January 29, 2021

2021-SMT-0001
10 CFR 70.17

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

References:
(1) U.S. Nuclear Regulatory Commission letter to SHINE Medical Technologies, LLC, dated July 1, 2019, "SHINE Medical Technologies, LLC – Issuance of Amendment Reflecting Indirect Transfer of Construction Permit No. CPMIF-001 (EPID No. L-2018-LLM-0154)" (ML19162A024)
(2) U.S. Nuclear Regulatory Commission Letter to SHINE Medical Technologies, LLC, dated August 14, 2020, "SHINE Medical Technologies, LLC Regulatory Audit RE: Accident Analysis and Criticality Safety Program Described in Operating License Application (EPID No. L-2019-NEW-0004)" (ML20226A262)

Request for Exemption from Criticality Accident Alarm System Monitoring Requirements for the SHINE Irradiation Unit Cells and Material Staging Building

SHINE Medical Technologies, LLC (SHINE) is the holder of a Construction Permit, issued pursuant to 10 CFR Part 50 (Reference 1), for the construction of a medical isotope production facility in Janesville, WI. While preparing responses to audit topics prior to the NRC's regulatory audit regarding accident analysis and criticality safety (Reference 2), SHINE determined that exemption from the monitoring requirements of 10 CFR 70.24(a) for the irradiation unit (IU) cells and the material staging building (MATB) is required.

Pursuant to 10 CFR 70.17(a), SHINE hereby requests an exemption from the monitoring requirements of 10 CFR 70.24(a) for the IU cells and the MATB. In the IU cells, in the highly unlikely event of an accidental criticality, personnel are protected by robust shielding such that there is no undue risk to personnel, the public, and the environment. In the MATB, a criticality is precluded by material composition of the packaged waste.

The evaluation provided in Enclosure 1 identifies the specific requirements in the regulation for which an exemption is requested and concludes that exempting both the IU cells and MATB from the monitoring requirements of 10 CFR 70.24(a) are authorized by law, will not endanger life, property, or the common defense and security, and are in the public interest.

Following NRC approval of the exemption request, SHINE will revise the Final Safety Analysis Report (FSAR) to reflect the fact that the IU cells and MATB are exempted from the monitoring requirements of 10 CFR 70.24(a).

Enclosure 1 provides the SHINE exemption request to the monitoring requirements of 10 CFR 70.24(a) for the IU cells and MATB. SHINE respectfully requests that the NRC approve this exemption request by June 30, 2021 to allow SHINE time to incorporate the approved exemption into the SHINE FSAR in a timeframe that meets the NRC's technical review schedule for the SHINE operating license application.

If you have any questions, please contact Mr. Jeff Bartelme, Director of Licensing, at 608/210-1735.

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

REQUEST FOR EXEMPTION FROM CRITICALITY ACCIDENT ALARM SYSTEM MONITORING REQUIREMENTS FOR THE SHINE IRRADIATION UNIT CELLS AND MATERIAL STAGING BUILDING

Background

SHINE Medical Technologies, LLC (SHINE) is the holder of a Construction Permit, issued pursuant to 10 CFR Part 50 (Reference 1), for the construction of eight utilization facilities and one production facility designed for the production of medical radioisotopes. SHINE has begun construction of the medical isotope production facility in Janesville, WI. While preparing responses to audit topics prior to the NRC's regulatory audit regarding accident analysis and criticality safety (Reference 2), SHINE determined that exemption from the monitoring requirements of 10 CFR 70.24(a) for the irradiation unit (IU) cells within the irradiation facility (IF) and the material staging building (MATB) was required.

10 CFR 70.24(a) requires that licensees authorized to possess certain quantities of special nuclear material (SNM) provide a monitoring system in each area in which such licensed SNM is handled, used, or stored meeting the requirements of 10 CFR 70.24(a)(1) or 10 CFR 70.24(a)(2), as appropriate, and using gamma- or neutron-sensitive radiation detectors that will energize clearly audible alarm signals if accidental criticality occurs.

