SHINE™ Medical Technologies

50-608

THIS LETTER CONTAINS ~~PROPRIETARY INFORMATION~~
~~IN ACCORDANCE WITH 10 CFR 2.390~~

March 17, 2017 SMT-2017-009

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

References: (1) U.S. Nuclear Regulatory Commission, "Definition of a Utilization Facility (10 CFR Part 50)," *Federal Register*, Vol. 79, No. 201, October 17, 2014, pp.62329–62335

SHINE Medical Technologies, Inc. Request for Confirmation Related to a Proposed Demonstration Project

SHINE Medical Technologies, Inc. (SHINE) plans to conduct a series of short-duration tests within a proposed demonstration unit, consisting primarily of a deuterium-tritium accelerator, full-scale multiplier, and a solution vessel. Based on the enclosed technical description and the regulatory evaluation conclusions, SHINE has determined that the proposed demonstration unit does not meet the 10 CFR 50.2 definition of "utilization facility" for docket number 50-608.

SHINE is hereby requesting confirmation by the NRC staff that the proposed demonstration unit does not meet the 10 CFR 50.2 definition of "utilization facility" for docket number 50-608. This confirmation will aid SHINE in determining the applicable regulatory requirements to support the planned tests involving the proposed demonstration unit.

Enclosure 1 provides the non-public (proprietary) version of the SHINE evaluation of the proposed demonstration project, including a technical description and a regulatory evaluation of the proposed demonstration unit against the safety considerations the NRC staff used as criteria for defining SHINE's production irradiation units as utilization facilities in a 2014 direct final rule (Reference 1). SHINE requests that the NRC withhold Enclosure 1 from public disclosure under 10 CFR 2.390.

Enclosure 2 provides the public (non-proprietary) version to the SHINE evaluation of the proposed demonstration project.

Enclosure 3 provides an affidavit supporting the proprietary treatment of the SHINE proprietary information pursuant to 10 CFR 2.390. Enclosure 1 contains information proprietary to SHINE. Upon removal of Enclosure 1, this letter is uncontrolled.

A001.
NRR

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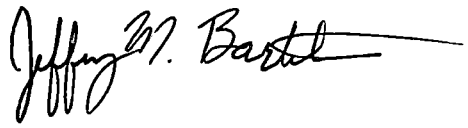
THIS LETTER CONTAINS ~~PROPRIETARY INFORMATION~~
~~IN ACCORDANCE WITH 10 CFR 2.390~~

If you have any questions, please contact me at 608/210-1735.

Very truly yours,



Jeffrey Bartelme
Licensing Manager
SHINE Medical Technologies, Inc.
Docket No. 50-608

Enclosures

cc: Project Manager, USNRC
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health
(w/o Enclosure 1)

ENCLOSURE 3

SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. REQUEST FOR CONFIRMATION RELATED TO PROPOSED DEMONSTRATION PROJECT

AFFIDAVIT OF JAMES COSTEDIO

2 pages follow

AFFIDAVIT OF JAMES COSTEDIO

STATE OF WISCONSIN)
) ss.
COUNTY OF ROCK)

I, James Costedio, Vice President of Regulatory Affairs and Quality of SHINE Medical Technologies, Inc. (SHINE), do hereby affirm and state:

1. I am authorized to execute this affidavit on behalf of SHINE. I am authorized to review information submitted to or discussed with the Nuclear Regulatory Commission (NRC) and apply for the withholding of information from public disclosure. The purpose of this affidavit is to provide the information required by 10 CFR 2.390(b) in support of SHINE's request for proprietary treatment of certain confidential commercial information submitted in the SHINE request for confirmation transmitted by letter SMT-2017-009 with enclosures. SHINE requests that the confidential information contained in Enclosure 1 be withheld from public disclosure in its entirety.

