February 23, 2018

2018-SMT-0011
10 CFR 50.4

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

References: (1) NRC letter to SHINE Medical Technologies, Inc., "SHINE Medical Technologies, Inc. – Issuance of Construction Permit for Medical Isotope Facility," dated February 26, 2016 (ML16041A473)
(2) SHINE Medical Technologies, Inc. letter to NRC, "Periodic Report Required by the License Conditions in Section 3.D.(1) of CPMIF-001," dated August 23, 2017 (ML17235A110)

Periodic Report Required by the License Conditions in Section 3.D.(1) of CPMIF-001

Pursuant to the License Conditions described in Section 3.D.(1) of the SHINE Medical Technologies, Inc. (SHINE) Construction Permit (Reference 1), SHINE is submitting the enclosed periodic report, updating the NRC staff on progress related to nuclear criticality safety and radiation protection since SHINE's previous periodic report (Reference 2).

If you have any questions, please contact Mr. Jeff Bartelme, Licensing Manager, at 608/210-1735.

I declare under the penalty of perjury that the foregoing is true and correct.
Executed on February 23, 2018.

Very truly yours,

James Costedio
Vice President of Regulatory Affairs and Quality
SHINE Medical Technologies, Inc.
Docket No. 50-608

Enclosure

cc: Project Manager, USNRC
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health

ENCLOSURE

SHINE MEDICAL TECHNOLOGIES, INC.

PERIODIC REPORT REQUIRED BY THE LICENSE CONDITIONS IN SECTION 3.D.(1) OF CPMIF-001

Pursuant to the License Conditions described in Section 3.D.(1) of the SHINE Medical Technologies, Inc. (SHINE) Construction Permit (Reference 1), SHINE is providing the following periodic report, updating the NRC staff on progress related to nuclear criticality safety and radiation protection.

License Condition 3.D.(1)(a)

The technical basis for the design of the criticality accident alarm system (CAAS), including a description of the methodology for determining detector placement. The technical basis shall demonstrate that the CAAS will meet the requirements of 10 CFR 70.24(a) and the commitments listed on page 6b-19 of the Preliminary Safety Analysis Report, Revision 0.

SHINE Update

Since the submittal of SHINE's previous periodic report updating the NRC staff on progress related to nuclear criticality safety and radiation protection (Reference 2), a preliminary analysis of the SHINE facility has been performed using a ray-tracing method to develop an initial estimate of the scope and complexity of the criticality accident alarm system (CAAS) installation that will be required to provide coverage for the SHINE facility. From this report, SHINE will develop a detailed analysis to determine the final placement of detectors as part of the technical basis for the design of the CAAS.

Future SHINE work includes developing the technical basis for the design of the CAAS, including a description of the methodology for determining detector placement, demonstrating that the CAAS meets the requirements of 10 CFR 70.24(a) and the commitments listed on Page 6b-19 of the SHINE Preliminary Safety Analysis Report (PSAR).

License Condition 3.D.(1)(b)

The basis for determining that criticality events are "not credible" for radioisotope production facility (RPF) processes even though fissile materials may be present. The basis shall demonstrate that the each such event satisfies the definition of "not credible," as described in the SHINE integrated safety analysis Summary.

SHINE Update

Since the submittal of SHINE's previous periodic report updating the NRC staff on progress related to nuclear criticality safety and radiation protection (Reference 2), SHINE has worked to update the validation of the use of Monte Carlo N-Particle (MCNP) in calculating reactivities at SHINE by applying additional benchmark experiments that bound the relevant nuclear parameters in the SHINE target solution. SHINE has also begun work on evaluating the impact

of pipe configuration on target solution reactivity. Additionally, preliminary work has been performed to evaluate the impact of target solution homogeneity on target solution reactivity. These analyses will support the final evaluation of criticality events for Radioisotope Production Facility (RPF) processes.

Future SHINE work includes evaluating criticality events for RPF processes. For any criticality event SHINE determines to be "not credible" even though fissile material may be present, SHINE will provide the basis for the determination, demonstrating that each such event satisfies the definition of "not credible," as described in the SHINE Integrated Safety Analysis (ISA) Summary.

