

ENCLOSURE 2

SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL TECHNOLOGIES, LLC APPLICATION FOR AN OPERATING LICENSE

**GENERAL AND FINANCIAL INFORMATION
PUBLIC VERSION**

5 pages follow

GENERAL AND FINANCIAL INFORMATION

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1. Introduction

The following information supports the SHINE Medical Technologies, LLC (SHINE) operating license (OL) application. SHINE has applied for a license to operate a medical isotope production facility for the purpose of producing molybdenum-99 (Mo-99) and other isotopes used for nuclear medicine procedures.

2. General Information in Accordance with 10 CFR 50.33

2.1 Applicant Information

The SHINE company address is:

SHINE Medical Technologies, LLC
101 E. Milwaukee St., Suite 600
Janesville, Wisconsin, 53545

The SHINE facility produces the medical isotope Mo-99, which is the parent isotope of the diagnostic imaging isotope, technetium-99m (Tc-99m). The SHINE facility also produces other medical isotopes such as iodine-131 (I-131) and xenon-133 (Xe-133). The SHINE facility location in Janesville, Wisconsin, is described in the SHINE Final Safety Analysis Report (FSAR), Section 2.1.

2.2 Company Structure, Directors, and Principal Officers

SHINE is a single member, Delaware limited liability company, owned and controlled by Illuminated Holdings, Inc. (Illuminated), a Delaware corporation. SHINE is member managed by Illuminated. Attachment 1 includes information regarding the directors and principal officers of Illuminated and SHINE. The directors and principal officers of SHINE and Illuminated are U.S. citizens except as indicated otherwise in Attachment 1.

2.3 Foreign Ownership or Control

SHINE is not owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government. SHINE is not acting as an agent or representative of another person in filing the OL application. SHINE is a private company. SHINE is wholly-owned by Illuminated and Illuminated is its only shareholder. To the best of SHINE's knowledge, current shareholders holding 1 percent or more of Illuminated stock are U.S. citizens or entities owned or controlled by U.S. citizens.

One member of the Illuminated Board of Directors is a Canadian citizen with U.S. permanent resident status as indicated in Attachment 1. The appointment of one citizen of Canada as a director of Illuminated does not impact compliance with the requirements regarding foreign ownership, control, or domination in 10 CFR 50.38.

2.4 Class and Type of License

SHINE is requesting issuance of a 30 year operating license under 10 CFR 50 for the operation of the SHINE medical isotope production facility. The SHINE medical isotope production facility includes eight utilization facilities and one production facility as defined in 10 CFR 50.2. SHINE is requesting a Class 103 license, in accordance with 10 CFR 50.22, for commercial and industrial facilities. Operation of the SHINE facility also includes receipt, possession, and use of byproduct material in accordance with 10 CFR 30, source material in accordance with 10 CFR 40, and special nuclear material in accordance with 10 CFR 70.

The NRC previously authorized construction of the SHINE medical isotope production facility via the issuance and subsequent amendment of Construction Permit No. CPMIF-001 (Reference 7.1).

2.5 Financial Qualification and Shareholder Relationships

In accordance with 10 CFR 50.33(f), information sufficient to demonstrate that SHINE is financially qualified to operate the SHINE medical isotope production facility is provided in Section 15.2 of the FSAR. SHINE has demonstrated reasonable assurance of obtaining the funds necessary to cover estimated operation costs for the period of the license. Financial reports and certified financial statements are submitted annually in accordance with 10 CFR 50.71(b). SHINE submitted the most recent financial report, including certified financial statements, via Reference 7.2.

The relationship between SHINE and Illuminated is described in Section 2.2 and Attachment 1. SHINE is a private company, member managed by Illuminated, whose shareholders elect the Illuminated Board of Directors. Shareholder votes are dependent on the number of shares and class of stock held.

SHINE has a financing arrangement with Deerfield Management Company, L.P. (Deerfield), a Delaware series limited partnership (Series C). The agreement includes a \$150 million financing commitment to SHINE. Deerfield provides financing for SHINE to draw upon in several tranches over time. [

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2.6 Decommissioning

In accordance with 10 CFR 50.33(k), information in the form of a report, as described in 10 CFR 50.75, indicating how reasonable assurance will be provided that funds will be available to decommission the facility, is provided in Section 15.3 of the FSAR.

