described in SHINE FSAR Chapter 3 is not affected by the phased approach to startup and that the design criteria and systems and components descriptions provided in SHINE FSAR sections 3.1 and 3.5, respectively, are applied to the phased approach to startup. The staff noted that the design criteria of SHINE FSAR section 3.1 include Criterion 6 for the control room.

SHINE Supplement chapter 7 states that the descriptions of the main control board, operator workstation, supervisor workstation, maintenance workstation, and other control room interface equipment provided in SHINE FSAR Subsections 7.6.1.1 through 7.6.1.5, respectively, are not affected by the phased approach to startup. SHINE Supplement chapter 7 also states that during the phased approach to startup, I&C systems required for the safe operation of the process equipment in each phase are fully tested and operable. PICS monitoring and controls associated with equipment that is not yet installed, or not yet operable, is tested and placed in operation as required for a given phase. Each input to PICS is 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 NDAS control system control stations are installed and operational prior to initial (i.e., Phase 1) operations, with the NDAS units being connected to the NDAS control system as they are installed to support the operation of a given phase.

SHINE Supplement Section 7.4, “Target Solution Vessel Reactivity Protection System,” states that the TRPS description provided in SHINE FSAR section 7.4.1 is not affected by the phased approach to startup and that each IU is supported by an IU-specific instance of the TRPS. SHINE Supplement section 7.4 also states that the description of human factors provided in SHINE FSAR subsection 7.4.3.7 is not affected by the phased approach to startup, with the exception of the implementation of the manual 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; 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 Supplement Section 7.5, “Engineered Safety Features Actuation System,” states that the ESFAS description provided in SHINE FSAR Subsection 7.5.1 remains accurate during the phased approach startup relative to the capabilities of the ESFAS. During phased startup, 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 Supplement Section 7.5 also states that the manual push buttons identified in SHINE FSAR Subsection 7.5.3.6 will only actuate safety functions utilized in a given phase.

The NRC 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 (ML. 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 the phased approach to startup. SHINE indicated that 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 NRC staff finds that the applicant has described the changes to HSIs that will be needed during the phased approach to startup. 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 on its review, the staff concludes that the modification of existing HSIs will be adequately managed and that the HFE evaluation previously conducted by the staff in Section 7.4.9 of this SER remains valid.

7.3.2 Management of Distractions

The NRC 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 in section 7.4.9 of this SER remains valid. SHINE Supplement chapter 7 states 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 Supplement chapter 7 also states that the description of the design basis provided in SHINE FSAR subsection 7.6.3 is not affected by the phased approach to startup. The staff noted that this is inclusive of SHINE FSAR subsection 7.6.3.3, which addresses the application of HFE principles. SHINE further stated that indication will be provided to the operator for components that have been disabled and for components that have not been field terminated.

The NRC 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 (ML22287A185). 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 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 the phased approach to startup, what indications will be in a status where a parameter value is displayed but has not yet been tested to verify its accuracy.

The NRC 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 on its review, the staff concludes that operator distractions and disruptions will be adequately managed and that the HFE evaluation previously conducted by the staff in Section 7.4.9 of this SER remains valid.

7.3.3 Procedure Changes

The NRC staff considered whether the installation of new facility equipment will impact procedures used during SHINE's proposed phased approach to startup and whether the related HFE evaluation previously conducted by the staff in section 7.4.9 of this SER remains valid. SHINE Supplement chapter 12 states that the conduct of operations described in SHINE FSAR chapter 12 is not affected by the phased approach to startup and that the organizational and programmatic descriptions provided in SHINE FSAR chapter 12 will be implemented to support initial (i.e., Phase 1) operations. The staff noted that SHINE FSAR chapter 12 includes the SHINE procedure management program and, furthermore, that procedure change control is a component of that program.

SHINE Supplement chapters 13a2 and 13b, Radioisotope Production Facility Accident Analysis," describe that new or different accident scenarios that were identified as part of the phased approach to startup resulted in several new specific administrative controls being credited. The NRC 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 specific administrative controls would be adequately supported by these management measures.

The NRC 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 (ML22287A185). During the audit discussion, SHINE clarified how it would 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 its response to Request for Confirmatory Information (RCI) HFE-1 (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 NRC staff finds that the applicant has described how the installation of new facility equipment will impact procedures used during the phased approach to startup. 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 on its review, the staff concludes that the evaluation of the applicant's procedure management program's support for the implementation of administrative controls previously conducted by the staff in Section 7.4.9 of this SER remains valid.

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 Criterion 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 under the phased approach to startup.

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 chapter 8a2 provides SHINE’s proposed phased approach to startup related to the SHINE IF electrical power systems.

SHINE Supplement section 8a2.1, “Normal Electrical Power Supply System,” states that the description of the NPSS in SHINE FSAR section 8a2.1 is not affected by the phased approach to startup and that the NPSS is installed in full to support initial (i.e., 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 continue to satisfy the codes and standards described in SHINE FSAR subsections 8a2.1.1, 8a2.1.3, 8a2.1.4, and 8a2.1.5. All raceway and cable routing is installed in full to support Phase 1.

SHINE Supplement Section 8a2.2, “Emergency Electrical Power Systems,” states that the description of the emergency electrical power systems in SHINE FSAR Section 8a2.2 is not affected by the phased approach to startup. All the emergency electrical power systems are installed in full to support initial (i.e., Phase 1) operations, including the [UPSS], the nonsafety-related [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. SHINE FSAR subsections 8a2.2.1, 8a2.2.2, 8a2.2.3, 8a2.2.7, and 8a2.2.8 are not impacted by isolating loads that are not yet installed or not yet operable. The UPSS will continue to satisfy the codes and standards described in SHINE FSAR Subsections 8a2.2.2 and 8a2.2.3.

8a.2 Technical Evaluation

The NRC staff performed an evaluation of the technical information presented in SHINE Supplement chapter 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.

With respect to the IF electrical power systems, all systems, i.e., the NPSS and the emergency electrical power systems, will be installed prior to initial (i.e., Phase 1) operations. Therefore, the IF electrical power systems are not affected by the phased approach to startup and they will

continue to meet all applicable portions of the codes and standards described in SHINE FSAR Chapter 8. SHINE uses 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 the isolation of electrical systems, as described in SHINE FSAR subsection 8a2.1.1. SHINE's conformance with the applicable portions of IEEE Std. 384-2008 provides reasonable assurance that equipment not yet operable or not yet installed during the phased approach to startup will be appropriately isolated from the NPSS and the emergency electrical power systems.

Based on the above, the NRC staff finds that the IF 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 IF 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 IF 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 applicable 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 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 that the phased approach to startup 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 IU units. The IU cells and primary cooling rooms are designed to allow access for maintenance or other operational needs while adjacent IUs are operating, including ICBS design, sufficient to minimize dose rates consistent with the ALARA principles at the facility.

