ENCLOSURE 1

SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL TECHNOLOGIES, LLC REQUEST TO AMEND CONSTRUCTION PERMIT NO. CPMIF-001 RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

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) license amendment request (LAR) (Reference 2). The following information is provided by SHINE in response to the NRC staff's request.

ITEM 5 – Radioactive Material

RAI 1

The requirements in 10 CFR 40.36, "Financial assurance and recordkeeping for decommissioning," establish financial assurance considerations for licensees possessing source material in a readily dispersible form.

Paragraph (f) of 10 CFR 50.33, "Contents of application; general information," states, in part, that the application should include "…information sufficient to demonstrate to the Commission the financial qualification of the applicant to carry out, in accordance with regulations in this chapter, the activities for which the permit or license is sought."

In the LAR SHINE requests to receive and possess natural uranium and depleted uranium in connection with the construction of the SHINE Medical Isotope Production Facility. However, SHINE does not identify whether the natural and depleted uranium would be in a readily dispersible form.

Update the LAR to state whether or not the natural and depleted uranium SHINE intends to receive and possess would be in a readily dispersible form. If the material is in a readily dispersible form, identity the appropriate amounts of financial assurance needed for the quantities dispersible source material.

This information is necessary to determine whether appropriate financial assurance requirements of 10 CFR 40.36 have been considered for the SHINE facility.

SHINE Response

The natural and depleted uranium SHINE intends to receive and possess are not in readily dispersible forms. The natural uranium solid metal is sealed inside the annular aluminum cladding of the neutron multipliers. The depleted uranium solid metal or oxide is sealed inside a stainless-steel vessel of the tritium storage beds. The neutron multipliers are described Subsection 4a2.2.6 of the FSAR. The tritium storage beds are described in Subsection 9a2.7.1 of the FSAR.

SHINE has revised the LAR to state that the natural uranium and depleted uranium are not in readily dispersible forms. The revised LAR is provided in Enclosure 2 (non-public) and Enclosure 3 (public).

ITEM 7 – Individuals Responsible for Radiation Safety Program and Their Training and Experience

RAI 2

Paragraph (a)(3) of 10 CFR 30.33, "General requirements for issuance of specific licenses," states that an application for byproduct material will be approved if "[t]he applicant 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."

Paragraph (b) of 10 CFR 40.32, "General requirements for issuance of specific licenses," states that an application for source material will be approved if "[t]he applicant is qualified by reason of training and experience to use the source material for the purpose requested in such manner as to protect health and minimize danger to life or property."

Paragraph (a)(9) of 10 CFR 50.34 states that an application should include "[t]he technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter."

The guidance in NUREG-1556, Vol. 7, Rev. 1 states that "[t]he Radiation Safety Officer's (RSO's) training and experience should be applicable to and generally consistent with the types and quantities of licensed material listed on the license for which the individual's authorization as an RSO is requested." While the LAR describes general qualifications and training expected of individuals responsible for radiation safety, the LAR does not identify specific individuals and qualifications of such individuals that will act as a radiation safety officers or authorized users.

a) Provide the name of the proposed RSO and information demonstrating that the proposed RSO is qualified by training and experience.

b) Provide the name of each proposed authorized user (AU), with the types and quantities of licensed material to be used, and information demonstrating that each proposed AU is qualified by training and experience to use the requested licensed materials.

This information is needed for the NRC staff to determine whether SHINE is qualified by training and experience to receive and possess the byproduct and source material described in the LAR.

SHINE Response

a) The proposed Radiation Safety Officer (RSO) is Drew Cummings. The information demonstrating that the proposed RSO is qualified by training and experience is provided in Attachment 1.

b) The proposed Authorized Users (AUs) are Drew Cummings and Patrick Schendel. Mr. Cummings and Mr. Schendel are each proposed AUs for the entire scope of licensed materials requested (Reference 2). The information demonstrating that each proposed AU is

qualified by training and experience to use the requested licensed materials is provided in Attachment 1.

ITEM 8 – Training for Individuals Working in or Frequenting Restricted Areas

RAI 3

Paragraph (a)(3) of 10 CFR 30.33 states that an application for byproduct material will be approved if "[t]he applicant 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."

Paragraph (b) of 10 CFR 40.32 states that an application for source material will be approved if "[t]he applicant is qualified by reason of training and experience to use the source material for the purpose requested in such manner as to protect health and minimize danger to life or property."

Paragraph (a)(9) of 10 CFR 50.34 states that an application should include "[t]he technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter."

