ENCLOSURE 2

SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL TECHNOLOGIES, LLC REQUEST TO AMEND CONSTRUCTION PERMIT NO. CPMIF-001 (PUBLIC VERSION)

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1. INTRODUCTION

In accordance with 10 CFR 50.90, SHINE Medical Technologies, LLC (SHINE) hereby requests to amend Construction Permit No. CPMIF-001 (Reference 1) to permit SHINE to receive and possess certain radioactive materials necessary for the continued construction of the SHINE medical isotope production facility.

SHINE requests that the NRC approve this amendment request by August 31, 2021 to allow SHINE time to procure, receive, and install the requested radioactive material, to support timely construction of the SHINE facility.

SHINE requests NRC authorization to receive and possess the following radioactive materials that are required to be installed within SHINE systems as part of construction activity sequencing:

- Natural uranium, in the form of neutron multipliers, for installation within the subcritical assembly systems (SCAS), as described in Subsection 4a2.2.6 of the Final Safety Analysis Report (FSAR) (Reference 2).
- Depleted uranium (DU), in the form of tritium storage beds, for installation within the tritium purification system (TPS), as described in Subsection 9a2.7.1 of the FSAR.
- Americium-241 beryllium (AmBe) sealed sources for installation within the SCAS, as subcritical multiplication sources (SMS), as described in Subsection 4a2.2.4 of the FSAR.

To ensure compliance with the applicable regulations of 10 CFR Parts 30 and 40, SHINE has prepared the content of this amendment request considering the guidance of NUREG-1556, Volume 7, Revision 1, “Consolidated Guidance About Materials Licenses – Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Electron Capture Devices and X-Ray Fluorescence Analyzers” (Reference 3). The content of the amendment request follows the Suggested Response guidance provided in Appendix B of NUREG-1556, Volume 7, by providing the information requested in Items 5 through 11 of NRC Form 313. The amendment request is independent of the on-going NRC review of the SHINE operating license application and does not rely on any programs or plans currently under review by the NRC Staff.

2. PROPOSED CHANGES

SHINE proposes that the following conditions be added to Section 3 of Construction Permit No. CPMIF-001:

E. Pursuant to the Act and 10 CFR Part 30, the following activities are included:

(1) to receive and possess, in connection with construction of the facility, up to [ ]^{SRI} of sealed americium-241 beryllium neutron sources.

F. Pursuant to the Act and 10 CFR Part 40, the following activities are included:

(1) to receive and possess, in connection with construction of the facility, up to 10,000 kg of natural uranium in the form of neutron multipliers; and

(2) to receive and possess, in connection with construction of the facility, up to 10 kg of depleted uranium in the form of tritium storage beds.

3. INFORMATION REQUESTED IN ITEMS 5 THROUGH 11 OF NRC FORM 313

The content of this section follows the Suggested Response guidance provided in Appendix B of NUREG-1556, Volume 7, by providing the information requested in Items 5 through 11 of NRC Form 313.

ITEM 5 – RADIOACTIVE MATERIAL

UNSEALED SOURCES		
Radioisotope	Natural uranium	Depleted uranium
Chemical / Physical Form	Solid metal	Solid metal or oxide
Maximum Possession Limit	10,000 kg	10 kg

SEALED SOURCE	
Radioisotope	Americium-241 / Beryllium
Chemical / Physical Form	Solid
Sealed Source Manufacturer or Distributor and Model Number	[ ]SRI
Sealed Source and Device (SSD) Registration Sheet Number	MA-1059-S-240-S
Maximum Activity Per Source	[ ]SRI
Maximum Number of Sources	16
Maximum Possession Limit	[ ]SRI

Each sealed source is registered as an approved sealed source by the NRC or an Agreement State and will be possessed and used in accordance with the conditions specified in the registration certificate, except as described in Item 10 concerning leak test intervals.

Pursuant to 10 CFR 30.35(g) and 10 CFR 40.36(f), SHINE will maintain records important to decommissioning. SHINE will transfer records important to decommissioning to an NRC or Agreement State licensee before licensed activities are transferred or assigned, in accordance with 10 CFR 30.34(b) and 10 CFR 40.46.