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 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 where uncompleted items of construction are being completed.

9a.2 Technical Evaluation

The NRC staff performed an evaluation of the technical information presented in SHINE Supplement chapter 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 NRC staff reviewed the pertinent information associated with the proposed phased approach to startup and the system isolations necessary for safe operation of the facility during the various phases and the completion of uncompleted items of construction as described in SHINE Supplement chapter 9a2.

The radiological ventilation (RV) system descriptions provided in SHINE FSAR subsection 9a2.1.1 are not affected by the phased approach to startup, with the exception of the following:

- The ventilation system zone designations identified in SHINE FSAR Figure 9a2.1-1 are not applicable for certain areas of the facility because they do not contain operational equipment during certain phases. Prior to Phase 1, IU-specific instances of RVZ1r and RVZ1e for IUs 1 and 2 are operational. The ICBS cover plugs for cooling rooms, TOGS cells, and IU cells are also installed. Once the cover plugs are installed, the IU cells, the TOGS cells, and RVZ1r for IUs 1 and 2 become part of ventilation zone 1. A similar sequencing for becoming a part of ventilation zone 1 is follow prior to Phase 2 for IUs 3, 4, and 5 and prior to Phase 3 for IUs 6, 7, and 8.

- RV interfaces with TPS Train A are operational for Phase 1, with TPS Train B and TPS Train C isolated during Phase 1. RV interfaces with TPS Train A and TPS Train B are operational for Phase 2, with TPS Train C isolated during Phase 2. RV interfaces with TPS Train A, TPS Train B, and TPS Train C are operational for Phase 3. RV interfaces with the IXP system are isolated during Phase 1 through Phase 3.

- The non-operating IUs during Phases 2 and 3 are part of ventilation zone 2 and become part of ventilation zone 1 for subsequent phases after their installation is completed and their ICBS cover plugs are installed.

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

Radiological Ventilation Zone 1

Since there are no common components or connections between the IU-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 the phased approach to startup.

The RVZ1e system interfaces with IU-specific instances of the PCLS within the IU cells (i.e., the PCLS expansion tank exhaust). The IU-specific portions of the RVZ1e system within the cooling rooms and the IU cells are installed to support the phased approach to startup 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 the IU cells by a manual isolation valve and a blind flange or cap to support the phased approach to startup.

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

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

Radiological Ventilation Zone 2

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

The 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 the phased approach to startup via two bubble-tight dampers.

Radiological Ventilation Zone 3

The phased approach to startup has no impact on the radiological ventilation zone 3 description provided in SHINE FSAR subsection 9a2.1.1.

Conclusion Regarding the Radiological Ventilation System

Based on the radiological ventilation system phased approach to startup descriptions in SHINE Supplement section 9a2.1.1, “Radiologically Controlled Area Ventilation System,” the main ventilation units located in the mezzanine levels of ventilation zones 2 and 4 will be installed and operational prior to initial (i.e., Phase 1) operations. They are the RVZ2 supply subsystem 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 prior to 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 NRC staff determined that the ventilation systems are described in sufficient detail to describe the interim configuration of the ventilation systems in each of Phases 1, 2, 3, and 4, including the isolations provided to the uncompleted items of construction during the different phases. 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 also described in sufficient detail. At the conclusion of Phase 4, the ventilation systems will be in full conformance with the SHINE FSAR.

The NRC staff reviewed the radiological ventilation systems information in SHINE Supplement 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 determined that it is

consistent with the description of the radiological controlled area ventilation in SHINE Supplement section 9a2.1.1.

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

Based on the above, the NRC staff concludes that the conclusions reached in SER section 9a regarding the ventilation systems are not affected by the proposed phased approach to startup. In addition, based on the above, the staff has reasonable assurance that the ventilation systems can operate safely during all four phases and remain unimpacted by the completion of uncompleted items of construction during the four phases.

Non-Radiological Ventilation and Support Systems

The non-radiological area ventilation system, the FCHS, the FHWS, handling and storage of target solution, fire protection systems and programs, communication systems, possession and use of byproduct, source, and SNM, and the NDAS service cell are not affected by the phased approach to startup. The NRC staff evaluated these systems and programs and concludes that the conclusions reached in SER section 9a regarding these systems and programs are not affected by the proposed phased approach to startup. In addition, based on the above, the staff has reasonable assurance that these systems and programs can operate safely during all four phases and remain unimpacted by the completion of uncompleted items of construction during the four phases.

Cover Gas Control in Closed Primary Coolant Systems

SHINE Supplement section 9a2.6, “Cover Gas Control in Closed Primary Coolant Systems,” states that the PCLS is the closed loop cooling system that provides cooling to the TSV. Cover gas control for the PCLS is described in Section 5a2.2 of the FSAR. The NRC staff evaluated the PCLS in Section 5a.2 of this appendix. The NRC evaluated the PCLS and finds that the design of the PCLS 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.

Tritium Purification System

SHINE Supplement section 9a2.7.1, “Tritium Purification System,” states that the TPS has three independent trains (i.e., Trains A, B, and C) that support the operation of the NDAS in specific IUs. TPS Train A supports IUs 1 and 2, TPS Train B supports IUs 3, 4, and 5, and TPS Train C supports IUs 6, 7, and 8. In Phase 1, IUs 1 and 2 and the associated TPS Train A are operational. In Phase 2, IUs 3, 4, and 5 and the associated TPS Train B are also operational. In Phase 3, the remaining IUs 6, 7, and 8 and the associated TPS Train C are operational.

SHINE Supplement Section 9a2.7.1 also states that each TPS train is designed to operate independently from the other TPS trains and contains its own instances of the isotope separation system, TPS-NDAS interface lines, secondary enclosure cleanup (SEC), vacuum/impurity treatment subsystem, NDAS SEC, and TPS glovebox. Each TPS train has its own tritium confinement boundary and is not impacted by the installation and testing of the other

trains. The interface points of uncompleted trains are isolated by manual valves, blind flanges, or caps, so that the installation of the new trains does not impact the operating trains.

Additionally, 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.

With respect to the TPS, SHINE Supplement section 13a2 identifies a new accident sequence and an increase in the likelihood of an existing scenario related to the phased approach to startup. 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 Appendix to the SER.

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 systems. The staff also finds that the isolation of systems that interface with the operating TPS trains is adequate to allow the completion of uncompleted items of construction during the phased approach to startup. Therefore, the staff concludes that the conclusions reached in SER Section 9a regarding the TPS are not affected by the proposed phased approach to startup and that the staff has reasonable assurance that the TPS can operate safely during all four phases and remain unimpacted by the completion of uncompleted items of construction during the four phases.