Those areas of the SHINE facility in which SNM above the threshold quantities provided in 10 CFR 70.24(a) is handled, used, or stored are the IU cells, the target solution vessel (TSV) off-gas system (TOGS) cells, the radioisotope production facility (RPF), and the MATB. The TOGS cells and the RPF are monitored by the criticality accident alarm system as described in Subsections 6a2.3.2 and 6b.3.3 of the Final Safety Analysis Report (FSAR), respectively.[1]

10 CFR 70.17 authorizes the NRC to grant exemptions from the requirements of its regulations as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Because SNM handled and used in the IU cells occurs within a light water pool, which itself is located within a robust shielded enclosure, and because the characterization of SNM in solidified waste staged for shipment in the MATB precludes the possibility of criticality, there is no need to provide a criticality accident alarm system in these areas of the SHINE facility, and not providing those systems will not endanger life or property or the common defense and security.

Irradiation Unit Cells

The IU cells comprise, in part, the irradiation cell biological shield (ICBS). The ICBS provides a barrier to protect SHINE facility personnel and members of the public by reducing their exposure

[1] A description of the criticality accident alarm system is provided in Subsection 6b.3.3 of the FSAR.

to sources of radiation. The design bases for the materials in the ICBS are described in Subsection 4a2.5.2.1 of the FSAR.

Within the IU cells, SNM is handled and used in components of the subcritical assembly system (SCAS) and components of the TOGS. These components are submerged in a light water pool which provides radiation shielding during both irradiation operations and an accidental criticality, as described in Section 4a2.2 of the FSAR. The light water pool and the radiological shielding provided thereby is described in Subsections 4a2.4.2 and 4a2.4.2.3 of the FSAR, respectively.

The SCAS components that contain SNM are the TSV, the TSV dump tank, and interconnecting piping.

The TSV maintains fissile material (enriched uranyl sulfate target solution) in a subcritical, but highly multiplying configuration during the irradiation process and is not subject to criticality safety requirements.

The TSV dump tank is an annular design that is subcritical under all normal and credible abnormal conditions. The TSV dump tank is normally utilized as a hold tank for target solution decay prior to transfer to the RPF. The TSV dump tank is located below the TSV to allow for the gravity transfer of the target solution from the TSV to the dump tank as part of normal operations, in the event of an abnormal TSV condition, or during an accident scenario. The TSV dump tank has a favorable geometry to prevent accidental criticality for the most reactive credible conditions including various upset conditions, and has sufficient capacity to hold the entire contents of the TSV. The TSV dump tank is submerged in the light water pool, which provides passive cooling and shielding that protects workers and the public during normal operations from the TSV and protects workers and the public from an accidental criticality within the TSV dump tank.

The interconnecting piping has a favorable geometry to prevent accidental criticality for the most reactive credible conditions, including various upset conditions. Based on the diameter of the interconnecting piping being significantly less than the single parameter limit for an infinite, water-reflected cylinder, no accident conditions have been identified that could lead to an accidental criticality in the interconnecting piping.

Each neutron flux detection system (NFDS) division includes a startup range detector and a power range detector with a minimum of two decades overlap. There are three divisions, spaced at approximately 120-degree intervals around the TSV. These detectors are primarily sensitive to thermal neutrons with excellent gamma rejection. Calculations show that the NFDS is able to detect the minimum accident of concern if a criticality were to occur in the TSV dump tank. This would show up as an increased count rate on the detectors, which is visible to operators through the process integrated control system.

The TOGS components are located in both the IU cells and the TOGS cells.[2] The TOGS components that are not located in the TOGS cells - including the condenser-demister units, recombiner demister, vacuum tank, and portions of the interconnecting piping - are located in the light water pool within the IU cell. The TOGS has been designed with favorable geometry to prevent accidental criticality for the most reactive credible conditions. Under normal operating conditions, the TOGS – both the portion in the IU cells and the portion in the TOGS cells - does

[2] As above, the criticality accident alarm system monitors criticality in the TOGS cells.

not contain sufficient quantities of fissile material to result in a criticality accident. However, under certain accident conditions, target solution could enter the system, posing a criticality risk. Those accident conditions would be detected with the safety-related high-high TSV dump tank level instrumentation, alerting operation personnel of the need to take appropriate response actions. Additional discussion of protection against inadvertent criticality in TOGS is provided in Subsection 4a2.8.5.1 of the FSAR.