2. I have knowledge of the criteria used by SHINE in designating information as sensitive, proprietary, or confidential.

3. Pursuant to the provisions of paragraph (a)(4) of 10 CFR 2.390, the following is furnished for consideration by the NRC in determining whether the information sought to be withheld from public disclosure should be withheld.

   a. The information sought to be withheld from public disclosure contained in Enclosure 1 of SMT-2017-009 is owned by SHINE, its affiliates, or third parties to whom SHINE has an obligation to maintain its confidentiality. This information is and has been held in confidence by SHINE.

   b. The information sought to be protected in Enclosure 1 is not available to the public to the best of my knowledge and belief.

c. The information contained in Enclosure 1 is of the type that is customarily held in confidence by SHINE, and there is a rational basis for doing so. The information that SHINE is requesting to be withheld from public disclosure includes trade secret, commercial financial information, commercial information, or information that is subject to export controls. SHINE limits access to these elements to those with a "need to know," and subject to maintaining confidentiality.

d. The proprietary information sought to be withheld from public disclosure in Enclosure 1 includes, but is not limited to: primary and supporting systems of the medical isotope facility and process details. Public disclosure of the information in Enclosure 1 would create substantial harm to SHINE because it would reveal trade secrets owned by SHINE, its affiliates, or third parties to whom SHINE has an obligation to maintain its confidentiality.

e. The information contained in Enclosure 1 of SMT-2017-009 is transmitted to the NRC in confidence and under the provisions of 10 CFR 2.390; it is to be received in confidence by the NRC. The information is properly marked.

I declare under the penalty of perjury that the foregoing is true and correct.
Executed on March 16, 2017.

James Costedio
Vice President of Regulatory Affairs and Quality
SHINE Medical Technologies, Inc.

ENCLOSURE 2

SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. REQUEST FOR CONFIRMATION RELATED TO PROPOSED DEMONSTRATION PROJECT

SHINE EVALUATION OF THE PROPOSED DEMONSTRATION PROJECT (PUBLIC)

Purpose

SHINE Medical Technologies, Inc. (SHINE) obtained a construction permit from the U.S. Nuclear Regulatory Commission (NRC) in February 2016 (CPMIF-001) to construct its facility near Janesville, Wisconsin for the production of medical isotopes. As part of design finalization, SHINE plans to conduct a series of short-duration tests within a proposed demonstration unit, consisting primarily of a deuterium-tritium accelerator, full-scale multiplier, and a solution vessel. SHINE provides a technical description of the demonstration project below.

Although the NRC staff concluded that SHINE production irradiation units (IUs) share many characteristics of non-power reactors, and should therefore be licensed as 10 CFR part 50 utilization facilities (Reference 1), the proposed demonstration unit differs significantly from the production IUs. SHINE provides a regulatory evaluation below of the proposed demonstration unit against the criteria the NRC staff relied on to conclude that the SHINE production IUs should be licensed as Part 50 utilization facilities in Reference 1. SHINE's evaluation demonstrates that the staff's earlier analysis does not apply to the proposed demonstration unit.

SHINE is hereby requesting confirmation by the NRC staff that the proposed demonstration unit, described below, does not meet the 10 CFR 50.2 definition of "utilization facility" for docket number 50-608. This confirmation will aid SHINE in determining the applicable regulatory requirements to support the planned tests involving the proposed demonstration unit described below.

Technical Description of the SHINE Demonstration Project

In the first half of 2017, SHINE intends on constructing a building of steel frame construction on a poured concrete slab with insulated, corrugated steel sheet walls and roof. This building is planned to be constructed adjacent to U.S. Highway 51, either on the proposed 91-acre SHINE site, or directly to the south. However, the building location could change, but that change has no bearing on this evaluation. The building will be used for demonstrating different components of SHINE's technologies, primarily for validating constructability, operability, and maintainability of systems. It will be inherently separate from the planned medical isotope production facility for which the NRC issued a construction permit via Reference 2.

Within this building, SHINE is planning to construct a demonstration unit cell. The cell will include a concrete, light water-filled pit of dimensions similar to the IU cells in the production facility. The proposed demonstration unit will primarily consist of a deuterium-tritium

accelerator, full-scale multiplier, and a solution vessel. Auxiliary systems are expected to include a demonstration off-gas system (not required for safety), neutron detection capabilities, temperature/pressure monitoring equipment, and piping/valving necessary to fill and empty the solution vessel.

Following construction of the building and assembly of the demonstration unit, SHINE intends on conducting a series of short-duration tests in the demonstration unit cell that includes irradiation of enriched uranium solution. SHINE expects these tests would start in late 2017.