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 applicable 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 section 9b.1, "Heating, Ventilation, and Ari Condition Systems," states that the HVAC system for the main production facility are common to the IF and RPF. Phased startup operations of the main production facility HVAC systems are described in Section 9a2.1 of the SHINE Supplement.

SHINE Supplement section 9b.2.1, "Target Solution Lifecycle," states that the target solution lifecycle description provided in Section 9b.2.1 of the FSAR is not affected by phased startup operations, except that target solution is not delivered to the iodine and xenon purification and packaging (IXP) system during Phase 1 through Phase 3. The IXP system is not installed, process connections to IXP are isolated, and the IXP hot cell is isolated during Phase 1 through Phase 3, as described in Section 4b.2 and Section 4b.3 of the FSAR.

SHINE Supplement section 9b.2.2, "Receipt and Storage of Unirradiated SNM," states that the description of receipt and storage of unirradiated SNM provided in Subsection 9b.2.2 of the FSAR is not affected by phased startup operations.

SHINE Supplement section 9b.2.3, "Target Solution Preparation," states that the target solution preparation description provided in Subsection 9b.2.3 of the FSAR is not affected by phased startup operations.

SHINE Supplement section 9b.2.4, "Target Solution Staging System," states that the TSSS description provided in Subsection 9b.2.4 of the FSAR is not affected by phased startup operations.

SHINE Supplement section 9b.2.5, "Vacuum Transfer System," states that the VTS description provided in Subsection 9b.2.5 of the FSAR is not affected by phased startup operations, VTS is available for operation in Phase 1. During Phase 1 and Phase 2, interfacing VTS connections to IU specific instances of IU systems and components (i.e., TSV, TSV dump tank, and TOGS) are isolated as described in Section 4a2.1 of the SHINE Supplement (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 VTS connections to the IXP system are isolated as described in Section 4b.3. Isolating the interfaces to individual IU systems and the

IXP system does not affect the capability of the VTS to perform its functions for other system interfaces.

SHINE Supplement section 9b.2.6, “Radioactive Liquid Waste Storage,” states that the RLWS system description provided in Subsection 9b.2.6 of the FSAR is not affected by phased startup operations.

SHINE Supplement section 9b.2.7, “Radioactive Liquid Waste Immobilization,” states that the RLWI system description in Subsection 9b.2.7 of the FSAR is not affected by phased startup operations, except that the adsorption columns to remove selective isotopes (e.g., Sr-90, Cs-137) are not available during Phase 1 and Phase 2. Additional description of RLWI operations during phased startup operations is provided in Section 9b.7.3 of the SHINE Supplement.

SHINE Supplement section 9b.2.8, “Solid Waste Packaging and Shipment,” states that the solid radioactive waste packaging (SRWP) system description provided in Subsection 9b.2.8 of the FSAR is not affected by phased startup operations, except that the MATB is not available during Phase 1 and Phase 2. 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. Additional description of SRWP operations during phased startup operations is provided in Subsection 9b.7.5 of the SHINE Supplement.

SHINE Supplement section 9b.2.9, “Criticality Control,” states that inadvertent criticality is prevented in RPF systems involved in the processing of fissile materials through the application of the nuclear criticality safety program, described in Section 6b.3 of the SHINE Supplement.

SHINE Supplement section 9b.3, “Fire Protection Systems and Programs,” states that the fire protection system and program for the SHINE facility are common to the IF and RPF. As described in Section 9a2.3 of the FSAR, the fire protection program and facility fire protection systems are implemented in full to support Phase 1 operations.

SHINE Supplement section 9b.4, “Communications Systems,” states that the communication systems for the SHINE facility are common to the IF and RPF. As described in Section 9a2.4 of the FSAR, the facility data and communication system is installed in full to support Phase 1 operations.

SHINE Supplement section 9b.5, “Possession and Use of Byproduct, Source, and Special Nuclear Material” states that the possession and use of byproduct, source, and special nuclear material (SNM) described in Section 9b.5 of the FSAR is not affected by phased startup operations, except that the IXP system is not operational until Phase 4. During Phase 1 through Phase 3, radioactive material is not present in the IXP system, iodine-131 and xenon-133 is not produced or shipped, and the quality control and analytical testing laboratories (LABS) does not process iodine-131 and xenon-133 samples for analysis. Quantities of materials described in Section 9b.5 of the FSAR remain bounding for Phase 1 through Phase 4 operations.

SHINE Supplement sections 9b.6.1, “Process Vessel Vent System,” and 9b.6.2, “Nitrogen Purge System,” discuss the impact of the phased approach to startup on SHINE FSAR section 9b.6, “Cover Gas Control in the Radioisotope Production Facility,” specifically SHINE FSAR sections 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 IUs 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 the PVVS discussed above before discharging to the stack.

SHINE Supplement section 9b.7.1, “Molybdenum Isotope Product Packaging System,” states that the MIPS description provided in SHINE FSAR subsection 9b.7.1 is not affected by the phased approach to startup, except that IXP is not available during Phase 1 through Phase 3. During Phase 1 through Phase 3, MIPS is isolated from the IXP as described in SHINE Supplement section 4b.3. SHINE Supplement section 4b.3 is discussed in Section 9a2 of this appendix to the SER.

SHINE Supplement section 9b.7.2, “Material Handling System,” states that the material handling system (MHS) description provided in SHINE FSAR Subsection 9b.7.2 is not affected by the phased approach to startup. The SHINE FSAR implements the material handling program in accordance with NUREG-0612, which is applicable during the phased approach to startup. The IF and RPF overhead cranes will be installed prior to initial (i.e., Phase 1) operations.

SHINE Supplement section 9b.7.3, “Radioactive Liquid Waste Immobilization System,” states that 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 indicated that the RLWI description provided in SHINE FSAR Subsection 9b.7.3 is not affected by the phased approach to startup, except that the selective removal process is not available during Phases 1 and 2 and its interfacing connections are isolated with a valve and a blind flange or cap.

