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

December 2, 2021

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

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – ISSUANCE OF AMENDMENT NO. 2 TO CONSTRUCTION PERMIT NO. CPMIF-001 FOR THE SHINE MEDICAL ISOTOPE PRODUCTION FACILITY RELATED TO THE RECEIPT AND POSSESSION OF CERTAIN RADIOACTIVE MATERIALS (EPID NO. L-2021-LLA-0104)

Dear Dr. Piefer:

The U.S. Nuclear Regulatory Commission (the Commission) has issued the enclosed Amendment No. 2 to Construction Permit No. CPMIF-001 for the SHINE Medical Technologies, LLC (SHINE) Medical Isotope Production Facility. The amendment adds two new conditions, 3.E and 3.F, and a new finding related to these conditions to the construction permit in response to the application dated April 29, 2021 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21119A165), as supplemented on August 20, 2021 and December 2, 2021 (ADAMS Accession Nos. ML21242A028 and ML21336A193, respectively). The amendment allows the receipt and possession of certain radioactive materials to be installed during the construction of the SHINE Medical Isotope Production Facility.

A copy of the related Safety Evaluation is also enclosed. The Notice of Issuance will be included in the Commission's monthly *Federal Register* notice.

If you have any questions, please contact Michael Balazik at (301) 415-2856, or by e-mail at Michael.Balazik@nrc.gov.

Sincerely,

Signed by Balazik, Michael
on 12/02/21

Michael F. Balazik, Project Manager
Non-Power Production and Utilization Facility
Licensing Branch
Division of Advanced Reactors and Non-Power
Production and Utilization Facilities
Office of Nuclear Reactor Regulation

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

Enclosures:
1. Amendment No. 2 to
   Construction Permit No. CPMIF-001
2. Safety Evaluation

cc w/enclosures: See next page

cc:

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SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – ISSUANCE OF AMENDMENT NO. 2 TO CONSTRUCTION PERMIT NO. CPMIF-001 FOR THE SHINE MEDICAL ISOTOPE PRODUCTION FACILITY RELATED TO THE RECEIPT AND POSSESSION OF CERTAIN RADIOACTIVE MATERIALS (EPID NO. L-2021-LLA-0104) DATED: DECEMBER 2, 2021

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ADAMS Accession No.: ML21320A225 **NRR-058**

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DATE	11/16/2021	11/17/2021	12/2/2021	11/29/2021
OFFICE	NMSS/REFS/ERLRB/BC	NRR/DANU/UNPL/BC	NRR/DANU/UNPL/PM	
NAME	RElliott	JBorromeo	MBalazik	
DATE	11/18/2021	11/19/2021	12/2/2021	

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SHINE MEDICAL TECHNOLOGIES, LLC

DOCKET NO. 50-608

SHINE MEDICAL ISOTOPE PRODUCTION FACILITY

AMENDMENT TO CONSTRUCTION PERMIT

Amendment No. 2
Construction Permit No. CPMIF-001

1. The U.S. Nuclear Regulatory Commission (the Commission) has found that:

   A. The application for an amendment to Construction Permit No. CPMIF-001 filed by SHINE Medical Technologies, LLC (the licensee) on April 29, 2021, as supplemented on August 20, 2021 and December 2, 2021, complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations set forth in Title 10 of the *Code of Federal Regulations* (10 CFR) Chapter I;

   B. The facility will be constructed in conformity with the application, as supplemented, the provisions of the Act, and the rules and regulations of the Commission;

   C. There is reasonable assurance that (i) the activities authorized by this amendment can be conducted without endangering the health and safety of the public, and (ii) such activities will be conducted in compliance with the Commission's regulations;

   D. The issuance of this amendment will not be inimical to the common defense and security or to the health and safety of the public; and

   E. The issuance of this amendment is in accordance with 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," of the Commission's regulations and all applicable requirements have been satisfied.

2. Accordingly, Construction Permit No. CPMIF-001 is amended as indicated in the attachment to this amendment.

3. This amendment is effective as of its date of issuance and shall be implemented within 90 days.

FOR THE NUCLEAR REGULATORY COMMISSION

Joshua M. Borromeo

Digitally signed by Joshua M. Borromeo

Joshua M. Borromeo, Chief
Non-Power Production and Utilization Facility
Licensing Branch
Division of Advanced Reactors and Non-Power
Production and Utilization Facilities
Office of Nuclear Reactor Regulation

Attachment:
Changes to Construction
Permit No. CPMIF-001

Date of Issuance: December 2, 2021

ATTACHMENT TO AMENDMENT NO. 2

SHINE MEDICAL ISOTOPE PRODUCTION FACILITY

CONSTRUCTION PERMIT NO. CPMIF-001

DOCKET NO. 50-608

Replace the following pages of Construction Permit No. CPMIF-001 with the attached revised pages. The revised pages are identified by amendment number and contain marginal lines indicating the areas of change.

