



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

May 16, 2022

Dr. Gregory Piefer
Chief Executive Officer
SHINE Technologies, LLC
3400 Innovation Court
Janesville, WI 53546

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – POTENTIAL IMPACTS TO
OPERATING LICENSE APPLICATION TECHNICAL REVIEW SCHEDULE
(EPID NO. L-2019-NEW-0004)

Dear Dr. Piefer:

The purpose of this letter is for the U.S. Nuclear Regulatory Commission (NRC) to communicate potential impacts to the review schedule for the SHINE Medical Technologies, LLC (SHINE) operating license application for its proposed SHINE Medical Isotope Production Facility (SHINE facility) (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19211C044). The NRC previously communicated that it plans to complete the operating license application review by October 2022, in accordance 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 (NEIMA) (ML22047A179). Due to uncertainty surrounding the timing of responses to information needs related to the SHINE Application for an Operating License Supplement No.15, Submittal of the Phased Startup Operations Application Supplement, dated January 27, 2022 (ML22027A354), the timing of the completion of the software engineering validation related to the digital instrumentation and control review, and the submittal of the SHINE cyber security plan, the NRC is considering the potential need to delay the schedule. Additional information needs may also be identified as the review progresses, due to recent and possible future design changes.

The NRC is currently following the schedule outlined in its SHINE Operating License Application Technical Review Schedule letter dated February 17, 2022 (ML22047A179), and the NRC staff will promptly communicate any schedule changes that would extend the expected review completion date beyond October 2022. Should such schedule changes impact the NEIMA milestone, the NRC will follow the established NEIMA reporting requirements, as required. At this point, the NRC does not anticipate any potential schedule delay will impact the staff's ability to complete the operating license application review in time to support the planned construction schedule for the SHINE facility to be substantially complete by May 2023.

If you have any questions, please contact me at (301) 415-1053, or by electronic mail at Holly.Cruz@nrc.gov.

Sincerely,



Signed by Cruz, Holly
on 05/16/22

Holly D. Cruz, Senior 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

cc:

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University of Maryland
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College Park, MD 20742-2115

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – POTENTIAL IMPACTS TO OPERATING
LICENSE APPLICATION TECHNICAL REVIEW SCHEDULE
(EPID NO. L-2019-NEW-0004) DATED: MAY 16, 2022

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ADAMS Accession No.: ML22125A040

NRR-106

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