SHINE Supplement section 9b.7.4, “Radioactive Liquid Waste Storage System,” states that the RLWS description provided in SHINE FSAR subsection 9b.7.4 is not affected by the phased approach to startup, except that the IXP system is not available during Phase 1 through Phase 3. SHINE Supplement figure 6b.3-1, “Radioactive Liquid Waste System Overview,” provides an overview of RLWS connections applicable to Phases 1, 2, and 3, which is consistent with SHINE FSAR Figure 6b.2-2 without IXP system connection. During Phase 1 through Phase 3, interfacing RLWS connections to the IXP system are isolated with a manual valve and a blind flange or cap. SHINE Supplement Chapter 4b indicates that the RLWS does not collect liquid wastes from the IXP system, as described in SHINE FSAR subsection 4b.1.3.7.2, 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, “Solid Radioactive Waste Packaging System,” states that SRWP system is not affected by the phased approach to startup, 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 for Phase 3. Solidified waste generated during Phase 1 and Phase 2 are stored in the subgrade bore holes in the RPF. As indicated in SHINE Supplement section 9b.2.8, solid wastes generated during Phase 1 and Phase 2 are stored in the 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, “Radioactive Drain System,” states that the RDS description in SHINE FSAR subsection 9b.7.6 is not affected by the phased approach to startup, except that IXP system 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 SHINE Supplement section 4b.1, 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, “Facility Potable Water System,” states that the FPWS is not affected by the phased approach to startup.

SHINE Supplement section 9b.7.8, “Facility Nitrogen Handling System,” indicates that the FNHS is not affected by the phased approach to startup and will be available for operation in Phase 1. SHINE described the 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, “Facility Sanitary Drain System,” indicates that the facility sanitary drain system (FSDS) is not affected by the phased approach to startup. The system is nonsafety-related and functions normally during the phased approach to startup.

SHINE Supplement Section 9b.7.10, “Facility Chemical Reagent System,” states that the FCRS is not affected by the phased approach to startup and that the FCRS is available in Phase 1.

9b.2 Technical Evaluation

The NRC staff performed an evaluation of the technical information presented in SHINE Supplement chapter 9b using the guidance and acceptance criteria from section 9b, “Radioisotope Production Facility Auxiliary Systems,” 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 and the system isolations necessary for safe operation of the facility during the various phases and the completion of uncompleted items of construction as described in SHINE Supplement chapter 9b.

Heating, Ventilation, and Air Condition Systems

The HVAC system is common to both the IF and RPF. The NRC staff evaluated the HVAC system in section 9a2 of this SER appendix.

Handling and Storage of Target Material

SHINE Supplement section 9b.2 describes the impacts of the phased approach to startup to systems used in the handling and storage of target material. SHINE 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 Phase 3. The NRC staff evaluated and found acceptable the isolations to the IXP system in section 4b.2 of this appendix to the SER.

SHINE Supplement section 9b.2 also states that the receipt and storage of unirradiated SNM, target solution preparation, target solution staging system, and criticality control are not

impacted by the phased approach to startup. The NRC staff reviewed SHINE Supplement sections 9b.2.2, 9b.2.3, 9b.2.4, and 9b.2.9 and did not identify any potential safety impacts to these systems and processes as a result of the phased approach to startup.

SHINE Supplement section 9b.2.5 states that the VTS is not affected by the phased approach to startup. During Phase 1, the VTS interfaces to IUs 3 through 8 and IU system components will be isolated as described in SHINE Supplement section 4b.3. The NRC staff evaluated and found acceptable the isolations of the VTS in section 4a.2 of this appendix to the SER.

The NRC staff evaluates the impact of the phased approach to startup to the RLWI system and the SRWP system below. SHINE Supplement section 1.1 states, in part, that the full capability of the RLWI system and waste staging is included in Phase 3. In its evaluation below, the staff finds that the RLWI system and the SRWP system are available for Phase 1 and Phase 2 and are not affected by the phased approach to startup.

Process Vessel Vent System

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

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 and 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 NRC staff finds that the isolation provisions provided in the PVVS lines for the phased approach to 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 during the completion of uncompleted items of construction.

Nitrogen Purge System

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

During Phase 1 and Phase 2, interfacing N2PS connections to IU-specific instances of 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 and 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 or 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 NRC staff finds that the isolation provisions provided in the N2PS lines for the phased approach to 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 during the completion of uncompleted items of construction.

Molybdenum Isotope Product Packing System

SHINE Supplement section 9b.7.1 states that the MIPS 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 and that the MIPS is isolated from the IXP system during these phases. The NRC staff evaluated and found acceptable the isolations to the IXP system in section 4b.2 of this appendix to the SER.

Material Handling System

The MHS includes overhead cranes and hoists that are used to move or manipulate radioactive material in the 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 ensure that the potential for a heavy load drop during construction is small. As described in SHINE 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 the phased approach to startup because these systems will not be complete during Phase 1 and Phase 2 and, therefore, ongoing work may be in process. SHINE FSAR section 13b.1.2.3 discusses potential accidents involving heavy load handling near the RLWI shielded enclosure or supercell during the phased approach to startup to account for the increased likelihood of the initiating event because of the on-going completion of uncompleted items of construction. A crane failure or operator error resulting in a heavy load drop on the RLWI shielded enclosure or supercell would cause damage to the affected structure and internal equipment. To prevent a heavy load drop on the RLWI shielded enclosure or supercell, crane operation procedures include safe load paths to avoid the enclosure and supercell, and require suspension of supercell and RLWI activities during a heavy lift.

While SHINE Supplement section 9b.7.2 indicates that the MHS description provided in SHINE FSAR section 9b.7.2 is not affected by the phased approach to startup, it was unclear to the NRC staff whether NUREG-0612 controls will be applied during the phased approach to startup. During an audit on May 24, 2022, SHINE verified that the SHINE FSAR Section 9b.7.2 crane program, including safe load paths, will be implemented for Phase 1 and that NUREG-0612 safety features will be applied throughout the phased approach to startup. The observations from this audit are documented in an audit report (ML22287A185).

SHINE Supplement section 13b.1.2.3 describes SHINE's modification of its evaluation related to heavy load drop onto the RLWI shielded enclosure or supercell during the phased approach to startup to account for an increased likelihood of the initiating event because of the on-going completion of uncompleted items of construction. SHINE indicated that 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 SHINE FSAR section 9b.7.2 and NUREG-0612 will be applied, potential accident conditions with the use of the IF and RPF cranes are minimized. Based on the above, the NRC staff finds that the conclusions reached in SER section 9b.4.7.2 are not affected by the proposed phased approach to startup.

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 SHINE FSAR subsection 4b.1.3.8.2. Using the selective removal process, 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 the unavailability of this process, 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 the RLWI to maximize the decay time and to limit the volume of solidified waste requiring disposal. Estimated waste streams during the phased approach to startup are described in SHINE Supplement section 11.2.

Because the RLWI is available to support initial (i.e., Phase 1) operations, with the exception of the selective removal process, which is isolated during Phase 1 and Phase 2, the RLWI is available to solidify blended liquid waste. SHINE will also maximize the decay time and limit the volume of solidified waste requiring disposal during Phase 1 and Phase 2 when the MATB is unavailable. Based on the above, the NRC staff finds that the conclusions reached in SER section 9b.4.7.3 are not affected by the proposed phased approach to startup.

