

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-608; NRC-2021-0140]

SHINE Medical Technologies, LLC;

SHINE Medical Isotope Production Facility

AGENCY: Nuclear Regulatory Commission.

ACTION: Environmental assessment and finding of no significant impact; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an environmental assessment (EA) and finding of no significant impact (FONSI) regarding the NRC's consideration of issuance of a proposed amendment to the SHINE Medical Technologies, LLC (SHINE, the licensee) Construction Permit No. CPMIF-001, issued on February 29, 2016. The permit authorizes the construction of the SHINE Medical Isotope Production Facility (SHINE facility) in Rock County, Wisconsin. If approved, the proposed amendment would authorize the receipt and possession of certain radioactive materials necessary for the continued construction of the SHINE facility.

DATE: The EA and FONSI referenced in this document are available on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Please refer to Docket ID **NRC-2021-0140** when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- **Federal Rulemaking Website:** Go to <https://www.regulations.gov> and search for Docket ID **NRC-2021-0140**. Address questions about Docket IDs in Regulations.gov to Stacy Schumann; telephone: 301-415-0624; email:

Stacy.Schumann@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **NRC's Agencywide Documents Access and Management System**

(ADAMS): You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to PDR.Resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the "Availability of Documents" section.

- **NRC's PDR:** You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Michael Balazik, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-2856; email: Michael.Balazik@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is considering issuance of an amendment to Construction Permit No. CPMIF-001, issued to SHINE for the construction of the SHINE facility in Rock County, Wisconsin. SHINE requested the amendment by letter dated April 29, 2021, as supplemented by letter dated August 20, 2021, in accordance with Section 50.90 of title

10 of the *Code of Federal Regulations* (10 CFR), “Application for amendment of license, construction permit, or early site permit,” and 10 CFR 50.34, “Contents of applications; technical information.” The amendment would authorize the receipt and possession of certain radioactive materials necessary for the continued construction of the SHINE facility.

In accordance with 10 CFR 51.21, “Criteria for and identification of licensing and regulatory actions requiring environmental assessments,” the NRC prepared an EA, pursuant to 10 CFR 51.30, “Environmental assessment,” that analyzes the environmental impacts of the proposed amendment and alternatives as appropriate. Based on the results of this EA, which is set forth in Section II in this document, and in accordance with 10 CFR 51.31(a), the NRC has determined not to prepare an environmental impact statement for the proposed amendment and is issuing a FONSI, which is set forth in Section III in this document.

II. Environmental Assessment

Description of the Proposed Action

The proposed action would amend Construction Permit No. CPMIF-001 to authorize SHINE to receive and possess the radioactive materials of natural uranium, depleted uranium, and americium-241/beryllium (AmBe), which are necessary for the continued construction of the SHINE facility in Rock County, Wisconsin. The proposed action is requested in the licensee’s application dated April 29, 2021, as supplemented by letter dated August 20, 2021.

Need for the Proposed Action

The radioactive materials described in the licensee’s application are byproduct and source materials required for the continued construction of the SHINE facility and would be installed within the facility’s tritium purification system and subcritical assembly

systems. The licensee's request to receive and possess these byproduct and source materials is in accordance with applicable provisions in 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," and 10 CFR Part 40, "Domestic Licensing of Source Material," respectively. Specifically, SHINE requested to receive and possess the source material of natural uranium in the form of neutron multipliers; the source material of depleted uranium in the form of tritium storage beds; and the byproduct material of AmBe sealed neutron sources. The natural uranium would be contained within neutron multipliers, as described in Subsection 4a2.2.6 of the SHINE Final Safety Analysis Report (FSAR), for installation within the subcritical assembly systems. The depleted uranium would be contained within tritium storage beds, as described in Subsection 9a2.7.1 of the SHINE FSAR, for installation within the tritium purification system. The AmBe sealed neutron sources would be used as subcritical multiplication sources, as described in Subsection 4a2.2.4 of the SHINE FSAR, for installation within the subcritical assembly systems.

The NRC regulations in 10 CFR Part 30 and 10 CFR Part 40 contain requirements for the receipt, possession, use, and transfer of byproduct material and source material, respectively.

Environmental Impacts of the Proposed Action

The NRC has completed its environmental review of the proposed action and concludes that there are no significant environmental impacts associated with the proposed action.

As an initial matter, the proposed action would amend the SHINE construction permit to authorize the receipt and possession of byproduct and source materials necessary for continued construction of the SHINE facility in accordance with applicable provisions in 10 CFR Parts 30 and 40, which ensure the safety of such receipt and

possession. Thus, before the NRC could approve the proposed action, it would have to conclude that the applicable provision in 10 CFR Parts 30 and 40 are satisfied.

Additionally, the NRC previously evaluated the environmental impacts associated with constructing, operating, and decommissioning the SHINE facility in NUREG-2183, “Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility,” dated October 2015. The licensee is also required to comply with occupational dose limits (10 CFR Part 20, Subpart C) and radiation dose limits for individual members of the public (10 CFR Part 20, Subpart D) at all times.

As provided in the application, the proposed amendment authorizing the receipt and possession of the requested byproduct and source materials would not change the types or amounts of radioactive materials in effluents, wastes, and products of the SHINE facility, nor would it increase the probability of accidents. The requested materials would be received and securely stored in an access-controlled area prior to installation into the tritium purification system and the subcritical assembly systems. SHINE would inspect, inventory, and place the requested materials into secure storage in accordance with the requirements of 10 CFR 20.1902, “Posting requirements.” Shielding would be used as appropriate to minimize radiation exposure of personnel while the requested materials are in storage in accordance with 10 CFR 20.1201, “Occupational dose limits for adults.” The requested materials would be in the form of sealed sources or solids contained within enclosed components that do not present contamination or accidental release hazards. Finally, the application provided that the receipt and possession of the requested materials would not result in the generation of radiological waste.

