

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

August 1, 2022

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

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC — UPDATE 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 inform SHINE Technologies, LLC (SHINE) of a schedule delay of the review of the operating license application for the proposed SHINE Medical Isotope Production Facility (SHINE facility) (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19211C044). The NRC previously communicated that it planned 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). Over the last few months, the NRC and SHINE staff have continued to work constructively to bring to closure the remaining safety aspects of the review and address SHINE's revised phased licensing approach, documented in SHINE Application for an Operating License Supplement No.15, Submittal of the Phased Startup Operations Application Supplement, dated January 27, 2022 (ML22027A354). These efforts have been successful in bringing resolution to many of the remaining topics. Nevertheless, a few outstanding topics require continued engagement between our organizations to fully resolve and require SHINE to provide the remaining information to the NRC to complete its review. As such, the NRC has determined that we will need to extend the review schedule beyond October 8, 2022, to enable continued engagement.

The NRC is confident that while issuance of a final safety evaluation will be slightly delayed, the NRC does not anticipate the schedule delay will impact the staff's ability to complete the operating license application review in time to support the current construction schedule for the SHINE facility to be substantially complete by May 2023. Achieving this goal is contingent on receiving timely and complete information from SHINE, that is sufficient to complete the review, within agreed upon schedules. The NRC staff will continue to communicate and engage with SHINE to efficiently review information as it is provided.

If you have any questions, please contact me at (301) 415-1053, or by email at <u>Holly.Cruz@nrc.gov</u>.

Sincerely,

Chally D. Cy Signed by Cruz, Holly on 08/01/22

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 Technologies, LLC

CC:

Jeff Bartelme Licensing Manager SHINE Technologies, LLC 3400 Innovation Court Janesville, WI 53546

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Shelley Warwick Environmental Analysis Specialist-South Team Wisconsin Department of Natural Resources 3911 Fish Hatchery Road Fitchburg, WI 53711

Test, Research and Training Reactor Newsletter Attention: Amber Johnson Dept of Materials Science and Engineering University of Maryland 4418 Stadium Drive College Park, MD 20742-2115 Docket No. 50-608

Mark Freitag City Manager P.O. Box 5005 Janesville, WI 53547-5005

Bill McCoy 1326 Putnam Avenue Janesville, WI 53546

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G. Piefer

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NRR-106

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