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 being sent 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 the RLWS is available to support initial (i.e., Phase 1) operations, with the exception of the IXP, which is isolated during Phase 1 through Phase 3, the RLWS is available to receive liquid waste. Based on the above, the NRC staff finds that the conclusions reached in SER section 9b.4.7.4 are not affected by the proposed phased approach to startup.

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 that there is adequate bore hole storage space for waste streams that may require encapsulation processing until the MATB is available during Phase 3.

Because the SRWP is available to handle solid waste, with the exception of the MATB, which is not available during Phase 1 and Phase 2, the NRC staff finds that the conclusions reached in SER section 9b.4.7.5 are not affected by the proposed phased approach to startup.

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 RDS operates by gravity drain, where overflows and leakage flow through installed piping drains directly to the RDS hold tanks.

Based on the RDS being functional and isolated from the collection of non-operational IXP process liquids or the overpressure protection for the IXP during Phase 1 through Phase 3, the RDS retains the ability to perform its function and the NRC staff finds that the conclusions reached in SER section 9b.4.7.6 are not affected by the proposed phased approach to startup.

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 FDWS and the FHWS. Because the FPWS interfaces contain backflow preventors to prevent inadvertent contamination from interfacing systems, the NRC staff finds that the conclusions reached in SER Section 9b.4.7.7 are not affected by the proposed phased approach to startup.

Facility Nitrogen Handling System

The FNHS is designed to supply liquid and compressed gaseous nitrogen to systems inside the RCA. As described in SHINE FSAR Section 9b.7.8, the FNHS is not relied upon to prevent accidents that could cause undue risk to the health and safety of the workers or the public or to control or mitigate the consequences of such accidents. SHINE Supplement Section 9b.7.8 summarizes the isolated interfaces for the FNHS 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 SHINE Supplement Section 4a2.1 (i.e., interfaces with IUs 3 through 8 are isolated during Phase 1 and interfaces with IUs 6 through 8 are isolated during Phase 2).

- During Phase 1 and Phase 2, interfacing FNHS connections to TPS trains are isolated as described in SHINE Supplement Section 9a2.7 (i.e., interfaces with TPS Train B and Train C are isolated during Phase 1 and 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 SHINE Supplement Section 4b.3.

Based on the availability of the FNHS for initial (i.e., Phase 1) operations and the isolation from the phase-dependent interfacing systems, the NRC staff finds that the FNHS retains the ability to support its function and is not affected by the proposed phased approach to startup.

Facility Sanitary Drain System

The FSDS collects domestic sanitary waste and wastewater outside the RCA and discharges it to a city sewer main. SHINE FSAR section 9b.7.9 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, the NRC staff finds that the conclusions reached in SER section 9b.4.7.9 are not affected by the proposed phased approach to startup.

Facility Chemical Reagent System

The FCRS provides storage and equipment for non-radioactive chemical reagents used in the SHINE processes. The SHINE Supplement describes that in Phase 1 and Phase 2, interfacing FCRS connections to IU-specific systems (i.e., TOGS) are isolated as described in SHINE Supplement section 4a2.1 (i.e., interfaces with IUs 3 through 8 are isolated during Phase 1 and 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 the availability of the FCRS for initial (i.e., Phase 1) operations and the isolation from the phase-dependent interfacing systems, the NRC staff finds that the FCRS retains ability to support its function and is not impacted by the proposed phased approach to startup.

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 applicable 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 in which workers are expected to be 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 the adjacent IU and TOGS cell 3. During Phase 2 with IU cells 1 through 5 operating, a worker could be in the adjacent IU and TOGS cell 6. In addition, the applicant provided information on the IXP hot cell dose rates for Phase 1 through Phase 3. During Phase 3 and Phase 4 for the IU and TOGS cells and during Phase 4 for the IXP hot cell, the occupational doses are expected to match the information in SHINE 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 for Phase 3. Any solidified waste generated during Phase 1 and Phase 2 will be stored in bore holes as discussed in SHINE FSAR Chapter 9b.

Radioactive waste streams expected to be produced during the phased approach to startup are provided in SHINE Supplement table 11.2-1, “Estimated As-Generated Annual Waste Stream Summary During Phased Startup Operations.” The radioactive waste streams expected to be disposed of during the phased approach to startup are provided in SHINE Supplement table 11.2-2, “Estimated As-Disposed Annual Waste Stream Summary During Phased Startup Operations.”

Releases of radioactive wastes are not affected by the phased approach to startup, except that the RLWI selective removal process is not available during Phase 1 and Phase 2, and the IXP system is not available during Phase 1 through Phase 3. The phased approach to startup entails that waste solidified during Phase 1 and Phase 2 may have higher dose rates and higher waste classifications than waste 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 the RLWI in order to maximize the decay time and to limit the volume of solidified waste requiring disposal.

11.2 Technical Evaluation

The NRC 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 its evaluation, the NRC staff determined the impacts of radiation exposures on workers that would work in non-operational cells adjacent to operational cells. The staff reviewed dose rates specified by the applicant and confirmed those results from the calculation files available to the staff during the audit conducted on May 26, 2022. The observations from this audit are documented in an audit report (ADAMS Accession No. ML22287A185. In its response dated August 1, 20222 (ML22213A049) to an RCI, 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 TSV near the south wall.

- The maximum dose rate in an adjacent 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 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.

Based on the above, the NRC staff finds that SHINE has an appropriate level of understanding of those areas that could be a concern for occupational exposures during the phased approach to startup. SHINE confirmed varying dose rates for these areas and acknowledged the use of radiation protection and ALARA work planning before entering these areas. Given this information and the commitments made in the SHINE FSAR, the staff has reasonable assurance that the SHINE facility will meet the ALARA guidelines in accordance with 10 CFR 20.1101(b).

The NRC staff review of the expected waste streams both produced and disposed of during the phased approach to startup determined that the information in SHINE Supplement tables 11.2-1 and 11.2-2 is consistent with the information provided in SHINE FSAR Table 11.2-1, as demonstrated by the fact that, as more IUs come online, the waste generation and disposal rates approach the values provided in SHINE FSAR Table 11.2-1. The information in SHINE Supplement tables 11.2-1 and 11.2-2 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. SHINE Supplement section 11.2.3, “Release of Radioactive Waste,” states that during Phase 1 and Phase 2, the solidified waste generated may have higher dose rates and waste classifications than would be observed in Phase 3 and Phase 4 because there is no RLWI selective removal process available. As a result, SHINE plans to maximize decay times using the below grade RLWS tanks prior to transfer to the RLWI.

Given that the MATB will not be used for the interim storage of waste until it is operational for Phase 3, SHINE stated that the use of the subgrade bore holes in the RPF will ensure that dose rates within the RFP remain ALARA. SHINE’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 because the bore holes are intended to be used for interim storage prior to disposals or movement into the MATB.

