



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

August 25, 2022

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

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – REQUEST FOR ADDITIONAL INFORMATION RELATED TO THE OFFICE OF THE GENERAL COUNSEL REVIEW OF THE PHASED STARTUP OPERATIONS APPLICATION SUPPLEMENT (EPID NO. L-2022-NEW-0004)

Dear Dr. Piefer:

By letter dated January 27, 2022 (Agencywide Documents Access and Management System Accession No. ML22027A353), SHINE Medical Technologies, LLC (SHINE) submitted to the U.S. Nuclear Regulatory Commission (NRC) "Application for an Operating License Supplement No.15, Submittal of the Phased Startup Operations Application Supplement," related to its operating license application for its proposed SHINE Medical Isotope Production Facility in accordance with the requirements contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions."

During the NRC staff's review of SHINE's phased startup operations application supplement, questions have arisen for which additional information is needed. The enclosed request for additional information (RAI) identifies information needed for the NRC staff to continue its review of the SHINE final safety analysis report, submitted in connection with the operating license application and phased startup operations application supplement, and prepare a safety evaluation report. The specific topic covered by these RAIs is SHINE's proposed phased approach to initial operations of the SHINE facility.

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

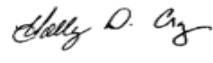
In accordance with 10 CFR 50.30(b), "Oath or affirmation," SHINE must execute its response in a signed original document under oath or affirmation. The response must be submitted in accordance with 10 CFR 50.4, "Written communications." Information included in the response that is considered sensitive or proprietary, that SHINE seeks to have withheld from the public, must be marked in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." Any information related to safeguards should be submitted in accordance with 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

Following receipt of the additional information, the NRC staff will continue its evaluation of the subject chapters and technical areas of the SHINE operating license application. As the NRC

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

If SHINE has any questions, or needs additional time to respond to this request, please contact me at (301) 415-1053, or via electronic mail at Holly.Cruz@nrc.gov.

Sincerely,

 Signed by Cruz, Holly
on 08/25/22

Holly D. Cruz, Senior Project Manager
Non-Power Production and Utilization
Facility Licensing Branch
Division of Advanced Reactors and Non-Power
Production and Utilization Facilities
Office of Nuclear Reactor Regulation

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

Enclosure:
As stated

cc w/enclosure: See next page

SHINE Medical Technologies, LLC

Docket No. 50-608

cc:

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SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – REQUEST FOR ADDITIONAL INFORMATION RELATED TO THE OFFICE OF THE GENERAL COUNSEL REVIEW OF THE PHASED STARTUP OPERATIONS APPLICATION SUPPLEMENT (EPID NO. L-2022-NEW-0004) DATED: AUGUST 25, 2022

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ADAMS Accession No.: ML22105A110

NRR-088

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OFFICE OF NUCLEAR REACTOR REGULATION
REQUEST FOR ADDITIONAL INFORMATION REGARDING
PHASED STARTUP OPERATIONS APPLICATION SUPPLEMENT
TO OPERATING LICENSE APPLICATION
CONSTRUCTION PERMIT NO. CPMIF-001
SHINE MEDICAL TECHNOLOGIES, LLC
SHINE MEDICAL ISOTOPE PRODUCTION FACILITY
DOCKET NO. 50-608

By letter dated January 27, 2022 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML22027A353), SHINE Medical Technologies, LLC (SHINE) submitted to the U.S. Nuclear Regulatory Commission (NRC) "Application for an Operating License Supplement No.15, Submittal of the Phased Startup Operations Application Supplement," related to its operating license application for its proposed SHINE Medical Isotope Production Facility in accordance with the requirements contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions."

During the NRC staff's review of SHINE's phased startup operations application supplement, questions have arisen for which additional information is needed. This enclosed request for additional information (RAI) identifies information needed for the NRC staff to continue its review of the SHINE final safety analysis report (FSAR), submitted in connection with the operating license application and phased startup operations application supplement, and prepare a safety evaluation report (SER). The specific topic covered by these RAIs is SHINE's proposed phased approach to initial operations of the SHINE facility.