The tests would individually demonstrate accelerator neutron yield and neutron multiplication in the multiplier through operation of the accelerator and direct measurement of neutron emission. Subsequently, the solution vessel will be filled with uranium solution containing no greater than a safe mass of special nuclear material (SNM) (i.e., $\leq$ 350 g ^{235}U) and irradiated for short durations to demonstrate that medical isotope yields are as modeled.

Also within this building, small samples of irradiated solution (i.e., containing less than 100 g of uranium) are expected to be processed with lab scale measurement techniques to quantify medical isotope yields.

Regulatory Evaluation of the SHINE Demonstration Project

In 2014, the NRC published a direct final rule (Reference 1) to amend the NRC regulations to add SHINE's production IUs to the definition of utilization facility in 10 CFR part 50. The NRC concluded that the proposed production IUs previously did not meet the definition of a utilization facility because the units did not, "singly or collectively sustain nuclear fission in a self-supporting chain reaction." The NRC considered the fission process in the production IUs and concluded that they should be licensed as Part 50 utilization facilities based on consideration of seven criteria related to safety considerations similar to those of non-power reactors.

This current definition of utilization facility in 10 CFR 50.2 includes:

(1) Any nuclear reactor other than one designed or used primarily for the formation of plutonium or U-233; or

(2) An accelerator-driven subcritical operating assembly used for the irradiation of materials containing special nuclear material and described in the application assigned docket number 50-608.

The proposed demonstration unit does not satisfy item (1) of this definition because it is not a reactor and does not "sustain nuclear fission in a self-supporting chain reaction." The proposed demonstration unit does not satisfy item (2) of this definition because it is not one of the production IUs described by SHINE in the application assigned docket number 50-608, and because the safety considerations the NRC staff used as criteria for defining the production IUs as utilization facilities are not applicable to the proposed demonstration unit, as described below. Therefore, the proposed demonstration unit is not covered by the changes to the NRC regulations made in the direct final rule discussed above.

The following provides a discussion of the technical details of the proposed demonstration unit with respect to each of the seven referenced safety considerations.

Provisions for removal of fission heat during operation.

SHINE plans to run the demonstration unit for short durations (e.g., several minutes at a time) followed by substantial off-time between runs (e.g., 24 hours). For these short durations, the system temperature does not increase such that cooling during operation is warranted. While the pit will be filled with light water, this only serves to aid reflective neutron multiplication and is not required for cooling the uranium solution. Due to the low power generation, no active flow of water around the solution vessel is required for safety.

Therefore, no provisions for removal of fission heat are needed during operation.

Consideration of decay heat generation after shutdown.

The demonstration unit will achieve a thermal power level substantially lower than the production IUs. The estimated power level from fission in the demonstration unit is [Proprietary Information].

Upon shutdown of the demonstration unit, decay power is an order of magnitude less than operational power and sharply decreases within a few minutes. After 5 minutes, post-shutdown, decay power is [Proprietary Information]. As the demonstration unit does not require cooling during the proposed short run times, there is no need for post-shutdown cooling.

Therefore, there is no design consideration needed for decay heat generation after shutdown.

Reactivity feedback mechanisms similar to non-power reactors.

During the tests involving irradiation of uranium solution, the volume of solution will be limited to that containing a safe mass of SNM (i.e., ≤ 350 g ^{235}U). Under optimum conditions (fully reflected spherical geometry), this volume of solution will not approach the minimally subcritical range of k_{eff} in which the production IUs will operate. SHINE estimates that the demonstration unit, even under these optimum conditions, would remain below a k_{eff} of 0.80. In addition, there are no means by which the proposed demonstration activities can attain optimum conditions, thereby further increasing the margin of subcriticality.

As the amount of SNM to be licensed for use in the demonstration unit will be limited to a safe mass (i.e., ≤ 350 g ^{235}U) and can therefore not be configured to sustain a chain reaction, reactivity feedback mechanisms are not of concern. As described above, achievable k_{eff} values are below 0.80, regardless of system configuration or operating conditions.

Therefore, there is no consideration needed for reactivity feedback mechanisms similar to non-power reactors.

Control of fission gas release during operation and subsequent gas management engineering safety features.

Fission gases released from the uranium solution will be retained in the solution vessel, which will be designed with enough head space to accommodate the very small amounts of fission gases produced. Should a release occur, the amount of fission gases produced

during the proposed short periods of irradiation does not require any mitigation systems to meet the limits of 10 CFR part 20. A demonstration off-gas system is planned to be included, but the purpose of the system is to test other operational characteristics (e.g., test flow rates, droplet pickup, and other capabilities), and is not needed for safety or compliance with Part 20.