License Condition 3.D.(1)(c)

Summaries of the criticality safety analysis for the affected processes that include the following: (1) a list of identified criticality hazards, (2) a list of controlled parameters, (3) a description of evaluated normal and abnormal conditions, (4) a description of the licensee's approach to meeting the double contingency principle, and (5) a list of anticipated passive and active engineered controls, including any assumptions, to ensure the process(es) will remain subcritical under normal and credible abnormal conditions. The criticality safety analysis summaries shall demonstrate that all RPF processes will remain subcritical under all normal and credible abnormal conditions and will satisfy the double contingency principle.

SHINE Update

Since the submittal of SHINE's previous periodic report updating the NRC staff on progress related to nuclear criticality safety and radiation protection (Reference 2), SHINE has worked to update the validation of the use of MCNP in calculating reactivities at SHINE by applying additional benchmark experiments that bound the relevant nuclear parameters in the SHINE target solution. SHINE has also begun work on evaluating the impact of pipe configuration on target solution reactivity. Additionally, preliminary work has been performed to evaluate the impact of target solution homogeneity on target solution reactivity. These analyses will support the final evaluation of criticality events for RPF processes and the identification of criticality hazards.

Future SHINE work includes evaluating criticality events for RPF processes. SHINE will summarize the evaluations of the affected processes, including a list of identified criticality hazards; a list of controlled parameters; a description of evaluated normal and abnormal conditions; a description of SHINE's approach to meeting the double contingency principle; and a list of anticipated passive and active engineered controls, including any assumptions, to ensure the processes will remain subcritical under normal and credible abnormal conditions. The summaries will demonstrate that all RPF processes will remain subcritical under all normal and credible abnormal conditions and will satisfy the double contingency principle.

License Condition 3.D.(1)(d)

The relevant nuclear criticality safety evaluations (NCSEs) shall address the reactivity contributions from all fissile isotopes or SHINE shall apply an additional subcritical margin to account for neglecting these nuclides. The treatment of fissile nuclides other than U-235, whether through the NCSEs or the addition of subcritical margin, shall demonstrate that all RPF processes will remain subcritical under all normal and credible abnormal conditions.

SHINE Update

Since the submittal of SHINE's previous periodic report updating the NRC staff on progress related to nuclear criticality safety and radiation protection (Reference 2), SHINE has continued work on evaluating reactivity contributions from all fissile isotopes and comparing those reactivity contributions against a bounding enrichment of U-235 to be used in nuclear criticality safety evaluations (NCSEs). Whichever condition provides a more conservative estimate of reactivity, as determined by this evaluation, will be used in future NCSEs.

Future SHINE work includes completing the reactivity evaluation and evaluating criticality events for RPF processes, addressing the reactivity contributions from all fissile isotopes or applying additional subcritical margin to account for neglecting these nuclides. The treatment of fissile nuclides other than U-235, whether through the NCSEs or the addition of subcritical margin, will demonstrate that all RPF processes will remain subcritical under all normal and credible abnormal conditions.

License Condition 3.D.(1)(e)

The design information on the RPF supercells, tank vaults containing the liquid waste storage tanks, evaporation hot cells, and liquid waste solidification hot cells demonstrating shielding, and occupancy times within the RPF are consistent with as low as is reasonably achievable practices and dose requirements of 10 CFR Part 20.

SHINE Update

Since the submittal of SHINE's previous periodic report updating the NRC staff on progress related to nuclear criticality safety and radiation protection (Reference 2), work on additional design information on RPF supercells, tank vaults containing liquid waste storage tanks, evaporation hot cells, and liquid waste solidification hot cells has continued to determine required tank vault sizing, tank elevations, and facility locations. SHINE has also determined RPF supercell shielding requirements.

Future SHINE work includes using the design information on RPF supercells, tank vaults containing liquid waste storage tanks, evaporation hot cells, and liquid waste solidification hot cells to update or perform shielding analyses and occupancy time analyses demonstrating shielding and occupancy times within the RPF are consistent with as low as is reasonably achievable practices and the dose requirements of 10 CFR Part 20.

REFERENCES

(1) NRC letter to SHINE Medical Technologies, Inc., "SHINE Medical Technologies, Inc. – Issuance of Construction Permit for Medical Isotope Facility," dated February 26, 2016 (ML16041A473)

(2) SHINE Medical Technologies, Inc. letter to NRC, "Periodic Report Required by the License Conditions in Section 3.D.(1) of CPMIF-001," dated August 23, 2017 (ML17235A110)