ITEM 6 – PURPOSES FOR WHICH LICENSED MATERIAL WILL BE USED

The natural uranium is contained within neutron multipliers, which are described in Subsection 4a2.2.6 of the FSAR, for installation within the SCAS.

The DU is contained within tritium storage beds, which are described in Subsection 9a2.7.1 of the FSAR, for installation within the TPS.

The AmBe sealed sources are used as SMSs, which are described in Subsection 4a2.2.4 of the FSAR, for installation within the SCAS.

ITEM 7 – INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

SHINE staff is qualified by training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property. The Commission has previously concluded that SHINE is technically qualified to engage in the activities authorized under the terms of the Construction Permit (Reference 4). The SHINE staff includes individuals responsible for radiation safety whose experience encompasses responsibilities such as:

- performing the duties of radiation safety officer and authorized user
- planning and conducting evaluations, surveys, and measurements
- hands on experience using licensed materials of similar types, forms, and quantities
- maintaining security and control of licensed materials
- monitoring inventory of materials possessed under the license; maintaining records of receipts, transfers, and disposal of licensed materials
- storing, handling, disposing, and documenting of radioactive waste materials
- planning, conducting, and documenting audits of the radiation safety program
- evaluating and documenting radiation exposures
- maintaining required records and providing required reports
- formal training or education in radiation safety including:
    - radiation protection principles
    - characteristics of ionizing radiation
    - units of radiation dose and quantities
    - radiation detection and measurement instrumentation
    - biological hazards of exposure to radiation
    - NRC regulatory requirements and standards

ITEM 8 – TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Individuals whose assigned duties involve exposure to radiation or radioactive material, and in the course of their employment are likely to receive in a year an occupational dose of radiation greater than 1 mSv (100 mrem), receive annual instruction commensurate with their duties and responsibilities, as required by 10 CFR 19.12. The design and implementation of the radiation safety training program complies with the requirements of 10 CFR 19.12. The development and implementation of the radiation safety training program considers the topics covered in:

- Regulatory Guide 8.10 - Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Reasonably Achievable (Reference 5),
- Regulatory Guide 8.13 - Instructions Concerning Prenatal Radiation Exposure (Reference 6),
- Regulatory Guide 8.29 - Instructions Concerning Risks from Occupational Radiation (Reference 7), and
- ASTM E1168-95 - Radiological Protection Training for Nuclear Facility Workers (Reference 8).

The level of radiation safety training is based on the potential radiological health risks associated with an employee's work responsibilities. Training is provided by personnel knowledgeable of the topics covered and may be in the form of lecture, demonstrations, videotape, computer-based training, or self-study. Training emphasizes practical subjects important to the safe use of licensed material. The training program is reviewed annually.

ITEM 9 – FACILITIES AND EQUIPMENT

The SHINE medical isotope production facility is located on the south side of the City of Janesville corporate boundaries, in Rock County, Wisconsin. Geographical coordinates of the SHINE site are provided in Section 2.1 of the FSAR (Reference 2). The SHINE main production facility consists of an irradiation facility (IF), radioisotope production facility (RPF), shipping and receiving area, and other areas that contain various support systems and equipment, each currently at various stages of construction. General arrangement floor plan and section drawings of the facility showing the layout of major structures are provided in Figures 1.3-1 and 1.3-2 of the FSAR. The SHINE facility site overview is provided in Figure 1.3-3 of the FSAR.

The materials specified in Item 5 are received and securely stored in an access-controlled area prior to installation. Licensed material is received and placed into secure storage (e.g., locked storage building, locked sea van, or locked intermodal container) located on the SHINE site, away from primary construction activities. The secure storage area is controlled as a restricted area and posted in accordance with the requirements of 10 CFR 20.1902. Upon receipt, incoming packages are inspected, inventoried, and placed into secure storage. Shielding is used as needed (e.g., AmBe shielded containers) to minimize radiation exposure of personnel while the material is in storage. The materials specified in Item 5 are sealed sources or solids contained within enclosed components which do not present contamination or accidental release hazards. Contamination of equipment, facility, or the environment is not expected. Internal dose hazards are not expected. Radiological waste is not expected during the scope of construction activities.