Construction Permit No. CPMIF-001

Remove	Insert
1	1
2	2
3	3
4	4

SHINE MEDICAL TECHNOLOGIES, LLC

DOCKET NO. 50-608

MEDICAL ISOTOPE PRODUCTION FACILITY

CONSTRUCTION PERMIT

Amendment No. 2
Construction Permit No. CPMIF-001

1. The Nuclear Regulatory Commission (NRC or the Commission) has found that:

   A. The application for a construction permit, as supplemented and revised (the application), filed by SHINE Medical Technologies, LLC (SHINE, the applicant), complies with the requirements of the Atomic Energy Act of 1954, as amended (the Act), and the rules and regulations of the Commission set forth in Title 10 of the *Code of Federal Regulations* (10 CFR) Chapter I – Nuclear Regulatory Commission. There is reasonable assurance that the activities authorized by the permit will be conducted in compliance with the rules and regulations of the Commission, and all required notifications to other agencies or bodies have been duly made;

   B. The applicant has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public;

   C. Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report;

   D. Safety features or components, if any, which require research and development have been described by the applicant. The applicant has identified, and will conduct, a research and development program reasonably designed to resolve any safety questions associated with such features or components;

   E. On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for the completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100,[1] the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public;

[1] While the site criteria contained in 10 CFR Part 100 are applicable to nuclear power reactors, and not the SHINE facility, the staff considered in Chapter 2 of its safety evaluation report, site-specific conditions similar to those listed in 10 CFR Part 100. Using the guidance in NUREG-1537, the staff evaluated SHINE's analysis of site geography and demography; nearby industrial, transportation, and military facilities; site meteorology; site hydrology; and site geology, seismology, and geotechnical engineering to ensure that issuance of the permit will not be inimical to the common defense and security or to the health and safety of the public.

F. The processes to be performed provide reasonable assurance the applicant will comply with the regulations in 10 CFR Chapter I, including the regulations in 10 CFR Part 20, and that the health and safety of the public will not be endangered.;

G. SHINE is technically qualified to design and construct the facility in accordance with the Commission's regulations set forth in 10 CFR Chapter I;

H. SHINE is financially qualified to design and construct the facility in accordance with the Commission's regulations set forth in 10 CFR Chapter I;

I. The issuance of a permit for the construction of the facility will not be inimical to the common defense and security or to the health and safety of the public; and

J. After weighing the environmental, economic, technical and other benefits of the facility against environmental and other costs and considering reasonable available alternatives, the issuance of this construction permit, subject to the conditions for protection of the environment set forth herein, is in accordance with Subpart A of 10 CFR Part 51 of the Commission's regulations and all applicable requirements have been satisfied.

K. The receipt and possession of byproduct and source material as authorized by this license will be in accordance with the Commission's regulations in 10 CFR Parts 30 and 40.

2. On the basis of the foregoing findings regarding this facility, construction permit No. CPMIF-001 is hereby issued to SHINE pursuant to Sections 103 and 185a of the Act and 10 CFR Part 50 for eight utilization facilities and one production facility designed for the production of medical radioisotopes, as described in the application, filed in this matter by the applicant and as more fully described in the evidence received at the public hearing upon that application. The facility, known as the SHINE Medical Isotope Production Facility, owned by SHINE Medical Technologies, LLC, will be located on previously undeveloped agricultural property in Rock County, Wisconsin, within the southern corporate boundaries of the City of Janesville, and is described in the application.

3. This permit shall be deemed to contain and be subject to the conditions specified in 10 CFR 50.54(b)-(f), (h), (v), (aa), and (cc) and 10 CFR 50.55; is subject to all applicable provisions of the Act, and rules, regulations, and orders of the Commission now or hereafter in effect; and is subject to the conditions specified or incorporated below:

A. The earliest date for the completion of the construction of the facility is December 31, 2017, and the latest date for completion is December 31, 2022.

B. The facility shall be constructed and located at the site as described in the application, in the City of Janesville, Rock County, Wisconsin.

C. The construction permit authorizes the applicant to construct the facility described in the application and the hearing record, in accordance with the principal architectural and engineering criteria and environmental protection commitments set forth therein.

