June 3, 2021

2021-SMT-0062
10 CFR 50.30

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

References:
(1) SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Application for an Operating License," dated July 17, 2019 (ML19211C143)
(2) NRC letter to SHINE Medical Technologies, LLC, "SHINE Medical Technologies, LLC – Request for Additional Information Related Meteorological Data, Cooling Systems, and Physical Security Plan (EPID No. L-2019-NEW-0004)," dated April 8, 2021 (ML21089A001)
(3) SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Application for an Operating License Response to Request for Additional Information", dated April 30, 2021 (ML21130A632)
(4) SHINE Medical Technologies, LLC, letter to the NRC, "SHINE Medical Technologies, LLC Application for an Operating License Response to Request for Additional Information", dated May 7, 2021 (ML21127A051)

SHINE Medical Technologies, LLC Application for an Operating License
Response to Request for Additional Information 4a-15

Pursuant to 10 CFR Part 50.30, SHINE Medical Technologies, LLC (SHINE) submitted an application for an operating license for a medical isotope production facility to be located in Janesville, WI via Reference 1. Via Reference 2, the NRC staff determined that additional information was required to enable the staff's continued review of the SHINE operating license application. SHINE responded to a portion of the NRC staff's request via References 3 and 4.

Enclosure 1 provides the SHINE response to Request for Additional Information (RAI) 4a-15.

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 June 3, 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 1

SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL TECHNOLOGIES, LLC APPLICATION FOR AN OPERATING LICENSE RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION 4A-15

The U.S. Nuclear Regulatory Commission (NRC) staff determined that additional information was required (Reference 1) to enable the continued review of the SHINE Medical Technologies, LLC (SHINE) operating license application (Reference 2). The following information is provided by SHINE in response to the NRC staff's request.

Chapter 4 – Irradiation Unit and Radioisotope Production Facility Description

RAI 4a-15

Paragraph (b)(2) of Section 50.34, "Contents of applications; technical information," to 10 CFR Part 50 requires, in part, that an FSAR include a description and analysis of the structures, systems, and components of the facility, with emphasis upon performance requirements, the bases, and the evaluations required to show that safety functions will be accomplished. The description shall be sufficient to permit understanding of the system designs and their relationship to safety evaluations.

The ISG to NUREG-1537, Part 2, Section 4a2.6, "Thermal-Hydraulic Design," states that the criteria for the thermal-hydraulic design should include that there be no coolant flow instability in any cooling coil that could lead to a decrease in cooling, and that the departure from nucleate boiling (DNB) ratio should be no less than 2.0 along a cooling coil. The NRC staff did not identify information in the FSAR to confirm that that any primary closed loop cooling system (PCLS) heat transfer surface, under any design conditions, will not undergo DNB.

Clarify whether any PCLS cooling surface, considering all system design conditions, could exceed critical heat flux resulting in DNB. If so, explain how such a condition is prevented and mitigated. If not, explain how much margin is available to avoid DNB in the worse-case scenario.

This information is necessary to confirm that primary coolant hydraulics and thermal conditions have been specified for the SHINE facility, consistent with the evaluation findings in the ISG to NUREG-1537, Part 2, Section 4a2.6. The analysis provided by the applicant should consider the various approaches and systems for heat removal, such as the cooling coils, the pool, and the gas management system. The analyses should give the limiting conditions of the features that ensure barrier integrity.

SHINE Response

The primary closed loop cooling system (PCLS) cooled components include the target solution vessel (TSV) and the neutron multiplier.

The PCLS cools the external surfaces of the TSV. The cooled material is uranyl sulfate target solution. The cooling water surrounding the TSV external surfaces cannot boil because the target solution is predominantly water. The target solution cannot increase in temperature beyond its boiling point due to phase change physics. The target solution is necessarily hotter than the cooling water because of the thermal resistance of natural convection between the target solution and TSV internal surfaces, conduction through the TSV walls, and forced convection between the TSV external surfaces and the cooling water. Additionally, the target solution cannot become significantly pressurized, as described in Subsection 4a2.7.6 of the FSAR. Therefore, the cooling water cannot reach its boiling point based on limitations of physics.