The natural uranium is contained within eight neutron multipliers for installation into the SCAS. The neutron multipliers are annular sleeves of natural uranium metal clad in aluminum installed in the subcritical assembly support structure (SASS) in each irradiation unit (IU) cell. Radiation from natural uranium in the neutron multipliers is shielded by the cladding of the multiplier. The multipliers are protected from physical damage that could result in a release of radioactive material while in storage, during installation, and after installation. Once a neutron multiplier is installed, the area is posted in accordance with the requirements of 10 CFR 20.1902. The neutron multiplier is not easily accessible within the SASS due to space restrictions of the IU cells and the weight of the multipliers and can not be removed without prior disassembly of neutron driver assembly system (NDAS) and SCAS components. The neutron multipliers are described in Subsection 4a2.2.6 of the FSAR. The IU cell locations are provided in Figure 1.3-1 of the FSAR. Natural uranium clad in aluminum does not present a significant radiological hazard.

The DU is contained within tritium storage beds for installation into the TPS. There are three independent TPS trains in the production facility, each with up to three tritium storage beds. The tritium storage beds are protected from physical damage that could result in a release of radioactive material while in storage, during installation, and after installation. Once installed, the tritium storage beds cannot be removed without prior disassembly of TPS components. Once a tritium storage bed is installed, the area is posted in accordance with the requirements

of 10 CFR 20.1902. The TPS is described in Subsection 9a2.7.1 of the FSAR. The TPS room location is provided in Figure 1.3-1 of the FSAR. DU in the tritium storage beds does not present a significant radiological hazard.

The AmBe sealed sources are used as SMSs for installation into the SCAS within the light water pool area of each IU cell. Two SMSs for each IU provide a predictable source of neutrons to monitor the reactivity of the subcritical assembly during filling operations of the target solution vessel. The AmBe sources are installed near the bottom of the SASS in the IU cell beneath the NDAS target chamber. After the target section in installed, the AmBe sources are inaccessible from the top of the SASS and cannot be removed without prior disassembly of NDAS and SCAS components. Once an SMS is installed, the area is posted in accordance with the requirements of 10 CFR 20.1902. The SMSs are described in Subsection 4a2.2.4 of the FSAR. The IU cell locations are provided in Figure 1.3-1 of the FSAR.

The radiological hazard associated with the AmBe sealed sources is external dose from neutron and gamma radiation. The AmBe sealed sources are transported in shielded containers and stored within shielded containers to mitigate radiological hazards. Transfers of the AmBe sealed sources between containers and installation in the IU cell is performed in a manner consistent with as low as reasonably achievable (ALARA) principles. The AmBe sealed sources are installed near the bottom of the SASS in the IU cell, greater than 2.5 meters below the floor of the IU cell and greater than 1 meter below the NDAS attachment point. The distance between the AmBe sealed sources and the areas of occupation during subsequent installation of the NDAS components is expected to provide adequate protection from radiological hazards. Temporary shielding and restricted area access control boundaries are used as needed to maintain ALARA principles.

The AmBe sealed sources are inspected for damage and leak tested upon receipt to minimize contamination of the facility. AmBe sealed sources are leak tested every 6 months while in secure storage. Once the AmBe sealed sources are installed, the sources are inaccessible except through disassembly of NDAS and SCAS components. Leak testing is not conducted after the sources are installed in order to limit radiation dose to workers during non-routine maintenance operations necessary for removal of the source from the SASS.

ITEM 10 – RADIATION SAFETY PROGRAM

Radiation Monitoring Instruments
SHINE will use instrumentation, such as the following, to perform required surveys:

- portable dose rate meter with ionization chamber or Geiger-Mueller (GM) probe (beta/gamma),
- portable dose rate meter with He-3 proportional probe (neutron), and
- frisker with GM pancake probe.

SHINE will use instruments that meet the radiation monitoring instrument specifications published in Appendix I of NUREG–1556, Volume 7, Revision 1, “Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.” SHINE reserves the right to upgrade survey instruments as necessary.

Instrument Calibration
Radiation monitoring instruments will be calibrated before first use, at least annually thereafter, and after any repair, by a vendor that the NRC or an Agreement State has licensed to perform instrument calibration.

Material Receipt and Accountability
SHINE will develop, implement, and maintain procedures for ensuring accountability of licensed materials at all times. Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license. Records of inventory will be maintained for a period of 5 years from the date of each inventory, and will include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

Occupational Dose
SHINE will monitor individuals in accordance with the guidance in the section titled, "Radiation Safety Program–Occupational Dose" in NUREG–1556, Volume 7, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development and Other Licenses of Limited Scope."