D. The permit is subject to, and SHINE shall comply with, the conditions specified and incorporated below:

(1) Prior to the completion of construction, SHINE shall submit periodic reports to the NRC, at intervals not to exceed six months from the date of this permit, providing the following information related to nuclear criticality safety and radiation protection:

(a) The technical basis for the design of the criticality accident alarm system (CAAS), including a description of the methodology for determining detector placement. The technical basis shall demonstrate that the CAAS will meet the requirements of 10 CFR 70.24(a) and the commitments listed on page 6b-19 of the Preliminary Safety Analysis Report, Revision 0.

(b) The basis for determining that criticality events are "not credible" for radioisotope production facility (RPF) processes even though fissile materials may be present. The basis shall demonstrate that the each such event satisfies the definition of "not credible," as described in the SHINE integrated safety analysis Summary.

(c) Summaries of the criticality safety analysis for the affected processes that include the following: (1) a list of identified criticality hazards, (2) a list of controlled parameters, (3) a description of evaluated normal and abnormal conditions, (4) a description of the licensee's approach to meeting the double contingency principle, and (5) a list of anticipated passive and active engineered controls, including any assumptions, to ensure the process(es) will remain subcritical under normal and credible abnormal conditions. The criticality safety analysis summaries shall demonstrate that all RPF processes will remain subcritical under all normal and credible abnormal conditions and will satisfy the double contingency principle.

(d) The relevant nuclear criticality safety evaluations (NCSEs) shall address the reactivity contributions from all fissile isotopes or SHINE shall apply an additional subcritical margin to account for neglecting these nuclides. The treatment of fissile nuclides other than U-235, whether through the NCSEs or the addition of subcritical margin, shall demonstrate that all RPF processes will remain subcritical under all normal and credible abnormal conditions.

(e) The design information on the RPF supercells, tank vaults containing the liquid waste storage tanks, evaporation hot cells, and liquid waste solidification hot cells demonstrating shielding, and occupancy times within the RPF are consistent with as low as is reasonably achievable practices and dose requirements of 10 CFR Part 20.

(2) The Environmental Protection Plan described in Appendix A of this permit is hereby incorporated into this permit.

E. Pursuant to the Act and 10 CFR Part 30, the following activities are authorized:

(1) to receive and possess, in connection with construction of the facility, sealed americium-241 beryllium neutron sources in amounts up to those specified on page 3 of the SHINE Medical Technologies, LLC Request to Amend Construction Permit No. CPMIF-001 dated April 29, 2021, as supplemented on August 20, 2021.

F. Pursuant to the Act and 10 CFR Part 40, the following activities are authorized:

(1) to receive and possess, in connection with construction of the facility, up to 10,000 kilograms (kg) of natural uranium in the form of neutron multipliers; and

(2) to receive and possess, in connection with construction of the facility, up to 10 kg of depleted uranium in the form of tritium storage beds.

4. This permit is subject to the limitation that a license authorizing operation of the facility will not be issued by the Commission unless: (a) the applicant submits to the Commission the complete final safety analysis report, portions of which may be submitted and evaluated from time to time; (b) the Commission finds that the final design provides reasonable assurance that the health and safety of the public will not be endangered by the operation of the facility in accordance with procedures approved by it in connection with the issuance of said license; (c) the Commission finds that operation of the facility will be in accordance with 10 CFR Part 51 of the Commission's regulations and all applicable requirements were satisfied; and (d) the applicant submits proof of financial protection and executes an indemnity agreement as required by Section 170 of the Act.

5. This permit is effective as of February 29, 2016 and shall expire on the latest completion date indicated in paragraph 3.A. above.

FOR THE NUCLEAR REGULATORY COMMISSION

/RA/

William M. Dean, Director
Office of Nuclear Reactor Regulation

Appendix:

Appendix A – Environmental Protection Plan

Date of Issuance: February 29, 2016

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

SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

RELATED TO AMENDMENT NO. 2 TO

CONSTRUCTION PERMIT NO. CPMIF-001

SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL ISOTOPE PRODUCTION FACILITY

DOCKET NO. 50-608

1.0 INTRODUCTION

By letter dated April 29, 2021 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21119A165), as supplemented on August 20, 2021 and December 2, 2021 (ADAMS Accession Nos. ML21242A028 and ML21336A193, respectively), SHINE Medical Technologies, LLC (SHINE) applied for an amendment to Construction Permit No. CPMIF-001 for the SHINE Medical Isotope Production Facility (the SHINE Facility). The license amendment request (LAR) proposed to add two new conditions, 3.E and 3.F, to the construction permit to allow for the receipt and possession of certain radioactive materials to be installed during the construction of the SHINE facility.