Additionally, the guidance in NUREG-1556, Vol. 7, Rev. 1 states that "[i]ndividuals whose assigned duties involve exposure to radiation or radioactive material (from both licensed and unlicensed sources) and in the course of their employment are likely to receive in a year an occupational dose of radiation greater than 1 millisievert (mSv) [100 millirem (mrem)], must receive instruction commensurate with their duties and responsibilities, as required by 10 CFR 19.12, "Instructions to Workers."

While the SHINE LAR gives examples of considerations used in the development of the radiation training program, including references to relevant regulatory guides, the LAR does not include specific information on the topics to be covered as part of training, how training will be assessed, or the qualifications of instructors.

Update the description of the radiation safety training program in the LAR to include the following:

a) Specific topics to be covered in training (e.g., identify specific subjects within cited regulatory guides that will be part of the radiation training program).

b) Groups of workers that will receive radiation training (e.g., differentiate between different levels of training to be provided based on potential radiological health risks associated with work responsibilities and duties).

c) A description of how training will be assessed.

d) Qualifications of instructors.

This information is needed for the NRC staff to determine whether SHINE is qualified by training and experience to receive and possess the byproduct and source material described in the LAR.

SHINE Response

a) SHINE has revised the LAR to describe specific topics to be covered in training.

b) SHINE has revised the LAR to describe the groups of workers that will receive radiation training and the different levels of training to be provided based on potential radiological health risks associated with work responsibilities and duties.

c) SHINE has revised the LAR to include a description of how training will be assessed.

d) SHINE has revised the LAR to include a description of instructor qualifications.

The revised LAR is provided in Enclosure 2 (non-public) and Enclosure 3 (public).

Environmental Considerations

RAI 4

As required by 10 CFR 51.21, "Criteria for and identification of licensing and regulatory actions requiring environmental assessments," and 10 CFR 51.30, "Environmental assessment," an environmental assessment prepared for an amendment to a construction permit shall include a description of the environmental impacts of the proposed action.

In the LAR, SHINE requests NRC authorization to receive and possess byproduct and source materials necessary for the continued construction of the SHINE Medical Isotope Production Facility. Since the receipt and possession of this material during the construction phase was not addressed in the SHINE construction permit application, additional information is needed for the NRC staff to assess the environmental impacts of this proposed action.

a) Describe any new or substantially different hazards (occupational and radiological) resulting from the receipt and possession of byproduct and source material described in the LAR.

b) Quantify any changes in types and Curies of radioactive materials packaged, transported, stored, and managed at the site or in the facility as compared to the descriptions in NUREG-2183, "Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility - Final Report."

c) On February 26, 2021, SHINE submitted an administrative letter describing its approach to staggered licensing, construction, and operation (ADAMS Accession No. ML21057A340). This letter provides a summary of SHINE's four-phased approach to completing construction, installing equipment, and beginning operation of the SHINE facility. Describe any impacts this staggered approach would have on the receipt, transportation, storage, or possession of the byproduct and source material described in the LAR.

SHINE Response

a) Radiological impacts to human health during construction are described in Section 4.8.1.1 of NUREG-2183, "Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility - Final Report" (Reference 3). While there are no specific radioactive materials identified in Section 4.8.1.1 of NUREG-2183, there are no new or substantially different radiological hazards resulting from the receipt and possession of the

byproduct and source material described in the LAR (Reference 2) from the radiological hazards described in Section 4.8.1.1 of NUREG-2183. As described in Item 9, “Facilities and Equipment,” of the LAR, the radiological hazards associated with the materials described in the LAR are minimal. The radioactive materials described in the LAR are sealed sources or solids contained within enclosed components which do not present contamination or accidental release hazards; therefore, contamination of equipment, facility, or the environment is not expected, internal dose hazards are not expected, and radiological waste is not expected during the scope of construction activities. The materials described in the LAR represent minimal external dose hazards which are mitigated as described in Item 9, “Facilities and Equipment,” of the LAR. SHINE has adequate controls in place to ensure that the dose to workers and the public is within the dose limits of 10 CFR Part 20; therefore, consistent with the conclusion stated in Section 4.8.1.1 of NUREG-2183, the radiological impacts to workers and the public during construction remain small.