Safe Use of Radionuclides, Security, and Emergency Procedures
SHINE will develop, implement, and maintain procedures for safe use, security, and emergencies.

Emergency Plan
An emergency plan is not required for the scope of materials.

Surveys
SHINE will survey the facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix M in NUREG–1556, Volume 7, Revision 1, "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope."

Leak Tests
Leak tests will be performed at the intervals approved by the NRC or an Agreement State and specified in the sealed source and device (SSD) registration certificate while the AmBe sealed sources are in secure storage. SHINE will implement the model leak test program published in Appendix N in NUREG-1556, Volume 7, Revision 1 "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licensees of Limited Scope." Leak tests will not be performed after the AmBe sealed sources are installed in the SCAS due to inaccessibility and ALARA concerns as described in Item 9.

ITEM 11 – WASTE MANAGEMENT

SHINE does not expect to generate radiological waste during construction activities.

4. ENVIRONMENTAL CONSIDERATION

SHINE has determined that the proposed amendment meets the categorical exclusion requirements of 10 CFR 51.22(c)(14)(x) and therefore an environmental assessment or an environmental impact statement is not required.

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

3. U.S. Nuclear Regulatory Commission, “Consolidated Guidance About Materials Licenses – Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Electron Capture Devices and X-Ray Fluorescence Analyzers,” NUREG-1556, Volume 7, Revision 1, February 2018

4. U.S. Nuclear Regulatory Commission Memorandum and Order, CLI-16-04, In the Matter of SHINE Medical Technologies, Inc. (Medical Radioisotope Production Facility), dated February 25, 2016 (ML16056A094)

5. U.S. Nuclear Regulatory Commission, “Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable,” Regulatory Guide 8.10, Revision 2, August 2016

6. U.S. Nuclear Regulatory Commission, “Instructions Concerning Prenatal Radiation Exposure,” Regulatory Guide 8.13, Revision 3, June 1999

7. U.S. Nuclear Regulatory Commission, “Instructions Concerning Risks from Occupational Radiation Exposure,” Regulatory Guide 8.29, Revision 1, February 1996

8. ASTM International, “Standard Guide for Radiological Protection Training for Nuclear Facility Workers,” ASTM E1168-95(2020), Last Reapproval 2020

ENCLOSURE 2
ATTACHMENT 1

SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL TECHNOLOGIES, LLC REQUEST TO AMEND CONSTRUCTION PERMIT NO. CPMIF-001 (PUBLIC VERSION)

CONSTRUCTION PERMIT (CHANGES) MEDICAL ISOTOPE PRODUCTION FACILITY CONSTRUCTION PERMIT NO. CPMIF-001

1 page follows

(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.

(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.

(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.

(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.

(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.

(2) The Environmental Protection Plan described in Appendix A of this permit is hereby incorporated into this permit.

E. Pursuant to the Act and 10 CFR Part 30, the following activities are included:

(1) to receive and possess, in connection with construction of the facility, up to [ ]^{SRI} of sealed americium-241 beryllium neutron sources.

F. Pursuant to the Act and 10 CFR Part 40, the following activities are included:

(1) to receive and possess, in connection with construction of the facility, up to 10,000 kg of natural uranium in the form of neutron multipliers; and

(2) to receive and possess, in connection with construction of the facility, up to 10 kg of depleted uranium in the form of tritium storage beds.

ENCLOSURE 2
ATTACHMENT 2

SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL TECHNOLOGIES, LLC REQUEST TO AMEND CONSTRUCTION PERMIT NO. CPMIF-001 (PUBLIC VERSION)

CONSTRUCTION PERMIT (CLEAN) MEDICAL ISOTOPE PRODUCTION FACILITY CONSTRUCTION PERMIT NO. CPMIF-001

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E. Pursuant to the Act and 10 CFR Part 30, the following activities are included:

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F. Pursuant to the Act and 10 CFR Part 40, the following activities are included:

(1) to receive and possess, in connection with construction of the facility, up to 10,000 kg of natural uranium in the form of neutron multipliers; and

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