August 22, 2018

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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 23, 2018 (ML18054A002)

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 22, 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 the criticality accident alarm system (Reference 2), SHINE has contracted the work necessary to determine appropriate placement and detector response functions associated with the CAAS in order to meet the requirements of 10 CFR 70.24(a). To date, the analysis has primarily been focused on development of the facility-specific minimum accident of concern (MAC) and transport source terms through generic facility walls. The detector responses associated with the transport source term are being compared to fully-coupled models using the MAC source term to assure appropriate fidelity in the data.

Future work includes integration of the transport source terms into the facility layout model, including tank vaults, valve pits, pipe trenches, the hot cells, the uranium receipt and storage area, and the target solution preparation room. Following the source term integration, detector response and placement will be determined, ensuring that each potential location is appropriately covered by two or more detectors with appropriate sensitivity to detect a criticality.

Documentation associated with development of the technical basis will be produced as needed to demonstrate that the CAAS meets 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 developed the following criteria for determining that criticality events are "not credible" for radioisotope production facility (RPF) processes even though fissile materials may be present:

Not Credible

- Event is not physically possible, or
- Event is caused by a sequence of events involving many unlikely human actions or errors for which there is no reason or motive.

The determination that a criticality event is not credible is made as part of the criticality safety evaluation process.

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 above 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 related to nuclear criticality safety and radiation protection (Reference 2), SHINE has begun drafting nuclear criticality safety evaluations (NCSEs) for the following systems:

- The target solution preparation system (TSPS),
- The radioactive liquid waste system (RLWS),
- The molybdenum extraction and purification system (MEPS),
- The uranium receipt and storage system (URSS), and
- The target solution staging system (TSSS).

Future SHINE work includes completing criticality safety evaluations 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 evaluated reactivity contributions from all fissile isotopes and compared those reactivity contributions against a bounding enrichment of U-235 to be used in NCSEs. The SHINE source term calculation uses a combination of SCALE, MCNP, and ORIGEN to determine a bounding mass of fissile nuclides assuming significantly off-normal operating parameters (high power, long irradiation times, short recovery time between irradiations). The bounding values from this calculation were compared to nominally 21% enriched 'fresh' target solution, with no credit taken for buildup of neutron absorbers. The 21% enriched 'fresh' solution was found to bound solution with a buildup of other fissile isotopes by a minimum of about 0.3% $\Delta k$ at all concentrations and temperatures. Therefore, criticality safety calculations and related evaluations use 21% enriched 'fresh' target solution in all calculations, which is a conservative estimate of system multiplication, in lieu of an arbitrary additional subcritical margin.

Future SHINE work includes performing NCSEs for RPF processes, using 21% enriched 'fresh' target solution in all calculations as a conservative estimate of system multiplication. The use of 21% enriched 'fresh' target solution in the NCSEs 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. Shield plug thickness requirements for tank vaults, valve pits, pipe trenches, and the carbon delay bed vault have been determined, and drip pan requirements for shielded cell and tank elevations have been determined for tank vaults, valve pits, and pipe trenches.

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 February 23, 2018 (ML18054A002)