Background

By letters dated March 26, 2013, May 31, 2013, and September 25, 2013 (ADAMS Accession Nos. ML13088A192, ML13172A361, and ML13269A378, respectively), as supplemented, SHINE submitted to the NRC a construction permit application for the SHINE facility. The SHINE construction permit application proposed a single facility for the manufacture of medical radioisotopes that would include both an irradiation facility (IF) and a radioisotope production facility (RPF). In turn, the IF would consist of eight irradiation units (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 NRC 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 NRC staff amended the NRC's

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definition of “utilization facility” at 10 CFR 50.2, “Definitions,” 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 authorizing the construction of the SHINE facility and its eight utilization facilities and one production facility, designed for the production of medical radioisotopes.

By letter dated February 26, 2021 (ADAMS Accession No. ML21057A340), SHINE informed the NRC staff of 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 main production facility structure and the nitrogen purge system structure, (2) the installation of IUs 1 and 2 and all associated auxiliary and support systems, and (3) the completion of the RPF and the installation of tritium purification system (TPS) train A. 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 radioactive liquid waste immobilization system (RLWI) selective removal components and the material staging building (MATB). Phase 4 would include the installation of iodine and xenon purification and packaging components.

In its “Application for an Operating License Supplement No.15, Submittal of the Phased Startup Operations Application Supplement,” SHINE supplemented its operating license application to describe the impacts of its proposed phased approach to initial operations 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 instrumentation and control 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 included FSAR Figure 1.1-1, “Physical Layout of Phased Approach to Operation,” which shows the entire SHINE facility and the portions of it that would be installed at each phase, with the vast majority installed as part of Phase 1.

On February 16, 2022, before the Advisory Committee on Reactor Safeguards non-power production or utilization facility subcommittee, a representative of SHINE further explained that with respect to the installation of the IUs, for the most part, their systems are on skids that will get mounted to the facility (ADAMS Accession No. ML22060A150).

Issue

In its “Application for an Operating License Supplement No.15, Submittal of the Phased Startup Operations Application Supplement,” SHINE explains the safety impacts of its proposed phased approach to initial operations of the SHINE facility. The NRC staff requests additional information on how SHINE intends to satisfy the NRC’s regulations for licensing the SHINE facility under this approach, in order for the NRC staff to understand the timing and to develop appropriate language for any operating license that may be issued.

Applicable Regulatory Requirements and Guidance Documents

The NRC staff is reviewing the SHINE operating license application and phased startup operations application supplement, using the applicable regulations, as well as the guidance contained in NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content,” issued February 1996 (ADAMS Accession No. ML042430055), and NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” issued February 1996 (ADAMS Accession No. ML042430048). The NRC staff is also using the “Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012 (ADAMS Accession No. ML12156A069), and “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012 (ADAMS Accession No. ML12156A075). As applicable, additional guidance cited in SHINE’s FSAR or referenced in NUREG-1537, Parts 1 and 2, or the ISG Augmenting NUREG-1537, Parts 1 and 2, has been utilized during this review.

For the purposes of this review, the term “reactor,” as it appears in NUREG-1537, the ISG Augmenting NUREG-1537, and other relevant guidance can be interpreted to refer to SHINE’s “IU,” “IF,” or “RPF,” as appropriate within the context of the application and corresponding with the technology described by SHINE in its application. Similarly, for the purposes of this review, the term “reactor fuel,” as it appears in the relevant guidance listed above, may be interpreted to refer to SHINE’s “target solution.”

Section 50.57, “Issuance of operating license,” paragraph (a) of 10 CFR 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...” Section 50.57(b) of 10 CFR 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.”

