



August 25, 2016

SMT-2016-039  
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)

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.

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 25, 2016.

Very truly yours,

A handwritten signature in black ink, appearing to read 'James Costedio', is written over the typed name.

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

Enclosure

cc: Administrator, Region III, USNRC  
Project Manager, USNRC  
Environmental 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 issuance of the SHINE Construction Permit (Reference 1), SHINE has worked with criticality accident alarm system (CAAS) equipment vendors on the development of an initial estimate of equipment quantities as part of a scoping effort for the CAAS. SHINE has not yet performed any formal work on detector locations.

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 issuance of the SHINE Construction Permit (Reference 1), no additional work has been performed on nuclear criticality safety evaluations (NCSEs) 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 issuance of the SHINE Construction Permit (Reference 1), no additional work has been performed on NCSEs for RPF processes.

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 issuance of the SHINE Construction Permit (Reference 1), no additional work has been performed on NCSEs for RPF processes.

Future SHINE work includes 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 issuance of the SHINE Construction Permit (Reference 1), no additional design information on the RPF supercells, tank vaults containing the liquid waste storage tanks, evaporation hot cells, or 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, has been developed.

Future SHINE work includes performing new and updating existing shielding analyses and occupancy time analyses for 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 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)