August 23, 2017

SMT-2017-053
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 February 24, 2017 (ML17055A573)

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 August 23, 2017.

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), no additional formal work has been performed on criticality accident alarm system (CAAS) equipment.

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 approved a portion of the required programmatic nuclear criticality safety (NCS) documentation (i.e., Criticality Safety Personnel Training and Qualification Program, Validation of Criticality Safety Calculational Methods, Nuclear Criticality Safety Calculations), and has begun work on additional programmatic NCS documentation (i.e., Criticality Safety Policy, Criticality Safety Program Description, Criticality Safety, Nuclear Criticality Safety Evaluations). This programmatic NCS documentation will be used to guide the development of nuclear criticality safety evaluations (NCSEs) for Radioisotope Production Facility (RPF) processes.

Future SHINE work includes completing NCS programmatic documentation and 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 and the NCS programmatic documents.

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 approved a portion of the required programmatic NCS documentation (i.e., Criticality Safety Personnel Training and Qualification Program, Validation of Criticality Safety Calculational Methods, Nuclear Criticality Safety Calculations), and has begun work on additional programmatic NCS documentation (i.e., Criticality Safety Policy, Criticality Safety Program Description, Criticality Safety, Nuclear Criticality Safety Evaluations). This programmatic NCS documentation will be used to guide the development of NCSEs for RPF processes.

Future SHINE work includes completing NCS programmatic documentation and 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 approved a portion of the required programmatic NCS documentation (i.e., Criticality Safety Personnel Training and Qualification Program, Validation of Criticality Safety Calculational Methods, Nuclear Criticality Safety Calculations), and has begun work on additional programmatic NCS documentation (i.e., Criticality Safety Policy, Criticality Safety Program Description, Criticality Safety, Nuclear Criticality Safety Evaluations). This programmatic NCS documentation will be used to guide the development of nuclear criticality safety evaluations (NCSEs) for Radioisotope Production Facility (RPF) processes.

Future SHINE work includes completing NCS programmatic documentation 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), SHINE has begun progressing with the design of RPF supercells, tank vaults containing liquid waste storage tanks, evaporation hot cells, and liquid waste solidification hot cells to determine required tank vault sizing, tank elevations, and locations within the SHINE facility.

Future SHINE work includes incorporating detailed design information into the existing shielding analyses and occupancy time analyses for the RPF supercells, tank vaults containing 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 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 February 24, 2017 (ML17055A573)