August 19, 2021

2021-SMT-0075
10 CFR 50.4

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

References: (1) NRC letter to SHINE Medical Technologies, LLC, "SHINE Medical Technologies, LLC - Issuance of Amendment Reflecting Indirect Transfer of Construction Permit No. CPMIF-001 (EPID NO. L-2018-LLM-0154)," dated July 1, 2019 (ML19162A024)
(2) SHINE Medical Technologies, LLC letter to NRC, "Periodic Report Required by the License Conditions in Section 3.D.(1) of CPMIF-001," dated February 19, 2021 (ML21050A003)

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, LLC (SHINE) Construction Permit as amended (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, Director of Licensing, at 608/210-1735.

I declare under the penalty of perjury that the foregoing is true and correct.
Executed on August 19, 2021.

Very truly yours,

DocuSigned by:
Jim Costedio
F52DB96989224FF...

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

Enclosure

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

ENCLOSURE

SHINE MEDICAL TECHNOLOGIES, LLC

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, LLC (SHINE) Construction Permit as amended (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), SHINE has submitted an operating license application supplement (Reference 3). As described in previous periodic reports (Reference 2 et al.), the design of the criticality accident alarm system (CAAS) has developed over time. The preliminary CAAS design, as described in the Preliminary Safety Analysis Report (PSAR) including the commitments listed on page 6b-19 of the PSAR, has been updated. The CAAS design description, including the information required by the license condition described in Section 3.D.(1)(a) of the SHINE Construction Permit (Reference 1), is provided in the Final Safety Analysis Report (FSAR) (Reference 3).

FSAR Section 6b.3.3 provides the technical basis for the design of the CAAS, including a description of the methodology for determining detector placement. The CAAS design, as described in the FSAR, demonstrates that the CAAS meets the requirements of 10 CFR 70.24(a) and conforms to the requirements in ANSI/ANS-8.3-1997, as endorsed by Regulatory Guide 3.71, Revision 3 (Reference 4).

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

The information required by the license condition described in Section 3.D.(1)(b) of the SHINE Construction Permit (Reference 1) is described in the SHINE Safety Analysis and summarized in the FSAR (Reference 3).

FSAR Section 6b.3.2 provides a summary of the criticality safety basis for each RPF process including the bases for determining that processes will remain subcritical under normal and credible abnormal conditions even though fissile materials may be present. The SHINE Safety Analysis includes the definitions of "credible" and "not credible" events. The bases for determining that RPF processes will remain subcritical under normal and credible abnormal conditions are consistent with these definitions.

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

The information required by the license condition described in Section 3.D.(1)(c) of the SHINE Construction Permit (Reference 1) is described in the SHINE Safety Analysis and summarized in the FSAR (Reference 3).

The SHINE Safety Analysis includes a list of identified criticality hazards for each RPF process, a description of controlled parameters used for each process, a description of evaluated normal and credible abnormal conditions, and a list of passive and active engineered controls related to the criticality safety analyses. FSAR Section 6b.3.2 provides a summary of the criticality safety basis for each process system, which includes summaries of the criticality safety analyses for the affected processes to ensure the processes will remain subcritical under normal and credible abnormal conditions. The criticality safety analysis summaries provided in the FSAR 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), there have been no changes in methodology related to the evaluation of reactivity contributions from all fissile isotopes. SHINE continues to perform 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 demonstrates 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

The information required by the license condition described in Section 3.D.(1)(e) of the SHINE Construction Permit (Reference 1) is provided in the FSAR (Reference 3).

FSAR Section 4b.2 provides a description and analysis of shielding designs for the areas in the RPF where radioactive materials are transferred, stored, and processed, including:

- Supercell, including the following cells:
  - Extraction (3 cells)
  - Purification (3 cells)
  - Packaging (2 cells)
  - Process vessel vent system (PVVS)
  - Iodine and xenon purification and packaging (IXP)
- Process tank vaults
- Process valve pits
- Pipe trenches
- Carbon delay bed vault
- Solid waste drum storage bore holes
- Radioactive liquid waste immobilization (RLWI) shielded enclosure

FSAR Section 11.1 describes the Radiation Protection Program and the As Low As Reasonably Achievable (ALARA) Program, which discuss, among other radiation protection principles, facility design considerations that minimize personnel occupancy times spent in radiation areas. FSAR Section 11.1.1 provides a description of radiation source locations and source term characterizations. FSAR Table 11.1-4 provides a table of normally-occupied and transient-occupied areas, projected dose rates, and area radiological designations. FSAR Figure 11.1-1 provides the facility radiologically controlled area (RCA) layout and projected radiation area designations within the RCA. The analyses presented in FSAR Section 11.1 demonstrates that the shielding designs described in FSAR Section 4b.2, along with the Radiation Protection Program and ALARA Program requirements described in FSAR Section 11.1, are consistent with ALARA practices and dose requirements of 10 CFR Part 20.

REFERENCES

(1) NRC letter to SHINE Medical Technologies, LLC, “SHINE Medical Technologies, LLC - Issuance of Amendment Reflecting Indirect Transfer of Construction Permit No. CPMIF-001 (EPID NO. L-2018-LLM-0154),” dated July 1, 2019 (ML19162A024)

(2) SHINE Medical Technologies, LLC letter to NRC, “Periodic Report Required by the License Conditions in Section 3.D.(1) of CPMIF-001,” dated February 19, 2021 (ML21050A003)

(3) SHINE Medical Technologies, LLC letter to NRC, “SHINE Medical Technologies, LLC Operating License Application Response to Request for Additional Information and Supplement No. 7,” dated March 23, 2021 (ML21095A241)

(4) U.S. Nuclear Regulatory Commission, “Nuclear Criticality Safety Standards for Nuclear Materials Outside Reactor Cores,” Regulatory Guide 3.71, Revision 3, October 2018 (ML18169A258)