



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

April 30, 2020

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 – 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), as supplemented by letters dated November 14, 2019 (ADAMS Accession No. ML19337A275), and March 27, 2020 (ADAMS Accession No. ML20105A295), 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," and 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions." The purpose of this letter is to communicate a revised review schedule of twenty-four months for the SHINE operating license application.

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 Number 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 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 is revising 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. The NRC staff is now establishing a detailed review schedule of twenty-four months from the time of docketing the application, which will support making a final determination whether an operating license should be issued to SHINE by October 2021. The NRC staff anticipates that the total level of effort needed to complete the milestones detailed in the technical review schedule will be up to 22,000 staff hours. The NRC staff has also budgeted for up to \$100,000.00 in contract support as a contingency for preparation of the supplemental environmental impact statement (EIS). Through the second quarter of fiscal year 2020, the NRC staff has expended 6,194.75 staff hours of the estimated 22,000 staff hours on the review of the SHINE operating license application.

This letter forwards the enclosed SHINE Operating License Application Technical Review Schedule, comprised of the safety and environmental review milestones supporting the NRC staff’s preparation of a final safety evaluation report and supplemental EIS supporting the final determination whether an operating license should be issued to SHINE. The NRC staff will follow the enclosed schedule to complete the reviews required by 10 CFR Part 50 and 10 CFR Part 51. This review schedule does not account for potential delays associated with the completion of construction of the facility.

In the coming months, the NRC staff expects to conduct additional regulatory audits and public meetings with SHINE to further the NRC staff’s understanding of the information provided in SHINE’s operating license application, as supplemented, and promote the efficiency of the NRC staff’s review. The NRC staff also expects to issue requests for additional information as part of its review to resolve information insufficiencies in the application and to 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. There are circumstances that may result in adjustments to the review schedule and resource estimate. Such circumstances include applicant delays in providing requested information to the NRC staff and the receipt of new information affecting the scope of the review. The NRC staff will promptly communicate any schedule or resource changes that would extend the expected review completion date beyond October 2021 or exceed the level of effort significantly beyond 22,000 hours.

If you have any questions, please contact me, the safety project manager, at (301) 415-1524, or by electronic mail at [Steven.Lynch@nrc.gov](mailto:Steven.Lynch@nrc.gov) or Jennifer Davis, the environmental project manager, at (301) 415-3835, or by electronic mail at [Jennifer.Davis@nrc.gov](mailto:Jennifer.Davis@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

Enclosure:  
As stated

cc: w/enclosure: See next page

SHINE Medical Technologies, LLC

Docket No. 50-608

cc:

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Environmental Analysis Specialist-  
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Resources  
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Fitchburg, WI 53711

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

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City Manager  
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SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – OPERATING LICENSE APPLICATION  
TECHNICAL REVIEW SCHEDULE (EPID NO. L-2019-NEW-0004)  
DATED: APRIL 30, 2020

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DTiktinsky, NMSS

**ADAMS Accession No.: ML20114E315****\*concurred via e-mail****NRR-106**

OFFICE	NRR/DANU/PM*	NRR/DANU/LA*	NMSS/REFS/BC*	NRR/DANU/BC*	NRR/DANU/PM*
NAME	SLynch	NParker	RElliott	GCasto	SLynch
DATE	4/30/2020	4/27/2020	4/30/2020	4/30/2020	4/30/2020

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**SHINE Medical Technologies, LLC**

## Operating License Application

## Technical Review Schedule

<b>Milestone</b>	<b>Technical Review Area</b>	<b>Scheduled Completion Date</b>	<b>Actual Completion Date</b>	<b>Status</b>
Receipt of Operating License Application	Safety and Environmental	August 2019	August 2019	Complete
Acceptance and Docketing of Operating License Application	Safety and Environmental	October 2019	October 2019	Complete
Environmental Scoping Meeting	Environmental	December 2019	December 2019	Complete
Issuance of Notice of Opportunity to Request Hearing	Safety and Environmental	January 2020	January 2020	Complete
Closing of Opportunity to Request Hearing	Safety and Environmental	March 2020	March 2020	Complete
NUREG Publication of Draft Supplemental Environmental Impact Statement	Environmental	September 2020	TBD	Pending
Advisory Committee on Reactor Safeguards (ACRS) Subcommittee Meeting	Safety	September 2020	TBD	Pending
ACRS Subcommittee Meeting	Safety	February 2021	TBD	Pending
NUREG Publication of Final Supplemental Environmental Impact Statement	Environmental	April 2021	TBD	Pending
ACRS Subcommittee Meeting	Safety	June 2021	TBD	Pending
Draft Safety Evaluation Report Complete	Safety	July 2021	TBD	Pending
ACRS Full Committee Meeting	Safety	September 2021	TBD	Pending
Final Safety Evaluation Report	Safety	September 2021	TBD	Pending
Final Determination on Issuance of Operating License Application	Safety and Environmental	October 2021	TBD	Pending

Enclosure