



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

March 22, 2019

Gregory Piefer, Ph.D.
Chief Executive Officer
SHINE Medical Technologies, Inc.
101 E. Milwaukee Street, Suite 600
Janesville, WI 53545

SUBJECT: SHINE MEDICAL TECHNOLOGIES, INC. – ACKNOWLEDGMENT OF
RECEIPT OF PERIODIC REPORT ON CONSTRUCTION PERMIT
CONDITIONS (EPID NO. L-2017-PMP-0014)

Dear Dr. Piefer:

In order to verify certain design developments related to nuclear criticality safety (NCS) and radiation protection in the SHINE Medical Technologies, Inc. (SHINE) radioisotope production facility (RPF), the U.S. Nuclear Regulatory Commission (NRC) collects periodic reports containing the information set forth in Section 3.D.(1) of SHINE Construction Permit No. CPMIF-001.

By letter dated February 22, 2019 (Agencywide Documents Access and Management System Accession No. ML19053A278), SHINE submitted to the NRC its sixth periodic report on NCS and radiation protection consistent with Section 3.D.(1) of its construction permit, CPMIF-001.

As described in its sixth periodic report, SHINE has performed work on the five license conditions described in Section 3.D.(1) of its construction permit. In support of developing the technical basis for the design of the criticality accident alarm system in License Condition (LC) 3.D.(1)(a), SHINE has completed a preliminary analysis using detector response functions in similar facilities to determine detector placement to meet the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 70.24, "Criticality accident requirements," paragraph (a).

With respect to the criticality safety considerations described in LCs 3.D.(1)(b) - (d), SHINE indicated that it has used criteria for determining that criticality events are not credible for RPF processes even though fissile materials may be present; completed preliminary NCS evaluations for various systems; and continues to evaluate reactivity contributions from all fissile isotopes to demonstrate that all RPF processes remain subcritical under all normal and credible abnormal conditions.

According to its sixth periodic report, SHINE continues to develop additional design information for the RPF supercells, tank vaults containing the liquid waste storage tanks, evaporation hot cells, and liquid waste solidification hot cells. SHINE indicated that it has determined expected direct dose rates throughout the proposed facility using conservative assumptions. SHINE has created dose maps for multiple analyzed operational scenarios using an as low as is reasonably achievable goal for dose rates in normally occupied locations during normal operation of 0.25 millirem per hour at 30 centimeters from the surface of the shielding. Additionally, administrative controls, such as occupancy times, will be used to ensure doses remain as low

as reasonably achievable (ALARA). This information will be presented as part of the SHINE operating license application to demonstrate that shielding and occupancy times within the RPF are consistent with ALARA practices and dose requirements of 10 CFR Part 20, "Standards for Protection against Radiation," as described in LC 3.D.(1)(e).

As of the writing of this letter, SHINE has neither initiated construction of its proposed facility nor submitted any additional design information as part of an operating license application or amendment to its construction permit for NRC review under Docket No. 50-608.

Based upon the information provided in SHINE's periodic reports, the status of activities authorized under Construction Permit No. CPMIF-001, and the status of applications submitted under Docket No. 50-608, no NRC action is necessary on SHINE's periodic reports at this time.

The NRC may request that SHINE provide clarifying or more detailed information in order to verify certain design developments as set forth in Section 3.D.(1) of SHINE's construction permit if the NRC considers this information necessary prior to the completion of construction. This may include requests that SHINE make reference material available through an electronic reading room or meet with NRC staff to support the planning and conduct of NRC inspections during construction.

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
Research and Test Reactors Licensing Branch
Division of Licensing Projects
Office of Nuclear Reactor Regulation

Docket No. 50-608

cc: See next page

SHINE Medical Technologies, Inc.

Docket No. 50-608

cc:

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Test, Research and Training
Reactor Newsletter
Attention: Amber Johnson
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