Nonradiological impacts to human health during construction are described in Section 4.8.1.2 of NUREG-2183. There are no new or substantially different nonradiological (occupational) hazards resulting from the receipt and possession of the byproduct and source material described in the LAR from the nonradiological hazards described in Section 4.8.1.2 of NUREG-2183; therefore, the nonradiological impacts during construction remain small.

b) The radioactive materials described in the LAR are not explicitly addressed in NUREG-2183. NUREG-2183 describes specific types and curies of radioactive materials in effluents, wastes, and products of the SHINE production facility. The materials described in the LAR do not represent changes in the types or curies of radioactive materials in effluents, wastes, and products of the SHINE production facility as compared to the descriptions in NUREG-2183. NUREG-2183 does not specifically describe types and curries of radioactive materials other than effluents, wastes, and products.

   Human health impacts are described in Section 4.8 of NUREG-2183, including the impacts during construction described in Sections 4.8.1.1 and 4.8.1.2, which encompasses impacts associated with radioactive materials stored and managed at the SHINE production facility during construction. As described in the SHINE Response to RAI 4(a), the radioactive materials described in the LAR do not impact the assessments described in Sections 4.8.1.1 and 4.8.1.2 of NUREG-2183. Consistent with the conclusions stated in Table 6-1 of NUREG-2183, the human health impacts during construction remain small.

   Transportation impacts during construction are described in Section 4.10.1 of NUREG-2183, including packaging and transportation of radioactive materials shipped to the SHINE production facility during construction. The radioactive materials described in the LAR do not impact the assessments described in Section 4.10.1 of NUREG 2183. Consistent with the conclusions stated Table 6-1 of NUREG-2183, the transportation impacts during construction remain small to moderate.

c) The phased approach to initial facility operations described in Reference 4 does not impact the receipt, transportation, storage, or possession of the material described in the LAR (Reference 2). The material described in the LAR will be transported to the SHINE construction site, received, and securely stored as described in Item 9, “Facilities and Equipment,” of the LAR. The material described in the LAR is required for continuing construction of the SHINE medical isotope production facility and will be installed in the tritium purification system (TPS) and the subcritical assembly system (SCAS) as described

in Item 9, “Facilities and Equipment,” of the LAR. The construction sequence, including the phased approach to initial facility operations described in Reference 4, is consistent with the LAR description of the receipt, transportation, storage, and possession of materials.

SHINE has revised the LAR to remove Section 4, Environmental Considerations. The revised LAR is provided in Enclosure 2 (non-public) and Enclosure 3 (public).

References

1. NRC letter to SHINE Medical Technologies, LLC, “SHINE Medical Technologies, LLC – Request for Additional Information Related to Construction Permit Amendment for the Receipt and Possession of Certain Radioactive Materials (EPID No. L-2021-LLA-0104),” dated July 29, 2021 (ML21196A493)

2. SHINE Medical Technologies, LLC letter to the NRC, “SHINE Medical Technologies, LLC Request to Amend Construction Permit No. CPMIF-001,” dated April 29, 2021 (ML21119A166)

3. U.S. Nuclear Regulatory Commission, “Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility - Final Report,” NUREG-2183, October 2015.

4. SHINE Medical Technologies, LLC letter to the NRC, “SHINE Medical Technologies, LLC Overview of Phased Approach to Initial Facility Operations,” dated February 26, 20 (ML21057A340)

ENCLOSURE 1
ATTACHMENT 1

SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL TECHNOLOGIES, LLC REQUEST TO AMEND CONSTRUCTION PERMIT NO. CPMIF-001 RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

PROPOSED RADIATION SAFETY OFFICER AND AUTHORIZED USERS TRAINING AND EXPERIENCE

3 pages follow

Drew Cummings

Mr. Cummings is a health physics professional who has over twenty years of experience including hands-on experience working with radioisotopes, experience applying radiation safety principles in an industrial setting, experience managing and implementing radiation protection programs, and experience as RSO identified on multiple radioactive materials licenses issued by the NRC and Agreement States. Mr. Cummings has experience commensurate with the scope of the proposed activities, including:

- RSO, Tracerco, Inc. (NRC-issued radioactive materials licenses for activities in Delaware and Indiana), responsible for overseeing and ensuring safe implementation of the Tracerco, Inc. radiation protection program (2007-2009).
- RSO, Quantum Technical Services, LLC (Agreement State-issued radioactive materials licenses for activities in Texas), responsible for overseeing and ensuring safe implementation of the Quantum Technical Services, LLC radiation protection program (2010-2018).
- Corporate RSO, Quantum Technical Services, LLC (Agreement State-issued radioactive materials licenses for activities in Texas, Louisiana, California, and Illinois), responsible for overseeing and ensuring safe implementation of the Quantum Technical Services, LLC radiation protection program (2018-2020).
- Radiation Safety Supervisor, SHINE Medical Technologies, LLC (Agreement State-issued radioactive materials license for activities in Wisconsin), responsible for supervising implementation of the SHINE Medical Technologies, LLC radiation protection program (2020-present)
- Experience managing radioactive materials licenses issued by the NRC and Agreement States (including reciprocity), maintaining regulatory compliance, and coordinating licensing amendments.
- Experience managing the security and control of licensed materials, monitoring inventory of licensed materials, and maintaining records.
- Experience planning and conducting audits/evaluations (both internal and external) of radioactive materials license compliance.
- Experience shipping and transporting radioactive material in accordance with U.S. Nuclear Regulatory Commission and U.S. Department of Transportation regulations.
- Direct hands-on experience working with radioactive materials including:
    - Cs-137 (sealed source)
    - Co-60 (sealed source)
    - Am-241 (sealed source)
    - Am/Be (sealed source)
    - Various fission products atomic numbers 1-83 (solid and liquid unsealed source)
    - Tritium (gas and liquid unsealed source)
    - Depleted uranium (solid unsealed source)
    - I-129 (solid unsealed source)
    - Na-24 (liquid and solid unsealed source)
    - Mn-56 (solid unsealed source)
    - Kr-75 (gas unsealed source)
    - Kr-79 (gas unsealed source)
    - Ar-41 (gas unsealed source)
    - Various other unsealed isotopes

Mr. Cummings has training commensurate with the scope of the proposed activities, including:

- Radiation Safety Training for Industrial Process Diagnostics and Tracer Studies Course, provided by Quest TruTec, LP.
- Hazardous Material (Radioactive Material) Training pursuant to 49 CFR Part 172, Subpart H, provided by Tracerco, Inc.
- General Employee Training - Radiation Safety (initial and annual requalification), provided by SHINE Medical Technologies, LLC.
- Radiation Worker Training (initial and annual requalification), provided by SHINE Medical Technologies, LLC.
- Radiation Safety Officer Certification, provided by Thomas Edison State University (expected completion: October 2021).

Mr. Cummings has direct working knowledge or specific training in radiation safety topics, including the following subjects:

- 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 and agreement state regulatory requirements and standards.
- Hands-on use of radioactive materials.

Patrick Schendel

Mr. Schendel holds an associate degree in Nuclear Technology and an associate degree in Health Physics/Radiation Protection from Lakeshore Technical College. He has experience commensurate with the scope of the proposed activities, including:

- Radiation Protection (RP) Technician, BHI Energy (contracted at Point Beach Nuclear Plant and Donald C. Cook Nuclear Plant), responsible for implementing radiation protection principles while working with nuclear power plant fission products and radioactive waste (March 2020 - October 2020).
- RP Technician, SHINE Medical technologies, LLC, responsible for implementing radiation protection principles while working with tritium, tritium contaminated waste, sealed sources, various unsealed isotopes, and depleted uranium tritium storage beds (2020-present).
- Direct hands-on experience working with radioactive materials including:
    - Am/Be (sealed source)
    - Cs-137 (sealed source)
    - Na-22 (sealed source)
    - Lu-177 (sealed source)
    - Ba-133 (sealed source)
    - Ce-139 (sealed source)
    - U-238 (solid unsealed source)
    - Depleted uranium (solid unsealed source)
    - Tritium (gas and liquid unsealed source)

Mr. Schendel has training commensurate with the scope of the proposed activities, including:

- Associate of Science degree in Nuclear Technology, Lakeshore Technical College, 2020

- Associate of Science in Health Physics/Radiation Protection, Lakeshore Technical College, 2020
- Radiation Protection Technician training, Nuclear Energy Institute (NEI) Nuclear Industry Standard Process (NISP), BHI Energy, 2020
- Radiation Worker Training, Institute of Nuclear Power Operations (INPO), National Academy for Nuclear Training Electronic Learning (NANTeL), NextEra Energy, 2020
- General Employee Training - Radiation Safety (initial and annual requalification), provided by SHINE Medical Technologies, LLC.
- Radiation Worker Training (initial and annual requalification), provided by SHINE Medical Technologies, LLC.

Mr. Schendel has direct working knowledge or specific training in radiation safety topics, including the following subjects:

- Radiation protection principles.
- Characteristics of ionizing radiation.
- Units of radiation dose and quantities.
- Radiation detection and measurement instrumentation.
- Biological hazards of exposure to radiation.
- Hands-on use of radioactive materials.