

June 18, 2018

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 REPORTS 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 letters dated August 23, 2017, and February 23, 2018 (Agencywide Documents Access and Management System Accession Nos. ML17235A110 and ML18054A002, respectively), SHINE submitted to the NRC its third and fourth periodic reports on NCS and radiation protection consistent with Section 3.D.(1) of its construction permit, No. CPMIF-001.

As described in its third and fourth periodic reports, SHINE has performed limited work on four of 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 (CAAS) in License Condition 3.D.(1)(a), SHINE has performed a preliminary analysis to develop an initial estimate of the scope and complexity of the CAAS installation.

With respect to the criticality safety considerations described in License Conditions 3.D.(1)(b)-(d), SHINE indicated that it has approved a portion of the required programmatic NCS documentation; worked to update the validation of the use of Monte Carlo N-Particle in calculating reactivities; begun evaluating the impact of pipe configuration on target solution reactivity; and initiated preliminary work on evaluating the impact of homogeneity on target solution reactivity. SHINE also indicated that it has worked on evaluating reactivity contributions from all fissile isotopes to develop a conservative estimate of reactivity for use in future NCS evaluations.

According to its third and fourth periodic reports, SHINE has also developed additional design information for the RPF supercells, tank vaults containing the liquid waste storage tanks, evaporation hot cells, and liquid waste solidification hot cells to determine tank vault sizing, tank elevations, facilities locations, and supercell shielding requirements. This information will be used to demonstrate that shielding and occupancy times within the RPF are consistent with as low as is reasonably achievable practices and dose requirements of Title 10 of the *Code of*

Federal Regulations Part 20, "Standards for Protection against Radiation," as described in License Condition 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 via electronic reading room or meet with NRC staff to support the planning and conducting 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

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