The PCLS cools the external surfaces of the neutron multiplier. The cooled material is natural uranium. The departure from nucleate boiling (DNB) ratio for the neutron multiplier in the worst-case power transient scenario is conservatively calculated to be 4.8 and DNB cannot occur.

SHINE has revised Subsection 4a2.7.3.1 of the FSAR to provide confirmation that PCLS heat transfer surfaces will not undergo DNB. A mark-up of the FSAR incorporating this change is provided as Attachment 1.

References

1. NRC letter to SHINE Medical Technologies, LLC, “SHINE Medical Technologies, LLC – Request for Additional Information Related Meteorological Data, Cooling Systems, and Physical Security Plan (EPID No. L-2019-NEW-0004),” dated April 8, 2021 (ML21089A001)

2. SHINE Medical Technologies, LLC letter to the NRC, “SHINE Medical Technologies, LLC Application for an Operating License,” dated July 17, 2019 (ML19211C143)

ENCLOSURE 1
ATTACHMENT 1

SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL TECHNOLOGIES, LLC APPLICATION FOR AN OPERATING LICENSE
RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION 4A-15

FINAL SAFETY ANALYSIS REPORT CHANGES
(MARK-UP)

1 page follows

[ ]PROP/ECI, the flow rate to CC3 is approximately [ ]PROP/ECI.

The cooling water supply to the lower plenum of the SASS is at a pressure of up to approximately 20 pounds per square inch gage (psig) (138 kilopascal [kPa]) and a temperature of 59°F to 77°F (15°C to 25°C). The maximum PCLS cooling water temperature of 77°F (25°C) is used in the calculations presented in Subsection 4a2.7.5, below. This temperature limit is protected by the TSV reactivity protection system (TRPS) IU Cell Safety Actuation setpoints.

The TSV headspace pressure is maintained slightly below atmospheric pressure. The pressure over the target solution in the TSV is normally between -2 psig (-14 kPa) and 0 psig (0 kPa).

The cooling water pressure difference across the TSV within the SASS is less than approximately 7 psid (48 kPa), which accounts for entrance and exit pressure losses and frictional pressure losses in the cooling channels. See Table 5a2.2-1 for the PCLS parameters. As the primary cooling water is maintained far from boiling even at atmospheric pressures, pressure profiles of the cooling water in the flow channels are not important for the heat transfer characteristics of the system. Total cooling water flow rate and inlet temperature are principal variables of importance for heat transfer. These variables are monitored by the TRPS.

As described above, the PCLS cools the external surfaces of the TSV. The cooled material is uranyl sulfate target solution. The PCLS cooling water surrounding the TSV external surfaces cannot boil because the target solution is predominantly water. The target solution cannot increase in temperature beyond its boiling point due to phase change physics. The target solution is necessarily hotter than the cooling water because of the thermal resistance of natural convection between the target solution and TSV internal surfaces, conduction through the TSV walls, and forced convection between the TSV external surfaces and the cooling water. Additionally, the target solution cannot become significantly pressurized, as described in Subsection 4a2.7.6. Therefore, the cooling water cannot reach its boiling point based on limitations of physics.

As described above, the PCLS also cools the external surfaces of the neutron multiplier. The cooled material is natural uranium. The departure from nucleate boiling (DNB) ratio for the neutron multiplier in the worst-case power transient scenario is 4.8 and DNB cannot occur.

4a2.7.3.2 Chemical Effects Related to Heat Transfer

The TSV is constructed of 347 stainless steel. The target solution is chemically compatible with this alloy of stainless steel. When 347 stainless steel is placed in a uranyl-sulfate solution at temperatures up to 212°F (100°C), the steel retains its metallic luster, and only after long periods of time does it develop a very thin tarnish film (Lane, 1958).

Plating out of chemicals on the TSV surfaces is not expected in the operating temperature range of the SHINE process. Plating out of chemicals onto surfaces can occur via two mechanisms: a layer of non-volatile material can be left on surfaces when water is removed by boiling or vaporizing, or a layer of material can form when soluble components are electro-chemically reduced to a non-soluble state. The TSV is maintained at a nominal 120°F (50°C) during irradiation, which is well below the boiling point of water, even at a pressure slightly below atmospheric. No plating out of chemicals is expected from boiling because no boiling will occur in the TSV. Evaporation of and collection of solid salts on the TSV walls at the liquid surface is