3. Fee Information in Accordance with 10 CFR 50.30(e) and 10 CFR 170.21

SHINE shall pay fees in accordance with 10 CFR 50.30(e) and 10 CFR 170.21.

4. Planned Start of Operations in Accordance with 10 CFR 50.30(d)

The SHINE medical isotope production facility is expected to be ready for operation in the fourth quarter of 2021.

5. Classified Information Agreement in Accordance with 10 CFR 50.37

The SHINE OL application does not contain Restricted Data as defined in 10 CFR 50.2 or classified National Security Information as defined in 10 CFR 25.5 and 10 CFR 95.5. SHINE will not permit any individual to have access to any facility to possess Restricted Data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR 25 and/or 10 CFR 95.

6. Technical Qualifications in Accordance with 10 CFR 50.34(b)(7)

SHINE is technically qualified to operate the facility. The primary basis for the SHINE technical qualification is the technical acumen of the SHINE management and staff. The NRC confirmed the technical qualification of SHINE via issuance of the Safety Evaluation by the Office of Nuclear Reactor Regulation for Indirect Transfer of and Conforming Amendment to Construction Permit No. CPMIF-001 (Reference 7.3). Since the initial issuance of the construction permit, SHINE has hired additional staff, including engineering staff, and updated the design of the facility, including the elimination of complex processes. SHINE continues to develop its technical qualifications through the construction and ongoing testing of an accelerator prototype similar to that which will be used within the irradiation units of the SHINE medical isotope production facility. SHINE has also established partnerships with Baker Concrete Construction, Inc.; Rock Creek Innovations, LLC; and Phoenix, LLC; companies specializing in construction, instrumentation and control protection systems, and accelerator technology, respectively. Additional information regarding staffing, organizational structure, training, and personnel qualifications is provided in Chapter 12 of the FSAR.

7. References

- 7.1 NRC letter to SHINE Medical Technologies, LLC, "SHINE Medical Technologies, LLC – Issuance of Amendment Reflecting Indirect Transfer of Construction Permit No. CPMIF-001 (EPID NO. L-2018-LLM-0154)" dated July 1, 2019 (ML19162A024)
- 7.2 SHINE Medical Technologies, Inc., letter to the NRC, "SHINE Medical Technologies, Inc. Submittal of Annual Financial Report," dated June 10, 2019 (ML19163A132)
- 7.3 NRC letter to SHINE Medical Technologies, Inc., "SHINE Medical Technologies, Inc. – Order Approving Indirect Transfer of and Conforming Amendment to Construction Permit No. CPMIF-001 (EPID NO. L-2018-LLM-0154)," dated May 20, 2019 (ML19102A323)

ATTACHMENT 1

DIRECTORS AND PRINCIPAL OFFICERS OF ILLUMINATED AND SHINE

COMPANY NAME:	Illuminated Holdings, Inc.
STATE OF INCORPORATION & CORPORATE FORM:	A Delaware corporation
BUSINESS ADDRESS (for Illuminated, as well as directors and principal officers):	101 E. Milwaukee St., Suite 600 Janesville, WI 53545
BOARD OF DIRECTORS:	Dr. Gregory Piefer Dr. Thomas "Rock" Mackie * Philip M. Halpern Todd Asmuth Gregory OD Smith Brad Wucherpfennig Gordon Gunnlaugsson
LIST OF PRINCIPAL OFFICERS:	Dr. Gregory Piefer, Chief Executive Officer Todd Asmuth, President & Chief Financial Officer

* Canadian Citizen and U.S. Permanent Resident

COMPANY NAME:	SHINE Medical Technologies, LLC
STATE OF INCORPORATION & CORPORATE FORM:	A Delaware limited liability company
BUSINESS ADDRESS (for SHINE, as well as principal officers):	101 E. Milwaukee St., Suite 600 Janesville, WI 53545
Member Manager:	Illuminated Holdings, Inc.
LIST OF PRINCIPAL OFFICERS:	Dr. Gregory Piefer, Chief Executive Officer Todd Asmuth, President & Chief Financial Officer Steve Miltenberger, Chief Operating Officer