



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

August 3, 2021

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

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – UPDATE TO OPERATING LICENSE
APPLICATION TECHNICAL REVIEW SCHEDULE (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 (SHINE 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,” and 10 CFR Part 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.” The most recent application supplement, dated March 23, 2021 (ADAMS Accession No. ML21095A235), contains the current version of the SHINE final safety analysis report (FSAR) and technical specifications¹. The purpose of this letter is to communicate an update for the SHINE operating license application review schedule.

In accordance with 10 CFR Part 2, “Agency Rules of Practice and Procedure,” 10 CFR Part 50, and 10 CFR Part 51, the NRC staff performed an acceptance review of the SHINE operating license application and, by letter dated October 8, 2019 (ADAMS Accession No. ML19276D409), concluded that the application was acceptable for docketing under Docket No. 50-608. Following the acceptance and docketing of the application, the NRC staff engaged SHINE in public meetings and audits to support the safety and environmental reviews; resolve information gaps in the application; and establish a detailed application review schedule. In support of the NRC staff’s safety review, public meetings were held on December 4 – 5, 2019 (ADAMS Accession No. ML19337B537), and March 4 - 5, 2020 (ADAMS Accession No. ML20056E142), and a regulatory audit was conducted in March 2020 (ADAMS Accession No. ML20057F949), on topics related to instrumentation and control systems; physical security; criticality safety; accident analysis; design changes associated with the SHINE tritium purification system; thermal hydraulic design; and approach to human factors engineering. In support of the NRC staff’s environmental review, an environmental site audit was conducted in February 2020 (ADAMS Accession No. ML19353C687), to identify information that differs or

¹ Previous application supplements containing updates to the SHINE FSAR, environmental report supplement, and technical specifications were submitted on dated November 14, 2019 (ADAMS Accession No. ML19337A275), March 27, 2020 (ADAMS Accession No. ML20105A295), August 28, 2020 (ADAMS Accession No. ML20255A027), November 13, 2020 (ADAMS Accession No. ML20325A026), December 10, 2020 (ADAMS Accession No. ML20357A084), and December 15, 2020 (ADAMS Accession No. ML21011A264).

reflects significant new information from what was evaluated in NUREG-2183, "Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility," dated October 2015 (ADAMS Accession No. ML15288A046), and verify information in SHINE's supplemental environmental report.

Taking into consideration the information exchanged during these public meetings and the regulatory audits, as well as the receipt of supplemental information provided by SHINE, the NRC staff revised its initial thirty-six month review schedule, which was established consistent with the generic milestone schedule for non-power production or utilization facility operating licensing application reviews as part of the NRC's implementation of Section 102(c) of the Nuclear Energy Innovation and Modernization Act. In a letter dated April 30, 2020 (ADAMS Accession No. ML20114E315), the NRC staff established a detailed review schedule of twenty-four months from the time of docketing the application, to support making a final determination whether an operating license should be issued to SHINE by October 2021.

By letter dated February 26, 2021 (ADAMS Accession No. ML21057A340), SHINE informed the NRC staff of a new phased approach to construction and operation, as well as its intent to submit additional licensing actions to be completed prior to the issuance of an operating license. As described in the February 2021 letter, SHINE anticipated submitting a supplement to its operating license application describing the technical, licensing, and administrative impacts of its new approach to phased construction and operation by June 2021. As of the date of this letter, such a supplement has not been received by the NRC staff and SHINE has not provided a new date for when such a supplement will be submitted to the NRC staff for review.

In its February 2021 letter, SHINE also described submitting licensing action requests for the receipt and possession of certain byproduct, source, and special nuclear material pursuant to 10 CFR Parts 30, 40, and 70 to support the construction of the SHINE facility and to support preparedness for initial facility operations upon issuance of an operating license. By letter dated April 29, 2021 (ADAMS Accession No. ML21119A166), SHINE applied for an amendment to Construction Permit No. CPMIF-001. The license amendment request (LAR) proposes to receive and possess certain byproduct and source materials necessary for the continued construction of the SHINE facility. The NRC staff expects to complete its review and make a final determination on the LAR by September 30, 2021. SHINE indicated that a subsequent request to receive and possess additional radioactive materials is expected to be submitted by December 2021.

Given the outstanding information related to SHINE's phased approach to construction and operation, the ongoing review of the construction permit LAR, and anticipated subsequent request to receive and possess additional radioactive materials, the NRC staff has determined that it is necessary to update its review schedule, including associated milestones, and estimated level of effort to complete its safety and environmental reviews of the SHINE operating license application. This forthcoming information related to SHINE's operating license application and associated licensing actions needed for the construction and operation of the SHINE facility is necessary support the NRC staff's findings of reasonable assurance that the activities described in the operating license application can be conducted without endangering the health and safety of the public, and that such activities would be conducted in compliance with the Commission's regulations. Such information is also necessary to support the scheduling of interim milestones, such as meetings with the Advisory Committee on Reactor Safeguards and issuance of the draft supplement to the Environmental Impact Statement.

Taking into consideration the time necessary to review information related to SHINE's future phased approach supplement and subsequent request to receive and possess radioactive materials, as well as the scheduling of interim review milestones, the NRC staff will need to revise its review schedule beyond the twenty-four month schedule established in April 2020. Therefore, the NRC staff requests that SHINE provide updated submission dates for its phased approach supplement and subsequent request to receive and possess radioactive material, as well as the current expected completion dates for each phase of construction within 30 days of the date of this letter. These dates are needed for the NRC staff to establish a revised review schedule consistent with the NRC's implementation of Section 102(c) of the Nuclear Energy Innovation and Modernization Act and projected level of effort to complete the detailed technical review.

The NRC staff will continue to review information previously submitted as part of SHINE's operating license application, as well as anticipated responses to outstanding RAIs related to SHINE's accident analysis, criticality safety program, instrumentation and control systems, and fire protection program.

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

Sincerely,

/RA/

Steven T. Lynch, Project Manager
Non-Power Production and Utilization
Facility Licensing Branch
Division of Advanced Reactors and Non-Power
Production and Utilization Facilities
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

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Reactor Newsletter
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SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – UPDATE TO OPERATING LICENSE APPLICATION TECHNICAL REVIEW SCHEDULE (EPID NO. L-2019-NEW-0004) DATED: AUGUST 3, 2021

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NRR-106

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