Inspection Procedure (IP) 69022, "Inspections of Operational Readiness during Construction of Non-Power Production and Utilization Facilities" (ADAMS Accession No. ML19193A110), states 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, in part:

At the time a licensee notifies the NRC that construction is substantially complete, the NRC expects that the safety-related Structures, Systems, and Components (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.

Requests for Additional Information

The RAIs that follow are intended to ensure that SHINE's proposed phased approach to initial operations of the SHINE facility is consistent with the NRC's regulations and is appropriately reflected in the timing and language of any operating license that may be issued.

RAI Phased-1 Pursuant to 10 CFR 50.57(a), unless the NRC finds that the construction of a "facility" has been "substantially completed," it may not issue an operating license for the facility. Pursuant to 10 CFR 50.57(b), each operating license will include such conditions as are required to assure that operation during the period of the completion of uncompleted items of construction will not endanger public health and safety. Based on these regulations, SHINE needs to address (1) how it interprets the term "facility" in 10 CFR 50.57(a) with respect to its operating license application, (2) how it interprets the term "substantially completed," in 10 CFR 50.57(a) with respect to this "facility" and, thus, when it believes that an operating license could be issued for the facility, and (3) what conditions it believes would need to be included in this license to satisfy 10 CFR 50.57(b).

-a Identify where in the operating license application, as amended, SHINE addresses, under its proposed phased approach to initial operations, (1) how the "substantially completed" criterion of 10 CFR 50.57(a) applies to the construction of the SHINE facility and (2) the license conditions that would be included, pursuant to 10 CFR 50.57(b), in any operating license to be issued pertaining to the installation of each grouping of IUs and their associated auxiliary and support systems and TPS train (i.e., IUs 1 and 2 and TPS train A (Phase 1); IUs 3, 4, and 5 and TPS train B (Phase 2); and IUs 6, 7, and 8 and TPS train C (Phase 3)) and the installations of RLWI selective removal components and the MATB (Phase 3) and iodine and xenon purification and packaging components (Phase 4). Otherwise, provide this information in response to this RAI.

- b** Explain how SHINE interprets the term “facility” in 10 CFR 50.57(a) in light of SHINE’s proposed phased approach to initial operations and SHINE’s previous descriptions of the SHINE facility in its construction permit and operating license applications. Does “facility” refer to the entire SHINE facility, to each phase of the SHINE facility, or to something else?
- c** If SHINE interprets the term “facility” in 10 CFR 50.57(a) to refer to the entire SHINE facility, explain when the construction of the entire SHINE facility will be “substantially complete,” as that term is used in 10 CFR 50.57(a) and discussed in IP 69022. For example, will the construction of the entire SHINE facility be substantially completed upon the completion of Phase 1, upon the completion of Phase 2, at some other defined point in time prior to the completion of Phase 4, etc.? Reflect in this response such factors as the percentage of the SHINE facility that would be completed, as well as the extent and location of the remaining construction activities as compared to those that have already been completed (e.g., whether throughout the facility or at discrete locations in the facility). Finally, explain when the facility would be functionally complete with respect to its purpose, stated in the construction permit as “the production of medical radioisotopes, as described in the [construction permit] application,” and whether this impacts the determination of when the construction of the entire SHINE facility has been substantially completed.
- d** If significant construction activities would remain to be completed after the point in time at which SHINE considers the construction of the entire SHINE facility to be substantially completed then, consistent with 10 CFR 50.57(b), provide the license conditions that would be required to be included in any operating license that may be issued to ensure that operation during the remainder of construction (e.g., during Phases 2, 3, and 4 if construction is considered to be substantially completed at the completion of Phase 1) will not endanger public health and safety. For example, in order to ensure that the related uncompleted items of construction are completed before SHINE operates any uncompleted phases, provide a license condition that would ensure that SHINE may proceed to operate subsequent phases only upon notifying the NRC (e.g., by written submission) of the completion of all uncompleted items of construction related to those phases. Similarly, in order to support the NRC oversight of the uncompleted items of construction, provide a license condition that would ensure that, prior to the operation of Phase 4, SHINE will provide to the NRC (e.g., through periodic reports) information on the status of uncompleted items of construction and the current schedule for the completion of significant milestones regarding the uncompleted items of construction.
- e** If SHINE interprets the term “facility” in 10 CFR 50.57(a) to refer to each phase of the SHINE facility (as opposed to the entire SHINE facility), explain how the application supports the issuance of an operating license upon the substantial completion of construction of Phase 1 that would authorize the operation of just Phase 1 and how the licensing Phases 2–4 would be accomplished. For example, would SHINE plan to request amendments to this operating license for each of the three remaining phases (i.e., submit a Phase 2 license amendment request (LAR), a Phase 3 LAR, and a Phase 4 LAR)? If so, would these LARs have new information or refer to the information in the NRC staff’s