The supplements letter dated August 20, 2021 and December 2, 2021, provided additional information that clarified the application and did not expand the scope of the application as originally noticed in the *Federal Register* on September 23, 2021 (86 FR 52928).

2.0 REGULATORY EVALUATION

The U.S. Nuclear Regulatory Commission (NRC, the Commission) staff reviewed the LAR and evaluated the proposed changes to the construction permit, based on the following regulations and guidance:

- Title 10 of the *Code of Federal Regulations* (10 CFR) Part 19, “Notices, Instructions and Reports to Workers: Inspection and Investigations,” 10 CFR Part 20, “Standards for Protection Against Radiation,” 10 CFR Part 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material,” and 10 CFR Part 40, “Domestic Licensing of Source Material,” which provide the requirements for radiation protection and the contents of applications for byproduct and source materials, including training and experience of individuals using licensed material, radiation safety, and waste management.

- NUREG-1556, Volume 7, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope, Including Electron Capture Devices and X-Ray Fluorescence Analyzers" (ADAMS Accession No. ML18065A006), which provides program-specific guidance to assist applicants and licensees in preparing applications for materials licenses for academic, research and development, and other licenses of limited scope (ARDL).

3.0 TECHNICAL EVALUATION

SHINE has proposed to construct and operate a facility in Janesville, Wisconsin for the production of molybdenum-99 (Mo-99) through the irradiation and processing of a uranyl sulfate solution. The proposed facility would comprise an irradiation facility and a radioisotope production facility. The irradiation facility would consist of eight subcritical operating assemblies (or irradiation units), which would each be licensed as a utilization facility, as defined in 10 CFR 50.2, "Definitions," and supporting structures, systems, and components (SSCs) for the irradiation of low-enriched uranium. The radioisotope production facility would consist of hot cell structures, licensed collectively as a production facility, as defined in 10 CFR 50.2, and associated SSCs for the processing of irradiated material and extraction and purification of Mo-99. The irradiation facility and radioisotope production facility are collectively referred to as the SHINE facility.

The SHINE facility is currently under construction at the site described in the application, in the City of Janesville, Rock County, Wisconsin. The SHINE construction permit, CPMIF-001, Amendment No. 1, does not authorize SHINE to receive or possess byproduct or source material. The LAR proposed to add two new conditions, 3.E and 3.F, to the construction permit to allow for the receipt and possession of certain radioactive materials to be installed during the construction of the SHINE facility. The NRC staff determined that minor changes to the proposed new conditions were necessary for accuracy and clarity for the NRC staff to find the conditions acceptable. SHINE agreed with the NRC staff's changes. The proposed new conditions, with the NRC staff's deletions in strike-through and additions in underline, are as follows:

E. Pursuant to the Act and 10 CFR Part 30, the following activities are ~~included~~ authorized:

(1) to receive and possess, in connection with construction of the facility, ~~up to [ ]SRI of~~ sealed americium-241 beryllium neutron sources in amounts up to those specified on page 3 of the SHINE Medical Technologies, LLC Request to Amend Construction Permit No. CPMIF-001 dated April 29, 2021, as supplemented on August 20, 2021.

F. Pursuant to the Act and 10 CFR Part 40, the following activities are ~~included~~ authorized:

(1) to receive and possess, in connection with construction of the facility, up to 10,000 kilograms (kg) of natural uranium in the form of neutron multipliers; and

(2) to receive and possess, in connection with construction of the facility, up to 10 kg of depleted uranium in the form of tritium storage beds.

The NRC staff evaluated the SHINE proposal to amend the SHINE facility construction permit to authorize the receipt and possession of sealed americium-241 beryllium neutron sources, natural uranium, and depleted uranium using the guidance in NUREG-1556, Volume 7, Revision 1. Specifically, the NRC staff used Appendix B to NUREG-1556, Volume 7,

Revision 1, which provides the suggested format for providing information requested in items 5 through 11 of NRC Form 313, "Application for Materials License," for the use of byproduct material for ARDL applicants. Although, NUREG-1556, Volume 7, Revision 1, does not explicitly cover source material, applicants and licensees may list source material in applications where use of the material is directly related to the use of byproduct material. In the LAR, SHINE requested to receive and possess the byproduct material of sealed americium-241 beryllium neutron sources and the source materials of natural uranium and depleted uranium to be installed during the construction of the SHINE facility.

The following sections provide the NRC staff's evaluation of the information that SHINE submitted to meet the applicable requirements of 10 CFR Parts 19, 20, 30, and 40 using Appendix B to NUREG-1556, Volume 7, Revision 1.