SHINE FSAR chapter 11 is not affected by the proposed phased approach to startup except for those areas discussed above. The applicant will continue to implement the Radiation Protection Program, the ALARA Program, the Radiation Monitoring and Surveying Program, and Radiation Exposure Control and Dosimetry, Contamination Control, Environmental Monitoring, and Radioactive Waste Management programs consistent with the information described in the SHINE FSAR. The applicant confirmed the expected dose rates and waste storage options at the facility during the completion of uncompleted items of construction. Based on the above, the staff finds that the SHINE Supplement appropriately addresses those areas where the phased approach to startup could be of concern for the issues of the radiation protection program and waste management.

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 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 applicable 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 proposed phased approach to startup was developed to minimize the complexities of maintaining process isolation and confinement requirements and to limit the number of physical locations where the completion of uncompleted items of construction would be occurring during operation to minimize the impacts on the operating portions of the facility. 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. Phase 4 adds iodine and xenon production capability.

SHINE used its SSA methodology described in SHINE FSAR chapter 13 to evaluate whether any new or different hazards are introduced by the phased approach to startup. Additional details on the safety analysis evaluation specific to the phased approach to startup are provided in SHINE Supplement chapter 13a2 and Chapter 13b. The results of this evaluation are that the phased approach to startup does not result in new accident categories, but does result in the following new accident sequences within the IF:

- 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 TOGS interface line during installation of the SCAS.

The results of the safety analysis evaluation specific to the phased approach to startup increased the likelihood of the following accident sequences within the IF:

- 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 RPF, the phased approach to startup does not result in new accident categories, but does result in the following new accident sequences:

- Improper target solution routing to the IXP cell, prior to Phase 4.
- Backflow of target solution to the IXP cell prior to Phase 4 operations.

The results of the safety analysis evaluation specific to the phased approach to startup increased the likelihood of the following accident sequences within the RPF:

- Heavy load drop onto the 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 chapter 13a2 and chapter 13b using the guidance and acceptance criteria from section 13a2, “Aqueous Homogeneous Reactor Accident Analyses,” and section 13b, “Radioisotope Production Facility Accident Analyses,” of the ISG augmenting NUREG-1537, Parts 1 and 2.

The SHINE IU systems are designed and operated at the unit level. The SHINE design criteria for each IU system, both general and system-specific, are met during all phases for the IU systems in operation. During each phase, the equipment necessary to support the operation of IU systems is functional and available for operation. As such, the ESFs required to mitigate the DBAs are not affected by the phased approach to startup. Additionally, support systems and auxiliary systems are installed prior to initial (i.e., Phase 1) operations. Support systems and process line interfaces with the IUs are isolated as needed to support the phased approach to startup.

Isolations at interface points with uninstalled systems are described throughout the SHINE 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 SHINE design criteria for the systems. As system installation progresses in preparation for the operation of the next phase, 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 the operable IUs 1 and 2 are operable. During Phase 2, the primary confinement boundaries for the operable IUs 1 through 5 are operable. The primary confinement boundaries for all 8 IUs are operable during Phase 3 and Phase 4. For the primary confinement boundaries for IUs that are not operable in Phase 1 and Phase 2, system isolations are in place to prevent the release of radiological or chemical hazards into the uninstalled IUs. For Phase 1, only Train A of the TPS is installed and supports the operation of IUs 1 and 2. For Phase 2, Trains A and B of the TPS are installed, with Train A supporting the IUs installed for Phase 1 (i.e., IUs 1 and 2) and Train B supporting the IUs installed for Phase 2 (i.e., IUs 3 through 5). For Phase 3 and Phase 4 operations, the IUs and TPS 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 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 that 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:

- RPCS supply and return lines.
- FNHS supply lines include one isolation valve.
- FCRS 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

SHINE Supplement section 13a2.1.4, “Mishandling or Malfunction of Target Solution,” identifies and evaluates the 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 prior to initial (i.e., Phase 1) operations and is maintained disconnected from power until the phase in which the associated IU is operable. Since this scenario has preventative measures in place, there are no radiological consequences. Based on the above, the NRC staff finds that the conclusions reached in SER section 13a.4.4 are not affected by the phased approach to startup.

System Interaction Events

SHINE Supplement section 13a2.1.4 identifies and evaluates the additional system interaction event of damage to a PVVS to TOGS interface line during installation of the SCAS during the phased approach to startup. The accident scenario of fire in the IF general area leading to damage of cooling room equipment was also modified and evaluated for an increased initiating event likelihood during the phased approach to startup. Errors during installation of SCAS equipment in a non-operable IU cell during Phase 1 or Phase 2 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 PCLS cooling in one or more IU cells or TOGS cells is modified during the phased approach to startup to account for an increased likelihood of the initiating event as a result of on-going completion of uncompleted items of construction. Radiological release due to this scenario is prevented by the credited controls currently in place. Since these events have preventative measures in place, there are no radiological consequences. Based on the above, the NRC staff finds that the conclusions reached in SER section 13a.4.11 are not affected by the phased approach to startup.

Facility-Specific Events

SHINE Supplement section 13a2.1.12, “Facility-Specific Events,” identifies and evaluates the additional facility-specific event of damage to an operating TPS train during the installation of another TPS train. The accident scenarios of a heavy load drop onto an open in-service IU cell or TOGS cell and a heavy load drop onto TPS equipment were also modified and evaluated for an increased initiating event likelihood during the phased approach to 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 could lead to a 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. This 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 sequence of a heavy load drop onto an in-service IU cell or TOGS cell and a heavy load drop onto TPS equipment is modified during the phased approach to startup to account for an increased likelihood of the initiating event as a result of on-going completion of uncompleted items of construction. These scenarios are prevented by a credited control currently in place (i.e., the single-failure-proof crane in the IF). Since these events have preventative measures in place, there are no radiological consequences. Based on the above, the NRC staff finds that the conclusions reached in SER section 13a.4.12 are not affected by the phased approach to startup.

Radioisotope Production Facility Critical Equipment Malfunction

SHINE Supplement section 13b.1.2.3, “RPF Critical Equipment Malfunction,” identifies and evaluates two additional RPF critical equipment malfunction scenarios of a target solution leak into the IXP cell. The initiating event in this 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 scenario, failure of the valve could cause leakage of target solution into the IXP cell, resulting in dose consequences to workers and the public. This scenario is prevented by a second locked closed manual valve between the MEPS and the IXP system, located in the IXP cell. The initiating event in the second RPF critical equipment malfunction scenario is the backflow of solution from the 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 was also modified and evaluated for an increased initiating event

likelihood during the phased approach to operations. 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 for control of heavy loads in the SHINE facility. Since these scenarios have preventative measures in place, there are no radiological consequences. Based on the above, the NRC staff finds that the conclusions reached in SER section 13a.4.6 are not affected by the phased approach to startup.