Therefore, no engineering safety features or safety systems are required to control fission gases during operation or subsequently to meet acceptable dose limits.

Control of radiolytic decomposition of water and generated oxygen and hydrogen gases.

Oxygen and hydrogen gases produced during irradiation will be contained in the head space of the solution vessel along with other fission gases produced. No active blowers or other safety systems are required to handle the generation of oxygen and hydrogen gases during operation to ensure hydrogen concentrations remain below the lower flammability limit (LFL). The small amount of generated gases will not be sufficient to increase the head space hydrogen concentration to unacceptable levels. Purging of gases between runs (and transferring to storage tanks for decay) is planned to be used to prevent long-term accumulation.

Given the very low generation rates, short run times, and the fact that gases will be purged between runs, no safety systems are required to control the radiolytic decomposition of water and generated oxygen and hydrogen gases.

Control of fission product inventory buildup.

Fission products will accumulate in the target solution, but the buildup is small and no control of the inventory is necessary.

[Proprietary Information]

Therefore, no control of fission product inventory buildup is necessary.

Accident scenarios similar to non-power reactors, such as release of fission products, reactivity additions, and loss of coolant.

SHINE reviewed Chapter 13 of the SHINE Preliminary Safety Analysis Report (PSAR) with respect to accident initiating events and scenarios specific to the production IU cell for comparison with the proposed demonstration tests. Key scenarios, such as release of fission products, reactivity additions, and loss of coolant are identified and discussed below:

- Maximum Hypothetical Accident (MHA) / Release of fission products

  The MHA is used to demonstrate that the maximum consequences in operating the production facility are within acceptable regulatory limits of 10 CFR 20.1201, "Occupational dose limits for adults," and 10 CFR 20.1301, "Dose limits for individual members of the public." The MHA is a non-credible accident scenario that results in a

release with radiological consequences that bound the design basis accidents. The analysis of the production facility MHA credits confinement boundaries, active dampers, and filtration units.

The worst-case scenario involving the demonstration unit is judged to comprise rupture of the solution vessel and release of the irradiated solution. Given the volume of material at risk and assuming conservative choices for airborne release fraction, respirable fraction, and leak path factor (assuming no surrounding building), the consequences of release to the environment from the solution vessel are estimated to be significantly below 10 CFR part 20 limits without mitigation. Thus, the demonstration unit neither contains, nor requires, confinement or other safety systems to protect the fission product inventory.

- Insertion of excess reactivity and inadvertent criticality

  As noted previously, the demonstration unit will be licensed to operate with no greater than a safe mass of SNM (i.e., ≤ 350 g ^{235}U). Thus, there are no initiating events or scenarios for which excess reactivity insertions or inadvertent criticality are a concern.

- Reduction in cooling / loss of coolant

  Cooling is not required for the demonstration unit during irradiation or post-shutdown. Therefore, mitigation of a reduction in cooling, regardless of the initiating event, does not need to be addressed.

As discussed above, the accident scenarios similar to non-power reactors are not of significant concern in the planned demonstration unit tests due to the low power level, low radioactive material inventory, and the safe mass of SNM.

Conclusion

The proposed demonstration unit differs significantly from the accelerator-driven subcritical operating assemblies described in the SHINE construction permit application (assigned docket number 50-608). Based on the above technical description and the regulatory evaluation conclusions, SHINE has determined that the proposed demonstration unit does not meet the 10 CFR 50.2 definition of "utilization facility" for docket number 50-608. SHINE hereby requests confirmation by the NRC staff that the proposed demonstration unit does not meet the 10 CFR 50.2 definition of "utilization facility" for docket number 50-608.

References

1. U.S. Nuclear Regulatory Commission, "Definition of a Utilization Facility (10 CFR Part 50)," *Federal Register*, Vol. 79, No. 201, October 17, 2014, pp.62329–62335

2. NRC letter to SHINE Medical Technologies, Inc., "SHINE Medical Technologies, Inc. - Issuance of Construction Permit for Medical Isotope Facility," dated February 26, 2016 (ML16041A473)