Item 5 – Radioactive Material

In its application, SHINE identified all sealed and unsealed sources to be included within the scope of the amended construction permit, including identification of each radioisotope (i.e., natural uranium, depleted uranium, and americium-241 beryllium). For each unsealed source, SHINE provided the chemical/physical form, as well as the maximum possession limit. For each sealed source, SHINE provided the chemical/physical form; manufacturer or distributor and model number; sealed source and device registration sheet number; maximum activity per source; maximum number of sources; and maximum possession limit.

SHINE also committed to maintaining records important to decommissioning and transferring such records to an NRC or Agreement State licensee before licensed activities are transferred or assigned, as required by the NRC's regulations.

The quantity, form, and type of byproduct material that the proposed amendment would allow SHINE to receive and possess in the form of americium-241 beryllium neutron sources do not require an emergency plan under paragraph (i) of 10 CFR 30.32, "Application for Specific Licenses," and 10 CFR 30.72, "Schedule C—Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release." The quantities, forms, and types of source materials that the proposed amendment would allow SHINE to receive and possess in the form of natural uranium and depleted uranium do not require an emergency plan under paragraph (j) of 10 CFR 40.31, "Application for Specific Licenses," because SHINE is not requesting to receive or possess uranium hexafluoride.

The quantity, form, and type of byproduct material that the proposed amendment would allow SHINE to receive and possess in the form of americium-241 beryllium neutron sources do not require a decommissioning funding plan or a certification of financial assurance for decommissioning under paragraph (h) of 10 CFR 30.32 and 10 CFR 30.35, "Financial Assurance and Recordkeeping for Decommissioning." The quantities, forms, and types of source materials that the proposed amendment would allow SHINE to receive and possess in the form of natural uranium and depleted uranium do not require a decommissioning funding plan or a certification of financial assurance for decommissioning under paragraph (i) of 10 CFR 40.31 and 10 CFR 40.36, "Financial Assurance and Recordkeeping for Decommissioning."

Therefore, the NRC staff determined that based on the quantities, forms, and types of materials that would be received and possessed by SHINE to be installed during the construction of the

SHINE facility that an emergency plan and evidence of decommissioning financial assurance are not required to support issuance of the proposed amendment to the construction permit.

Based on its review of the information provided by SHINE, the NRC staff finds that SHINE has provided information consistent with the guidance regarding Item 5 in Appendix B to NUREG-1556, Volume 7, Revision 1 and meets the applicable regulatory requirements in 10 CFR Parts 30 and 40, including 10 CFR 30.32, 10 CFR 30.33, "General Requirements for Issuance of Specific Licenses," paragraph (b) of 10 CFR 30.34, "Terms and Conditions of Licenses," paragraph (g) of 10 CFR 30.35, 10 CFR 30.72, 10 CFR 40.31, 10 CFR 40.32, "General Requirements for Issuance of Specific Licenses," 10 CFR 40.46, "Inalienability of Licenses," and paragraph (f) of 10 CFR 40.36.

Item 6 – Purpose(s) for which Licensed Material Will Be Used

In its application, SHINE listed the specific purpose for each radionuclide by referencing detailed descriptions provided in the final safety analysis report (FSAR) supporting the SHINE application for an operating license for the SHINE facility. The specific purpose during operation for each radionuclide requested by SHINE to be installed during the construction of the SHINE facility are as follows:

- As described in Subsection 4a2.2.4, "Subcritical Multiplication Source" (ADAMS Accession No. ML21095A226), of the FSAR, the sealed americium-241 beryllium neutron sources are to be used as subcritical multiplication sources. The subcritical multiplication sources are "fixed neutron source[s] in the subcritical assembl[ies] … used to facilitate the monitoring of the reactivity of the assembl[ies] when the neutron driver[s] [are] not producing neutrons…. [They] provide[] a stable level of background neutrons so that neutron multiplication in the subcritical assembl[ies] can be accurately and reliably measured while filling the [target solution vessels] with target solution."

- As described in Subsection 4a2.2.6, "Neutron Multiplier" (ADAMS Accession No. ML21095A226), of the FSAR, the natural uranium is to be used as part of neutron multipliers for installation within the subcritical assembly systems. The neutron multipliers serve to "moderate and multiply the fast neutrons coming from the fusion reactions initiated by the neutron driver[s]."

- As described in Subsection 9a2.7.1, "Tritium Purification System" (ADAMS Accession No. ML21095A225), of the FSAR, the depleted uranium is to be used as part of tritium storage beds for installation within the tritium purification system. Specifically, the depleted uranium is to be used as storage beds for tritium gas.