Radioisotope Production Facility Fire

SHINE Supplement section 13b.1.2.5, "RPF Fire," identifies and evaluates an increase in the initiating event likelihood for a fire in the RPF general area during the phased approach to startup operations, which resulted in an increase in the likelihood index for the initiating event. The new specific administrative control of suspension of radiological material processing in the adjacent cell during hot work was applied in addition to the existing RPF fire controls. Since this scenario has preventative measures in place, there are no radiological consequences. Based on the above, the NRC staff finds that the conclusions reached in SER section 13b.4.8 are not affected by the phased approach to startup.

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:

(1) 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 applicable 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 to the Application

SHINE identified that the proposed phased approach to startup has impacts on the SHINE SSA. These impacts and the evaluations of the impacts are summarized in the SHINE Supplement, including chapter 13, and a supplement to the SSA Summary (hereafter, the SSA Supplement), as amended. The evaluations include the identification of new accidents or revisions to accident evaluations in the SHINE FSAR and SSA and new safety-related controls to ensure that the new and revised accidents will not exceed the SHINE safety criteria as specified in SHINE FSAR section 3.1. SHINE's approach is to provide a supplement to the SSA Summary (i.e., the SSA Supplement) that addresses the impacts due to the phased approach to startup that is intended to address the facility, including operations and the impacts of the completion of uncompleted items of construction for all the phases prior to the phase (i.e., Phase 4) in which the facility is complete and fully operational in accordance with the SHINE FSAR. This SSA Supplement is a separate part of the SSA Summary that is to be removed when the final phase of the SHINE facility is complete and in operation.

13.5.2 Technical Evaluation

The purpose of the NRC staff's review regarding the phased approach to startup is to confirm that, with the SSA Supplement, the SSA and SHINE's safety program are adequate to ensure the health and safety of the public and workers during the phased approach to startup. The staff's review does this by evaluating the SSA Supplement to confirm:

- Consistency with the SHINE FSAR as modified by the SHINE Supplement for the phased approach to startup,

- The SSA Supplement demonstrates that impacts from the phased approach to startup have been identified and evaluated and that appropriate safety-related controls and reliability management measures have been identified and will be put in place to prevent or mitigate accident sequences so as to not exceed the SHINE safety criteria as specified in SHINE FSAR Section 3.1,

- Implementation of the SSA method in the SSA Supplement, and

- SHINE's approach to phased startup adequately implements SHINE's commitments regarding the SSA.

The NRC staff reviewed the SSA Supplement pursuant to the ISG augmenting NUREG-1537, Parts 1 and 2, which endorses the use of integrated safety analysis methodologies as described in 10 CFR Part 70 and NUREG-1520, but also allows for alternatives with adequate justification. For its review, the staff reviewed the SSA Supplement and the SHINE Supplement. The staff also referred to relevant sections of the SHINE FSAR and SSA to support its review of the supplements. As part of this review, the staff conducted an audit and issued a report for the phased approach to startup (ML22287A185).

As described in SHINE Supplement Section 1.1, 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. Phase 4 adds iodine and xenon production capability, at which point all

systems and processes will be in place in accordance with the descriptions in the SHINE FSAR and operating license application.

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

The NRC staff compared the information in the SHINE Supplement to that in the SHINE FSAR to understand the differences in the systems and operations and to identify differences in the facility and systems' configurations that could impact the safety analysis. Particularly, the staff sought to identify where differences could introduce new accident sequences or result in changes in consequences or likelihoods of analyzed accident sequences. The staff also looked to identify where new safety-related controls might be needed or where already identified safety-related controls may need to perform their functions differently or need different reliability management measures.

Through its review, the NRC staff identified configuration differences and activities that the staff considered as having the potential for accident sequences of increased consequences (e.g., leak of materials through connections to yet-to-be-installed systems or system components), introducing new accident sequences, or increasing likelihoods of accident sequences, including due to human error (e.g., errors in performing activities associated with the completion of uncompleted items of construction affecting already installed and operating facility systems). . The staff also considered that the amount of licensed material being processed in earlier phases will be less (i.e., fewer IUs in operation), which means that the consequences for some accidents will be less than that analyzed in the SSA because the material available for release will be less as compared to full facility operation.

Based on the information in the SHINE Supplement, the NRC staff identified components and personnel actions that would seem to be needed and relied on to prevent or mitigate accidents during the different phases. The staff reviewed systems descriptions in the SHINE FSAR to determine if and how these components had been described. The staff also audited the SSA Summary to determine if and how these components and personnel actions had been identified and evaluated as safety-related controls. Additionally, the staff considered whether differences in configuration would affect those components identified as safety-related controls in terms of their safety function (e.g., continuous isolation vs. isolation upon demand). The staff further considered that components that are not relied on as safety-related controls for the full facility could be needed as safety-related controls during one or more phases prior to the final phase where the facility is complete and fully operational. Certain operations, such as those to be done in the MATB, would be done in a different location within the radiological controlled area. Thus, in its review, the staff determined whether the operations, including safety-related controls, would be conducted in the same manner and how the operations being in a different location may impact other facility operations. Additionally, as part of the phased approach to startup, uncompleted items of construction will be completed while installed systems are operating.

The NRC staff then reviewed SHINE Supplement chapter 13 and the SSA Supplement to determine whether the applicant's accident analysis adequately addresses the potential impacts that the staff identified from its review. The applicant identified that the phased approach to startup introduced a limited number of new accident sequences. The applicant also identified that the phased approach to startup affected a few of the accident sequences in the SSA in a way that increased likelihoods or consequences. For those accident sequences where the likelihoods or consequences were reduced, the applicant did not perform a new evaluation. The staff considered whether there may be additional accident sequences, either new or affected sequences (with higher likelihoods or greater consequences), from the completion of

uncompleted items of construction (e.g., heavy load drops), potential human error-induced events, and differences in operations arising from systems being not yet installed during certain phases. Based on this review and evaluation of the descriptions of the differences between the facility and facility systems during the earlier phases of startup versus the final phase regarding the considerations identified above, the staff finds that the applicant has identified and evaluated the appropriate accident sequences for the phased approach to startup.

