



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

October 8, 2019

Gregory Piefer, Ph.D.  
Chief Executive Officer  
SHINE Medical Technologies, LLC  
101 E. Milwaukee Street, Suite 600  
Janesville, WI 53545

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – ACCEPTANCE OF THE  
APPLICATION FOR OPERATING LICENSE APPLICATION  
(EPID NO. L-2019-NEW-0004)

Dear Dr. Piefer:

By letter dated July 17, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19211C044), SHINE Medical Technologies, LLC (SHINE) submitted to the U.S. Nuclear Regulatory Commission (NRC) an operating license application for its proposed SHINE Medical Isotope Production Facility in accordance with the requirements contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities."

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 of 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 Medical Isotope Production Facility. Issuance of the operating license would authorize SHINE to operate the SHINE Medical Isotope Production Facility for a 30-year period.

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 concluded that it is acceptable for docketing under Docket Number 50-608. As part of its decision to accept and docket the application, the NRC staff determined that doing so would

facilitate the review of novel or first-of-a-kind application, and would be in the interest of public health, safety, and security, given the following rare circumstances:

- The SHINE operating license application is a first-of-a-kind submission involving a novel use of technology for which there is limited precedent to establish consistent standards for acceptance;
- In light of recurring global supply chain disruptions, the establishment of a domestically-produced commercial supply of Mo-99 is in the interest of public health; and
- The production of Mo-99 without the use of highly-enriched uranium supports U.S. national security interests and nuclear nonproliferation policy objectives.

Notwithstanding the acceptance and docketing of the application, the NRC staff has determined that additional information is necessary to complete a detailed technical review. As such, the NRC staff plans to promptly engage SHINE in public meetings and conduct regulatory audits to efficiently resolve certain information gaps as part of a detailed technical review of the application. Safety-significant topics to be addressed and covered during public meetings or regulatory audits include, but are not limited to:

- The design bases of the instrumentation and control systems, including descriptions of how design criteria are met, and safety-related functions are performed, as required by 10 CFR 50.34(b)(2)(ii); and
- Accident analyses and methodologies, including the final analysis and evaluation of the design and performance of structures, systems, and components supported by calculations and use of maximum hypothetical accident and integrated safety analysis techniques, as required by 10 CFR 50.34(b)(4).

Specific information to be covered on these and other safety, environmental, and security topics during the regulatory audit will be identified as part of a comprehensive audit plan, which will be provided to SHINE by separate correspondence within approximately 30 days from the date of this letter. Information covered as part of the regulatory audit that results in significant re-analysis or the development of new information could impact other technical areas of SHINE's application and necessitate additional audits, application supplements, or requests for information.

The submission of high-quality license applications supports the efficient review of material and timely regulatory decisions. In instances where additional information is needed for the NRC staff to complete its review, an applicant should expect that application supplements, extended schedules, and increased costs may be necessary. Taking into consideration the information gaps identified in the SHINE operating license application, the NRC staff estimates that completion of the review will take thirty-six months from the date of this letter, consistent with the generic milestone schedule for non-power production or utilization facility operating licensing application reviews established as part of the NRC's implementation of Section 102(c) of the Nuclear Energy Innovation and Modernization Act. Following the completion of the regulatory audit and receipt of any associated supplemental information provided by SHINE, the NRC staff will establish 1) a detailed review schedule, which may be longer or shorter than the initial thirty-six-month estimate, and 2) a projected level of effort to complete the detailed technical review.

Enclosed is a copy of the *Federal Register* Notice of acceptance for docketing to be forwarded to the Office of the Federal Register. In accordance with the provisions of 10 CFR 2.105, "Notice of proposed action," a separate notice will be published regarding the opportunity to file a petition for leave to intervene in a hearing regarding this application.

The need for proactive engagement with the NRC staff to resolve information gaps and establish a specific review schedule was discussed with you and other SHINE executives and managers on during an October 3, 2019, teleconference with NRC staff.

If you have any questions, please contact me at (301) 415-1524 or by electronic mail at [Steven.Lynch.gov](mailto:Steven.Lynch.gov).

Sincerely,

*/RA/*

Steven T. Lynch, Project Manager  
Research and Test Reactors Licensing Branch  
Division of Licensing Projects  
Office of Nuclear Reactor Regulation

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

cc: See next page

SHINE Medical Technologies, LLC

Docket No. 50-608

cc:

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Test, Research and Training  
Reactor Newsletter  
Attention: Ms. Amber Johnson  
Dept of Materials Science and Engineering  
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4418 Stadium Dr.  
College Park, MD 20742-2115

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SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – ACCEPTANCE OF THE APPLICATION FOR OPERATING LICENSE APPLICATION (EPID NO. L-2019-NEW-0004) DATE OCTOBER 8, 2019

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**ADAMS Accession No. ML19276D409** **\*concurred via email** **NRR-088**

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