Based on its review of the information provided by SHINE, the NRC staff finds that SHINE has specified the purpose for which each radionuclide to be installed during the construction of the SHINE facility will be used during operation consistent with the guidance regarding Item 6 in Appendix B to NUREG-1556, Volume 7, Revision 1 and meets the applicable regulatory requirements in 10 CFR Parts 30 and 40, including 10 CFR 30.33(a)(1) and 10 CFR 40.32(a).

Item 7 – Individual(s) Responsible for Radiation Safety Program and their Training and Experience

In its application, SHINE provided the name of the proposed radiation safety officer (RSO) and the names of each authorized user (AU), as well as information demonstrating that the

proposed RSO and each AU are qualified by training and experience. Information that SHINE provided included the following:

- formal training and education in radiation safety
- experience using licensed materials
- experience performing the duties of an RSO

Based on its review of the information provided by SHINE, the NRC staff finds that the proposed RSO's training and experience is applicable to and consistent with the types and quantities of licensed material to be listed on the SHINE facility construction permit. The NRC staff also finds that each AU has adequate training and experience with the types and quantities of licensed material that SHINE proposes to receive and possess. As such, the NRC staff finds that SHINE has provided information consistent with the guidance regarding Item 7 in Appendix B to NUREG-1556, Volume 7, Revision 1 and meets the applicable regulatory requirements in 10 CFR Parts 30 and 40, including 10 CFR 30.33(a)(3) and 10 CFR 40.32(b).

Item 8 – Training for Individuals Working in or Frequenting Restricted Areas (Occupationally Exposed Individuals and Ancillary Personnel)

In its application, SHINE provided a description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training.

Based on its review of the information provided by SHINE, the NRC staff finds that individuals whose assigned duties involve exposure to radiation or radioactive material and in the course of their employment are likely to receive in a year an occupational dose of radiation greater than 1 millisievert (100 millirem), will receive instruction commensurate with their duties and responsibilities, as required by 10 CFR 19.12, "Instruction to Workers." As such, the NRC staff finds that SHINE has provided information consistent with the guidance regarding Item 8 in Appendix B to NUREG-1556, Volume 7, Revision 1 and meets the applicable regulatory requirements in 10 CFR Parts 19, 30, and 40, including 10 CFR 19.11, "Posting of Notices to Workers," 10 CFR 19.12, 10 CFR 30.33(a)(3), and 10 CFR 40.32(b).

Item 9 – Facilities and Equipment

In its application, SHINE described the facilities and equipment that will be available at each location where radioactive material would be received, stored, and installed during construction. The application includes a description of the area(s) assigned for the receipt, storage, security, installation, and use of radioactive materials. SHINE referenced Figures 1.3-1, "Main Production Facility Building General Arrangement," 1.3-2, "Main Production Facility Building General Arrangement Section 'A-A'," and 1.3-3, "Site Overview" (ADAMS Accession No ML21095A221), of the FSAR, which provide depictions of the general arrangement floor plan; section drawings of the SHINE facility showing the layout of major structures; and the SHINE facility site overview. These figures show the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. The application describes how the SHINE facility design and procedures for construction will minimize contamination of the facility and the environment.

Based on its review of the information provided by SHINE, the NRC staff finds that the facilities and equipment described by SHINE will be adequate to protect health and minimize danger to life or property. Facilities and equipment will minimize the possibility of contamination and keep

exposures to workers and the public consistent with as low as is reasonably achievable (ALARA) principles. The SHINE facility design and procedures for construction will minimize, to the extent practicable, contamination of the facility and the environment. As such, the NRC staff finds that SHINE has provided information consistent with the guidance regarding Item 9 in Appendix B to NUREG-1556, Volume 7, Revision 1 and meets the applicable regulatory requirements in 10 CFR Parts 20, 30, and 40, including paragraph (b) of 10 CFR 20.1101, "Radiation Protection Programs," 10 CFR 20.1406, "Minimization of Contamination," 10 CFR 20.1902, "Posting Requirements," 10 CFR 30.33(a)(2), and 10 CFR 40.32(c).

Item 10 – Radiation Safety Program

Radiation Monitoring Instruments and Calibration

In its application, SHINE described the instrumentation that will be used to perform required surveys, which includes portable dose rate meters with ionization chambers or Geiger-Mueller probes; portable dose rate meters with helium-3 proportional probes; and friskers with Geiger-Mueller pancake probes.

