

**NUCLEAR REGULATORY COMMISSION**

[Docket No. 50-608; NRC-2019-0173]

**SHINE Medical Technologies, LLC**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Operating license application; acceptance for docketing.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) staff accepts and docketing an application submitted by SHINE Medical Technologies, LLC (SHINE), dated July 17, 2019, filed pursuant to the Atomic Energy Act of 1954, as amended, and the NRC's regulations, for an operating license for the SHINE Medical Isotope Production Facility.

**DATES:** This action takes effect on October 15, 2019.

**ADDRESSES:** Please refer to Docket ID **NRC-2019-0173** when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <https://www.regulations.gov/> and search for Docket ID **NRC-2019-0173**. Address questions about NRC docket IDs in [Regulations.gov](https://www.regulations.gov/) to Anne Frost; telephone: 301-287-9232; e-mail: [Anne.Frost@nrc.gov](mailto:Anne.Frost@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 e-mail to [pdresource@nrc.gov](mailto:pdresource@nrc.gov). The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

**FOR FURTHER INFORMATION CONTACT:** Steven T. Lynch, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001, telephone: 301-415-1524; e-mail: [Steven.Lynch@nrc.gov](mailto:Steven.Lynch@nrc.gov).

**SUPPLEMENTARY INFORMATION:**

By letter dated July 17, 2019 (ADAMS Accession No. ML19211C044), SHINE filed with the NRC, pursuant to Section 103 of the Atomic Energy Act and part 50, "Domestic Licensing of Production and Utilization Facilities," of title 10 of the *Code of Federal Regulations* (10 CFR), an application for an operating license for the SHINE Medical Isotope Production Facility to be located in Janesville, Wisconsin (ADAMS Package Accession No. ML19211C143). A notice of receipt and availability of this application was previously published in the *Federal Register* on September 10, 2019 (84 FR 47557).

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. As described in the operating license application, the proposed facility would comprise an irradiation facility and 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 Medical Isotope Production Facility. Issuance of the operating license would authorize the applicant to operate the SHINE Medical Isotope Production Facility for a 30-year period.

By letters dated March 26 and May 31, 2013 (ADAMS Accession Nos. ML13088A192 and ML13172A361, respectively), SHINE (at the time known as SHINE Medical Technologies, Inc.) submitted a two-part construction permit application, as updated in 2015, for its eight utilization facilities and one production facility (ADAMS Package Accession No. ML15258A431). The NRC issued Construction Permit No. CPMIF-001 to SHINE on February 29, 2016 (ADAMS Package Accession No. ML16041A473), as supported by NUREG-2189, “Safety Evaluation Report Related to SHINE Medical Technologies, Inc. Construction Permit Application for a Medical Radioisotope Production Facility,” dated August 2016, (ADAMS Accession No. ML16229A140) and NUREG-2183, “Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility,” dated October 2015 (ADAMS Accession No. ML15288A046).

In accordance with 10 CFR part 2, “Agency Rules of Practice and Procedure,” and part 50, the NRC staff performed an acceptance review of the SHINE operating license application and, by letter dated October 8, 2019 (ADAMS Accession No. ML19276D411), concluded that the application is acceptable for docketing under Docket Number 50-608.

As part of a detailed technical review of the SHINE application, the NRC staff will prepare and document its findings in a safety evaluation report. Additionally, in accordance with 10 CFR part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," the NRC staff will also prepare a supplemental environmental impact statement for the proposed action.

Following additional interactions with SHINE, the NRC staff will establish a review schedule that identifies significant milestones and expected review completion date. Docketing of the application does not preclude the NRC staff from requesting additional information from SHINE as the review proceeds, nor does it predict whether the Commission will grant or deny the operating license.

The application will be referred to the Advisory Committee on Reactor Safeguards for review and report, which will be provided to the Commission in accordance with 10 CFR 50.58, "Hearings and report of the Advisory Committee on Reactor Safeguards." If the Commission finds that the SHINE operating license application meets the applicable standards of the Atomic Energy Act and the Commission's regulations, and that required notifications to other agencies and bodies have been made, the Commission will issue an operating license containing conditions and limitations that the Commission finds appropriate and necessary.

In accordance with the provisions of 10 CFR 2.105, "Notice of proposed action," a separate notice of opportunity to file a petition for leave to intervene in a hearing will be published at a later date.

Dated at Rockville, Maryland, this 8<sup>th</sup> day of October, 2019.

For the Nuclear Regulatory Commission.

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