SER on the operating license application? Explain when SHINE would submit each LAR in relation to the timing of the substantial completion of construction of each phase and what SHINE would request as the effectiveness date and implementation date for each LAR.

-f If SHINE interprets the term “facility” in 10 CFR 50.57(a) to refer to something other than the entire SHINE facility or to each phase of the SHINE facility, then explain this interpretation and how it would affect (1) the timing of the “substantially completed” finding/operating license issuance under 10 CFR 50.57(a) and (2) the conditions that would have to be included in the license under 10 CFR 50.57(b).

-g However SHINE may interpret the term “facility” in 10 CFR 50.57(a), does SHINE plan to operate this facility before its construction is substantially completed? If so, how would this approach be consistent with the NRC’s regulations? Would SHINE request an exemption from 10 CFR 50.57(a)? If so, how would SHINE ensure that operation during the period of the completion of construction will not endanger public health and safety? For example, would the operating license include license conditions that prohibit the operation of each uncompleted phase? Upon the completion of each of these phases, would SHINE then remove these prohibitions from the operating license through license amendments?

RAI Phased-2 The FSAR states that RLWI solidification equipment is available in Phase 1, but that the RLWI selective removal process is not available until Phase 3. Therefore, waste solidified during Phases 1 and 2 may have higher dose rates and higher waste classifications than wastes solidified during Phases 3 and 4. The FSAR further states that the MATB is not available until Phase 3. Therefore, solidified waste generated during Phases 1 and 2 would be stored in the subgrade bore holes in the RPF with additional radioactive storage areas available within the radiologically controlled area of the main production facility.

-a Given the above information, is there a point in time, prior to the installation of RLWI selective removal components and the MATB, at which the waste generated by the continuous operation of Phases 1 and 2 could exceed the SHINE facility’s waste storage capabilities (if waste disposal shipments are discounted)? If so, provide a conservative estimate for this point in time.

-b Propose a license condition that would ensure sufficient waste storage capabilities at the SHINE facility during the proposed phased approach to initial operations of the SHINE facility. For example, such a condition could state that if the installation of RLWI selective removal components and the MATB is not completed prior to the point in time at which the SHINE facility’s waste storage capabilities could be exceeded, SHINE will either cease activities that could lead to the generation of additional waste or calculate, based on current circumstances, a new point in time at which the SHINE facility’s waste storage capabilities could be exceeded.

RAI Phased-3 The January 27, 2022, supplement to the operating license application states that normal operation of the SHINE facility within the limits of the proposed technical specifications (TSs) during the proposed phased approach to initial

operations of the SHINE facility will not result in offsite radiation exposure in excess of 10 CFR Part 20, "Standards for Protection against Radiation," guidelines. However, this does not address whether the language of the proposed TSs needs to be modified to reflect that a SHINE facility operating license could be issued before the completion of Phases 2, 3, or 4. Therefore, identify any language in the proposed TSs that would be affected by SHINE's proposed phased approach and propose changes to this language that would account for the phased approach.