SHINE also stated that it would meet the radiation monitoring instrument specifications in Appendix I, "Radiation Monitoring Instrument Specifications and Model Radiation Survey Instrument and Air Sampler Calibration Program," in NUREG-1556, Volume 7, Revision 1. This appendix covers the acceptable types of instrumentation for radiation safety and compliance activities. It also covers the calibration of dose and dose rate measurement instruments, surface contamination measurement instruments, and instruments used to collect samples for indirect dose measurements such as air sampling.

SHINE stated that radiation monitoring instruments "will be calibrated before first use, at least annually thereafter, and after any repair, by a vendor that the NRC or an Agreement State has licensed to perform instrument calibration."

Based on its review of the information provided by SHINE, the NRC staff finds that SHINE will possess, or have access to, radiation monitoring instruments that are necessary to protect health and minimize danger to life or property. As such, the NRC staff finds that SHINE has provided information consistent with the guidance regarding Item 10 in Appendix B to NUREG-1556, Volume 7, Revision 1 and meets the applicable regulatory requirements in 10 CFR Parts 20, 30, and 40, including 10 CFR 20.1501, "General," paragraph (a) of 10 CFR 20.2103, "Records of Surveys," 10 CFR 30.33(a)(2), and 10 CFR 40.32(c).

Material Receipt and Accountability

In its application, SHINE stated the following, consistent with the guidance regarding Item 10 in Appendix B to NUREG-1556, Volume 7, Revision 1:

> SHINE will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times. Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license. Records of inventory will be maintained for a period of 5 years from the date of each inventory, and will include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

Based on its review of the above statement made by SHINE in its application, the NRC staff finds that SHINE meets the applicable regulatory requirements in 10 CFR Parts 20, 30, and 40, including 10 CFR 20.1501(a), 10 CFR 20.1801, “Security of Stored Material,” 10 CFR 20.1802, “Control of Material Not in Storage,” 10 CFR 30.51, “Records,” and 10 CFR 40.61, “Records.”

Occupational Dose

In its application, SHINE stated the following, consistent with the guidance regarding Item 10 in Appendix B to NUREG-1556, Volume 7, Revision 1:

> SHINE will monitor individuals in accordance with the guidance in the section titled, “Radiation Safety Program-Occupational Dose” in NUREG-1556, Volume 7, Revision 1….

Based on its review of the above statement made by SHINE in its application, the NRC staff finds that SHINE will evaluate the potential occupational exposure of all workers and monitor occupational exposure consistent with the guidance in NUREG-1556, Volume 7, Revision 1 and meets the applicable regulatory requirements in 10 CFR Parts 19 and 20, including 10 CFR 19.13, “Notifications and Reports to Individuals,” 10 CFR 20.1201, “Occupational Dose Limits for Adults,” 10 CFR 20.1501, and 10 CFR Part 20 Appendix B, “Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage.”

Safe Use of Radionuclides, Security, and Emergency Procedures

In its application, SHINE stated the following, consistent with the guidance regarding Item 10 in Appendix B to NUREG-1556, Volume 7, Revision 1: “SHINE will develop, implement, and maintain procedures for safe use, security, and emergencies.”

The quantity, form, and type of byproduct material that the proposed amendment would allow SHINE to receive and possess in the form of americium-241 beryllium neutron sources do not require an emergency plan under paragraph (i) of 10 CFR 30.32 and 10 CFR 30.72. The quantities, forms, and types of source materials that the proposed amendment would allow SHINE to receive and possess in the form of natural uranium and depleted uranium do not require an emergency plan to be prepared under paragraph (j) of 10 CFR 40.31 because SHINE is not requesting to receive or possess uranium hexafluoride.

The quantity, form, and type of byproduct material that the proposed amendment would allow SHINE to receive and possess in the form of americium-241 beryllium neutron sources fall below the threshold for physical security requirements under Appendix A, “Category 1 and Category 2 Radioactive Materials,” to 10 CFR Part 37, “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.”

Therefore, the NRC staff determined that based on the quantities, forms, and types of material that would be received and possessed by SHINE to be installed during the construction of the SHINE facility that an emergency plan and a security plan are not required to support issuance of the proposed amendment to the construction permit.

Based on its review of the above statement made by SHINE in its application and the descriptions of facilities and equipment provided in support of Item 9, the NRC staff finds that SHINE will keep radiation doses to workers and members of the public ALARA and ensure

security of licensed material and meets the applicable regulatory requirements in 10 CFR Part 20, including 10 CFR 20.1101, 10 CFR 20.1406, 10 CFR 20.1801, and 10 CFR 20.1802.