The TSV operates at a maximum licensed power level of 125 kW, which corresponds to an equivalent fission rate of approximately 3.9×10^{15} fissions per second. Appendix A of ANSI/ANS-8.3-1997, "Criticality Accident Alarm System," (Reference 3) shows that enriched uranium solution criticality experiments demonstrate peak power levels between 7.8×10^{14} and 7.4×10^{15} fissions per second and average power levels for these excursions between approximately 1.3×10^{14} to 1.3×10^{15} fissions per second. Thus, a criticality accident in the IU cell would produce radiation similar to the radiation produced during normal operation of the subcritical assembly. Thus, a criticality accident would not produce additional risk to workers or the public.

In addition, and as described above, the NFDS would detect the minimum accident of concern if a criticality were to occur in the TSV dump tank. Similarly, accident conditions that could cause the target solution to enter the TOGS thereby posing a criticality risk would be detected with safety-related level instrumentation, alerting operations personnel of the need to take appropriate response actions.

Further, with the exception of the TSV, which is not subject to criticality safety requirements, the SCAS and TOGS components within the IU cells where SNM may be present are designed to be subcritical under all normal and credible abnormal conditions. In the event of a criticality accident within the IU cell, the accident would occur within the robust concrete shielding provided by the ICBS and water shielding provided by the light water pool.

The design of structures, systems, and components, along with the indication of an abnormal condition within the IU cells provided by the NFDS and level instrumentation, are sufficient to prevent undue risk to workers, the public, and the environment from a criticality accident resulting from SNM handled and used within the IU cells. Therefore, SHINE is requesting exemption from the monitoring requirements of 10 CFR 70.24(a) for the IU cells.

<u>Material Staging Building</u>

As described in Subsection 6b3.2.11 of the FSAR, the MATB provides a location for packaged radioactive material – both as-generated solid waste and solidified liquid waste - to decay until it can be transported to an off-site final disposal location.

As-Generated Solid Waste

Section 4.1.1 of NUREG/CR-7239, "Review of Exemptions and General Licenses for Fissile Material in 10 CFR 71" (Reference 4), observes that criticality resulting from the accumulation of a large number of packages that meet the requirements of 10 CFR 71.15(a) does not appear to be credible, based on the number and volume of packages required to approach criticality. As-generated solid wastes (e.g., contaminated glassware and used neutron drivers), packaged and staged for transport in the MATB, meet the requirements of 10 CFR 71.15(a). Thus, the NRC has concluded that SHINE's as-generated solid waste stored in those packages is unlikely to become critical.

Solidified Liquid Waste

Section 4.1.3 of NUREG/CR-7239 states that packages that meet the requirements of 10 CFR 71.15(c) preclude nuclear criticality safety concerns by limiting the mass concentration and requiring a nearly uniform mixture of fissile and nonfissile materials. SHINE will store its solidified liquid waste in the MATB in packages that meet the requirements of 10 CFR 71.15(c). Thus, the NRC has concluded that SHINE's solidified liquid waste is unlikely to become critical.

Because the NRC has concluded that waste stored in accordance with the requirements of 10 CFR 71.15(a) or 10 CFR 71.15(c) is unlikely to become critical, and because SHINE's SNM-containing waste staged for transport in the MATB meets the requirements of 10 CFR 71.15(a) or 10 CFR 71.15(c), the NRC has concluded that SHINE's SNM-containing waste that meets the requirements of 10 CFR 71.15(a) or 10 CFR 71.15(c), is unlikely to become critical. Accordingly, SHINE is requesting an exemption from the monitoring requirements of 10 CFR 70.24(a) for the MATB.

