



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

June 8, 2021

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

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – ACCEPTANCE OF THE
APPLICATION FOR A CONSTRUCTION PERMIT AMENDMENT RELATED TO
THE RECEIPT AND POSSESSION OF CERTAIN RADIOACTIVE MATERIALS
(EPID NO. L-2021-LLA-0104)

Dear Dr. Piefer:

By letter dated April 29, 2021 (Agencywide Documents Access and Management System Accession No. ML21119A166), SHINE Medical Technologies, LLC (SHINE) applied for an amendment to Construction Permit No. CPMIF-001 for its Medical Isotope Production Facility. The license amendment request (LAR) proposes to receive and possess certain radioactive materials necessary for the continued construction of the SHINE Medical Isotope Production Facility. Consistent with Title 10 of the *Code of Federal Regulations* (10 CFR) 50.90, "Application for amendment of license, construction permit, or early site permit," an application to amend the construction permit must fully describe the changes desired and follow, as far as applicable, the form prescribed for original applications. The requirements in 10 CFR 50.34, "Contents of applications; technical information," cover the technical information to be included in the application and stipulate that it address design and operating characteristics, unusual or novel design features, and principal safety considerations.

The U.S. Nuclear Regulatory Commission (NRC) staff performed an acceptance review of the LAR and concluded that it includes sufficient information for the NRC staff to begin its detailed technical review. Notwithstanding the acceptance review, the NRC staff may require additional information to complete the detailed technical review. If needed, the NRC staff will request this information by separate correspondence within approximately 30 days of the date of this letter.

Based on the acceptance review, the NRC staff expects to complete its review and make a final determination on the LAR by August 31, 2021. This date could change due to several factors, including requests for additional information, unanticipated changes to the scope of the review, unsolicited supplements to the LAR, and others. If the forecasted date changes, the NRC staff will notify SHINE in writing of the new date and an explanation of the reason for the change.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Steven T. Lynch".

Signed by Lynch, Steven
on 06/08/21

Steven T. Lynch, 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

cc: See next page

SHINE Medical Technologies, LLC

Docket No. 50-608

cc:

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Licensing Manager
SHINE Medical Technologies, LLC
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Nathan Schleifer
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1000 Independence Avenue, SW
Washington, DC 20585

Mark Paulson
Supervisor
Radiation Protection Section
Wisconsin Department of Health Services
P.O. Box 2659
Madison, WI 53701-2659

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

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

Bill McCoy
1326 Putnam Avenue
Janesville, WI 53546

Alfred Lembrich
541 Miller Avenue
Janesville, WI 53548

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ADAMS Accession No. ML21158A070**NRR-106**

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