

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of)	
)	
SHINE Medical Technologies, Inc.)	
)	
)	
SHINE Medical Isotope Production Facility)	Docket No. 50-608
)	Construction Permit No. CPMIF-001

ORDER APPROVING THE INDIRECT TRANSFER OF LICENSE
AND CONFORMING AMENDMENT

I.

SHINE Medical Technologies, Inc. (SHINE) is the holder of Construction Permit No. CPMIF-001, which authorizes construction of the SHINE Medical Isotope Production Facility. 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 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 Title 10 of the *Code of Federal Regulations* (10 CFR) 50.2, "Definitions." The radioisotope production facility would consist of three hot cell structures, licensed collectively as a production facility, as defined in 10 CFR 50.2. The irradiation facility and radioisotope production facility are collectively referred to as the SHINE Medical Isotope Production Facility.

II.

By application dated December 11, 2018 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML18347A215), as supplemented by letter dated March 8, 2019 (ADAMS Accession No. ML19071A055), SHINE requested that the U.S. Nuclear

Regulatory Commission (NRC, the Commission) consent to the indirect transfer of Construction Permit No. CPMIF-001 for the SHINE Medical Isotope Production Facility, currently held by SHINE. The indirect transfer would result from the establishment of a holding company, Illuminated Holdings, Inc. (Illuminated). The indirect transfer request was submitted to the NRC for approval pursuant to Section 184, "Inalienability of Licenses," of the Atomic Energy Act of 1954, as amended (AEA), and 10 CFR 50.80, "Transfer of licenses."

SHINE also requested, pursuant to 10 CFR 50.90, "Application for amendment of license, construction permit, or early site permit," the issuance of an administrative conforming amendment to the license to reflect the proposed transfer. Specifically, the amendment would revise SHINE's construction permit to reflect SHINE's new name, SHINE Medical Technologies, LLC (SHINE LLC), resulting from its conversion from a corporation into a single-member limited liability company, owned and controlled by Illuminated.

Notice of NRC consideration of the indirect license transfer application was published in the *Federal Register* (FR) on February 20, 2019 (84 FR 5116), and included an opportunity to comment, request a hearing, and petition for leave to intervene. No comments or hearing requests were received.

Pursuant to 10 CFR 50.80, no license for a production or utilization facility, or any right thereunder, shall be transferred, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission gives its consent in writing. Upon review of the information in the application, as supplemented, and other information before the Commission, and relying upon the representations and agreements contained in the application, as supplemented, the NRC staff has determined that SHINE LLC would be qualified to be the holder of Construction Permit No. CPMIF-001, and that the indirect transfer of the license, as described in the application, as supplemented, is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto.

Upon review of the application for a conforming amendment to Construction Permit No. CPMIF-001 to reflect the indirect transfer of the license, the NRC staff determined the following:

- (1) The application for the proposed license amendment complies with the standards and requirements of the AEA, and the Commission's rules and regulations set forth in 10 CFR Chapter I, "Nuclear Regulatory Commission."
- (2) 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.
- (3) There is reasonable assurance that the activities authorized by the proposed license amendment can be conducted without endangering the health and safety of the public, and that such activities will be conducted in compliance with the Commission's regulations.
- (4) The issuance of the proposed license amendment will not be inimical to the common defense and security or to the health and safety of the public.
- (5) The issuance of the proposed license amendment is in accordance with 10 CFR Part 51 of the Commission's regulations, and all applicable requirements have been satisfied.

The findings set forth above are supported by an NRC safety evaluation dated May 20, 2019, which is available at ADAMS Accession No. ML19102A326.

III.

Accordingly, pursuant to Sections 161b, 161i, and 184 of the AEA, Title 42 of the United States Code Sections 2201(b), 2201(i), and 2234; and 10 CFR 50.80, IT IS HEREBY ORDERED that the application for the indirect transfer of the license, as described herein, is approved for the SHINE Medical Isotope Production Facility.

IT IS FURTHER ORDERED that, consistent with 10 CFR 2.1315, "Generic determination regarding license amendments to reflect transfers," paragraph (b), the license amendment that makes changes, as indicated in Enclosure 2 to the cover letter forwarding this Order, to conform the license to reflect the subject indirect license transfer is approved. The amendment shall be issued and made effective at the time the proposed indirect license transfer is completed.

IT IS FURTHER ORDERED that SHINE shall, at least 2 business days prior to closing, inform the Director of the Office of Nuclear Reactor Regulation in writing of the date of closing of the indirect license transfer for the SHINE Medical Isotope Production Facility. Should the proposed transfer of the license not be completed within 1 year of this Order's date of issuance, this Order shall become null and void, provided, however, that upon written application and for good cause shown, such date may be extended by order.

This Order is effective upon issuance.

For further details with respect to this Order, see the application dated December 11, 2018, as supplemented by letter dated March 8, 2019, and the associated NRC safety evaluation dated May 20, 2019, which are available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available documents created or received at the NRC are accessible electronically through ADAMS in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. Persons who encounter problems with ADAMS

should contact the NRC's PDR reference staff by telephone at 1-800-397-4209 or 301-415-4737 or by e-mail to pdr.resource@nrc.gov.

Dated at Rockville, Maryland this 20th day of May, 2019.

FOR THE NUCLEAR REGULATORY COMMISSION

/RA/

Tamara E. Bloomer, Acting Deputy Director,
Division of Licensing Projects,
Office of Nuclear Reactor Regulation.