Specific Exemption Request

In accordance with 10 CFR 70.17(a), "Specific Exemptions," SHINE requests NRC approval of an exemption from the monitoring requirements of 10 CFR 70.24(a) for the IU cells and the MATB.

Upon approval of the exemption request, SHINE will revise the FSAR to reflect the fact that the IU cells and MATB are exempted from the monitoring requirements of 10 CFR 70.24(a). Implementation of the requested exemption ensures the design of the SHINE facility is consistent with the requirements of 10 CFR 70.24, including documenting in the SHINE licensing basis the approved exception to the requirements for those areas of the SHINE facility where the requirements need not be met.

The Requested Exemption is Authorized By Law

The NRC has the authority under the Atomic Energy Act to grant exemptions from its regulations if doing so would not violate the requirements of law. No law exists that precludes the activities covered by this exemption request. The provisions of 10 CFR 70.24(a) were adopted at the discretion of the Commission consistent with its statutory authority. No statute required the NRC to adopt the specific provisions from which SHINE seeks an exemption. The NRC may determine that alternative means are adequate to provide reasonable assurance of safety.

The Requested Exemption Will Not Endanger Life, Property, or the Common Defense and Security

The design of the SCAS and TOGS components and the shielding provided by the ICBS and the light water pool are sufficient to prevent undue risk to workers, the public, and the environment from a criticality accident resulting from fissile material (SNM) within the IU cells. The as-generated solid and solidified liquid wastes staged within the MATB meet the requirements of 10 CFR Part 71.15, assuring there is no possibility of criticality. Therefore, an exemption from 10 CFR 70.24(a) for both the IU cell and the MATB will not endanger life, property, or the common defense and security.

The Requested Exemption is in the Public Interest

NRC approval of the requested exemption is in the public interest because it will allow SHINE to implement a controlled and safe approach to handling, using, and storing SNM. The facility has redundant and adequate protection for the health and safety of the public and facility workers. Additionally, timely construction of the SHINE facility supports the establishment of a domestically produced commercial supply of molybdenum-99, which is in the interest of public health. NRC denial of the requested exemption is not in the public interest because it will result in increased cost, delayed completion of the SHINE facility, and the associated economic losses, all without an appreciable safety benefit.

Therefore, granting the requested exemption is in the public interest.

Conclusion

Applying the monitoring requirements of 10 CFR 70.24(a) to the IU cells and MATB provides no appreciable benefit to the health and safety of the worker or to the public, as the design of IU cells and MATB structures and processes provide adequate protection against the occurrence of an accidental criticality, as described above. SHINE is committing to revise the FSAR to ensure the approved exemption is appropriately captured in the SHINE licensing basis. Further, the requested exemption is authorized by law and will not endanger life or property or the common defense and security and is otherwise in the public interest.

Since the provisions of 10 CFR 70.17(a) are satisfied, the requested exemption should be granted. Approval of the exemption is requested by June 30, 2021, to allow SHINE time to incorporate the approved exemption into the FSAR in a timeframe that meets the NRC's technical review schedule for the SHINE operating license application.

References

1. U.S. Nuclear Regulatory Commission letter to SHINE Medical Technologies, LLC, dated July 1, 2019, "SHINE Medical Technologies, LLC – Issuance of Amendment Reflecting Indirect Transfer of Construction Permit No. CPMIF-001 (EPID No. L-2018-LLM-0154)" (ML19162A024)

2. U.S. Nuclear Regulatory Commission Letter to SHINE Medical Technologies, LLC, dated August 14, 2020, "SHINE Medical Technologies, LLC Regulatory Audit RE: Accident Analysis and Criticality Safety Program Described in Operating License Application (EPID No. L-2019-NEW-0004)" (ML20226A262)

3. American National Standards Institute/American Nuclear Society, "Criticality Accident Alarm System," ANSI/ANS-8.3-1997 (R2017), La Grange Park, IL

4. U.S. Nuclear Regulatory Commission, "Review of Exemptions and General Licenses for Fissile Material in 10 CFR 71," NUREG/CR-7239, January 2018 (ML18052A520)