Additionally, the application provided that there would be no new or substantially different radiological hazards resulting from the receipt and possession of the requested

byproduct and source materials as compared to the construction-related radiological hazards discussed in Section 4.8.1.1, "Radiological," of NUREG-2183. In NUREG-2183, the NRC staff determined that SHINE has adequate controls in place to ensure that the dose to workers and the public from radioactive materials is within the dose limits of 10 CFR Part 20, including a radiation safety program.

The transportation of the requested byproduct and source materials would be required to adhere to the applicable regulatory packaging and transportation requirements in NRC regulations (10 CFR Parts 20, 40, and 71), the State of Wisconsin Administrative Code Chapter 326, "Transportation," and Department of Transportation requirements (49 CFR Parts 172 and 173).

Based on the above, the NRC staff concludes that the proposed action would not have significant radiological human health impacts.

Nonradiological impacts to human health of the construction, operation, and decommissioning of the SHINE facility were previously assessed in Section 4.8.1.2 of NUREG-2183. The application provided that the proposed amendment would not result in any new or substantially different nonradiological hazards resulting from the receipt and possession of the requested byproduct and source materials; therefore, the NRC staff concludes that nonradiological impacts during construction would remain small.

The proposed action would result in no additional direct impacts on land use or water resources, including terrestrial and aquatic biota, because the proposed action involves no new construction or modification of SHINE facility operational systems previously assessed in NUREG-2183. For this same reason, there would be no changes to the types or quantity of nonradiological effluents previously assessed in NUREG-2183 and, therefore, no changes to the facility's Wisconsin Pollutant Discharge Elimination System permit are needed. Similarly, there would be no changes in ambient

air quality, no noticeable effect on socioeconomic conditions in the region, no environmental justice impacts, and no impacts to historic and cultural resources.

Therefore, the NRC staff concludes that there would be no significant nonradiological impacts associated with the proposed action.

Environmental Impacts of the Alternatives to the Proposed Action

As an alternative to the proposed action, the NRC staff considered denial of the proposed action (i.e., the “no-action” alternative). Denial of the license amendment request would result in the licensee being unable to complete construction and begin operation of the SHINE facility. However, because the direct impacts on land use and water resources from construction have largely already occurred and because the remaining construction, operating, and decommissioning impacts would generally be small as evaluated in NUREG-2183, the environmental impacts of the proposed action and the alternative action are similar.

Alternative Use of Resources

There are no unresolved conflicts concerning alternative uses of available resources under the proposed action.

Agencies and Persons Consulted

No additional agencies or persons were consulted regarding the environmental impact of the proposed action. On November 15, 2021, the NRC notified the Wisconsin Department of Health Services of the EA and FONSI. The state provided no comments. The NRC staff determined that the proposed action would have no effect on Federally listed threatened or endangered species or critical habitat that could occur on or near the SHINE facility site and would have no effect on any historic properties. Therefore, consultation was not required under Section 7 of the Endangered Species Act of 1973, as amended, or under Section 106 of the National Historic Preservation Act of 1966, as

amended.

III. Finding of No Significant Impact

The proposed action is the issuance of an amendment to SHINE Construction Permit No. CPMIF-001 to authorize SHINE to receive and possess certain source and byproduct materials necessary for the continued construction of the SHINE facility in Rock County, Wisconsin.

Consistent with 10 CFR 51.21, the NRC prepared an EA to determine the impacts of the proposed action. On the basis of the EA included in Section II in this document and incorporated by reference in this finding, the NRC concludes that the proposed action would not have a significant adverse effect on the probability of an accident occurring and would not have any significant radiological or nonradiological impacts. Therefore, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

Other than the application dated April 29, 2021, as supplemented by letter dated August 20, 2021, the related environmental document is NUREG-2183. NUREG-2183 provides the latest environmental review of the construction, operation, and decommissioning of the SHINE facility and description of the environmental conditions at the SHINE facility.

This EA and FONSI and other related documents are accessible online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC's PDR reference staff at 1-800-397-4209, 301-415-4737, or by email to PDR.Resource@nrc.gov.

IV. Availability of Documents

The documents identified in the following table are available to interested persons through ADAMS, as indicated.

DOCUMENT	ADAMS ACCESSION NO.
NUREG-2183, Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility, dated October, 2015	ML15288A046
Construction Permit No. CPMIF-001 for the SHINE Medical Isotope Production Facility, dated February 29, 2016	ML16041A473
SHINE Medical Technologies, LLC's Revisions to Final Safety Analysis Report, Chapter 4, Irradiation Unit and Radioisotope Production Facility Description, Rev. 1, dated March 23, 2021	ML21095A226
SHINE Medical Technologies, LLC's Revisions to Final Safety Analysis Report, Chapter 9, Auxiliary Systems, Rev. 0, dated March 23, 2021	ML21095A225
SHINE Medical Technologies, LLC, Request to Amend Construction Permit No. CPMIF-001, dated April 29, 2021	ML21119A165 (Package)
SHINE Medical Technologies, LLC, Request to Amend Construction Permit No. CPMIF-001 Response to Request for Additional Information, dated August 20, 2021	ML21242A028 (Package)

Dated: November 23, 2021.

For the Nuclear Regulatory Commission.

/RA/

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