Surveys and Leak Tests

In its application, SHINE stated the following, consistent with the guidance regarding Item 10 in Appendix B to NUREG-1556, Volume 7, Revision 1:

> SHINE will survey the facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix M in NUREG-1556….
>
> Leak tests will be performed at the intervals approved by the NRC or an Agreement State and specified in the sealed source and device (SSD) registration certificate while the [sealed americium-241 beryllium neutron] sources are in secure storage. SHINE will implement the model leak test program published in Appendix N in NUREG-1556…. Leak tests will not be performed after the [sealed americium-241 beryllium neutron] sources are installed in the [subcritical assembly systems] due to inaccessibility and ALARA concerns as described in Item 9.

Based on its review of the above statements made by SHINE in its application, the NRC staff finds that SHINE will make the required 10 CFR 20.1501 surveys of potential radiological hazards to determine whether there is any radioactive leakage from sealed sources. As such, the NRC staff finds that SHINE has provided information consistent with the guidance regarding Item 10 in Appendix B to NUREG-1556, Volume 7, Revision 1 and meets the applicable regulatory requirements in 10 CFR Parts 20, 30, and 40, including 10 CFR 20.1501, 10 CFR 20.2103, “Records of surveys,” 10 CFR 30.53, “Tests,” and 10 CFR 40.63, “Tests.”

Item 11 – Waste Management

In its application, SHINE stated that it “does not expect to generate radiological waste during construction activities.” As such, SHINE would not need to meet the requirements for waste disposal in accordance with the regulations in Subpart K, “Waste Disposal,” of 10 CFR Part 20.

Based on its review of the information provided by SHINE, the NRC staff finds that SHINE is not expected to generate radiological waste during construction activities based on the proposed receipt and possession of radioactive materials to be installed during the construction of the SHINE facility.

Findings

Based on the above information, the NRC staff finds that the proposed amendment to the SHINE facility construction permit to authorize the receipt and possession of sealed americium-241 beryllium neutron sources, natural uranium, and depleted uranium to be installed during the construction of the SHINE facility meets the applicable requirements of 10 CFR Parts 19, 20, 30, and 40. The information in the application demonstrates that SHINE has taken the appropriate considerations to protect health and minimize danger to life or property. Facilities and equipment will minimize the possibility of contamination and keep exposures to workers and the public consistent with ALARA principles. The SHINE facility design and procedures for

construction will minimize, to the extent practicable, contamination of the facility and the environment. The RSO's training and experience is applicable to and generally consistent with the types and quantities of licensed material to be listed on the SHINE facility construction permit. The AU has adequate training and experience with the types and quantities of licensed material SHINE proposes to receive and possess. Individuals whose assigned duties involve exposure to radiation or radioactive material will receive instruction commensurate with their duties and responsibilities. Therefore, the NRC staff concludes that the addition of conditions 3.E and 3.F, including the NRC staff's minor changes thereto, to Construction Permit No. CPMIF-001 for the SHINE facility to authorize the receipt and possession of certain radioactive materials to be installed during the construction of the SHINE facility is acceptable. To memorialize this conclusion, the NRC staff added the following new finding as paragraph 1.K to Construction Permit No. CPMIF-001:

> The receipt and possession of byproduct and source material as authorized by this license will be in accordance with the Commission's regulations in 10 CFR Parts 30 and 40.

4.0 STATE CONSULTATION

In accordance with the Commission's regulations, the Wisconsin State official was notified on November 30, 2021, of the proposed issuance of the amendment (ADAMS Accession No. ML21335A037). The State official had no comments.

5.0 ENVIRONMENTAL CONSIDERATION

Pursuant to 10 CFR 51.21, "Criteria for and Identification of Licensing and Regulatory Actions Requiring Environmental Assessments," 10 CFR 51.32, "Finding of No Significant Impact," and 10 CFR 51.35, "Requirement to Publish Finding of No Significant Impact; Limitation on Commission Action," an environmental assessment and finding of no significant impact regarding the LAR was published in the *Federal Register* on November 29, 2021 (86 FR 67737). Accordingly, based upon the environmental assessment, the Commission has determined that the issuance of the amendment will not have a significant effect on the quality of the human environment.

6.0 CONCLUSION

The Commission has concluded, based on the considerations discussed above, that (1) there is reasonable assurance that the health and safety of the public will not be endangered by construction in the proposed manner, (2) there is reasonable assurance that such activities will be conducted in compliance with the Commission's regulations, and (3) the issuance of the amendment will not be inimical to the common defense and security or to the health and safety of the public.

Principal Contributor: S. Lynch, NRR

Date: December 2, 2021