To ensure that the new and modified accident sequences do not exceed the SHINE safety criteria as described in SHINE FSAR Section 3.1, the applicant identified new engineered and administrative safety-related controls. In its review of the SHINE Supplement, the NRC staff determined that a number of valves are relied on for isolation of connections to uninstalled systems. SHINE Supplement chapter 13 and the SSA Supplement only identify a few of these valves as new safety-related controls. Therefore, the staff reviewed the system descriptions in the SHINE FSAR and the SSA Summary to determine whether these documents already identify the remaining valves discussed in the SHINE Supplement as part of the facility's systems' designs and as safety-related controls. For any valves not described in the SHINE FSAR and SSA Summary as part of the systems' designs and safety-related controls, the staff used the information in the SHINE FSAR and SHINE Supplement to evaluate whether the SSA Supplement and SHINE Supplement Chapter 13 should identify them as safety-related controls.

Based on this review, the NRC staff determined that some of these valves are already part of the systems' designs and are already identified as safety-related controls in the SSA Summary. Also, some safety-related controls in the SSA Summary involve multiple systems, structures, and components (e.g., controls identified for confinement functions). Valves that are added to or included among the systems, structures, and components identified to be part of such safety-related controls and that are used for isolation during the phased approach to startup would then be part of that safety-related control. Also, some of the valves need not be safety-related controls because the nature of the accident that they would prevent is captured already by accidents evaluated in the SSA without the need to rely on these valves. Thus, the staff finds that the applicant appropriately identified those valves that should be new safety-related controls.

The NRC staff also considered the reliability management measures for the new safety-related controls and for those safety-related controls (including those controls that are valves) that are identified in the SSA Summary and that are also relied on in the SSA Supplement. The staff reviewed whether the reliability management measures are appropriate for the type and nature of the control and how the control performs the required function. In this review, the staff confirmed that measures identified for engineered controls are appropriate for engineered controls and that measures identified for administrative controls are appropriate for administrative controls. The staff also identified that the measures are consistent with the nature of the control. The staff's review included consideration of differences in how the control performs its function and the potential differences in the nature of the accidents they control (whether prevention or mitigation) for the earlier phases of startup versus the final phase (e.g., valves that perform continuous isolation versus isolation on demand). The staff considered that these differences have potential implications for the reliability management measures that would be necessary for these controls. In its review, the staff determined that the applicant adequately accounted for these considerations. The staff also determined that the identified reliability management measures do not include items that are in fact administrative safety-related controls.

Based on its review of the SHINE FSAR and the SSA Summary, as modified by the SHINE Supplement and the SSA Supplement, the NRC staff finds that the SSA Supplement is consistent with the SHINE FSAR, as modified by the SHINE Supplement, for the phased approach to startup. The staff also finds that the SSA Supplement demonstrates that the applicant has adequately identified and evaluated the impacts from the phased approach to startup and has identified appropriate safety-related controls and reliability management measures to prevent or mitigate accident sequences. Therefore, the staff has reasonable assurance that operations of the SHINE facility will not exceed the SHINE safety criteria, thus ensuring the health and safety of the public and workers.

13.5.4 SSA Method Implementation

The applicant used the same SSA methods for the analysis of the phased approach to startup as for the SSA for the operating license application, which is summarized in SHINE FSAR Section 13a2. Thus, the NRC staff's review of the SSA Supplement included confirmation that the SSA methods were implemented appropriately in the SSA Supplement. The staff considered the accident sequence evaluations in the SSA Supplement. The staff also considered the identification and evaluation of safety-related controls and the identification of reliability management measures in the SSA Supplement. These considerations include the failure frequency and failure probability indices that the applicant assigned to the safety-related controls. Based on this review, the staff determined that the evaluations in the SSA Supplement are consistent with the applicant's SSA method and, therefore, the staff finds that the applicant appropriately implemented its SSA method for evaluating the phased approach to startup.

13.5.5 SSA Implementation

The SSA needs to be maintained to ensure that it reflects the as-built and as-operated facility, including as it is described in the SHINE FSAR, and that the SSA demonstrates that the facility ensures the health and safety of the public and workers. Management of the SSA also ensures that the necessary safety-related controls and their reliability management measures are identified and maintained, with appropriate controls exercised over changes to them, particularly for those safety-related controls that are not captured in TSs.

SHINE's approach in support of the phased approach to startup is to append a supplement to the SSA (i.e., the SSA Supplement), which will be removed when the facility is in Phase 4. However, the NRC staff notes that the management of the SSA, including SHINE's configuration management program in TS 5.5.4 and the SHINE nuclear safety program in TS 5.5.1, applies to the as-built facility and as facility operations progress from phase to phase. This includes following SHINE's change control program and ensuring that the SSA, with the SSA Supplement, reflect the as-built and as-operated facility, including the impacts of any ongoing completion of uncompleted items of construction in each phase. Thus, SHINE will need to perform the activities and evaluations at each phase to maintain the SSA.

The SSA Supplement is part of the SSA Summary. Thus, with the SSA Supplement including accident sequences that are similar to those in the SSA Summary, the NRC staff considers it important that the sequences in the SSA Supplement be adequately distinguishable from those similar sequences in the SSA Summary. Otherwise, the same accident sequence will have two different, concurrent analyses that indicate different consequences or frequencies for the same initiating events or include new safety-related controls in order to not exceed the SHINE safety criteria. This would seem to be inconsistent with the commitment to maintain the SSA Summary and the purpose of that commitment. In its review, the staff identified that accident sequences in

the SSA Supplement that are similar to sequences in the SSA Summary have descriptions that distinguish them from each other such that it is sufficiently clear that they are different accident sequences. Based on the applicant's modifications and explanations, the staff finds the applicant's approach to the SSA for evaluating the phased approach to startup to be acceptable and consistent with the purpose of the SSA.

13.5.6 Conclusion

Based on its review of the SHINE FSAR, as modified by the SHINE Supplement; the SSA, as modified by the SSA Supplement; the TSs; and SHINE's commitments captured in the SHINE FSAR and TSs, the NRC staff finds that:

- The SSA Supplement is consistent with the SHINE FSAR, as modified by the SHINE Supplement for the phased approach to startup;

- The SSA Supplement demonstrates that the applicant has adequately identified and evaluated the potential safety impacts from the phased approach to startup and has identified appropriate safety-related controls and reliability management measures to prevent or mitigate accident sequences;

- The applicant appropriately implemented its SSA method in evaluating the phased approach to startup, and the staff finds this SSA method acceptable; and

- The applicant's approach to the SSA for evaluating the phased approach to startup is consistent with its commitments regarding the SSA and with the purpose of the SSA.

Therefore, based on these findings, the NRC staff has reasonable assurance that operations of the SHINE facility will not exceed the SHINE safety criteria and that SHINE's SSA, with the SSA Supplement, and SHINE's safety program will be adequate for ensuring the health and safety of the public and workers during the phased approach to startup in accordance with 10 CFR 50.34(b)(2) and 10 CFR 50.57(a)(3).

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 technical specifications (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.