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SHINE™ Medical Technologies

May 9, 2012

Mr. Timothy McGinty
Director, Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Mail Stop 0-12-E-1
11555 Rockville Pike
Rockville, MD 20852

SHINE Medical Technologies, Inc.
SMT-2012-017
Project No. 0792

Subject: Response to Request for Additional Information

Reference: 1) D. Morey (NRC) to G. Piefer (SHINE),"Project No. 0792, SHINE Updated Request for Regulatory Interpretations and Request for Additional Information Concerning Restricted Data", dated June 6, 2011 (ML111360165)

Dear Mr. McGinty:

The purpose of this letter is to provide a response to the Request for Additional Information (RAI) questions provided in the referenced letter.

The enclosure to this letter provides our responses to the RAI questions.

There are no new regulatory commitments in this letter.

If you have any questions regarding this letter, please contact Mr. James Freels, Licensing Project Manager, at 865.719.5061.

Sincerely,

[signature]

Richard Vann Bynum, PhD
Chief Operating Officer
SHINE Medical Technologies, Inc.

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Enclosure

Response to Request for Additional Information

SHINE Medical Technologies, Inc.

REQUEST FOR ADDITIONAL INFORMATION SHINE MEDICAL ISOTOPES

To enable the U.S. Nuclear Regulatory Commission (NRC) to make an informed determination of the classification of the information, provide the following:

1. A detailed description of the process and equipment which you will be using to make the ^{99}Mo, and that will produce the plutonium. This description should include any information that will allow NRC to determine if your process is a new or novel approach to making plutonium.

2. We would also need accurate projections of the amounts of materials that will be produced in the process. This should include all fission and activation products, including waste stream amounts. How much plutonium and other fission and activation products will be produced per amount of feed material used? How much feed material will be used per batch and per year?

Response:

Question 1:

The following describes the ^{99}Mo production steps as currently detailed. Slight changes to system details may occur during design steps, but will not impact the overall production process description:

1. At the top of the device (see **Figure 1**), an ion source provides a deuterium ion beam and collimates it to approximately 1 cm^2.
2. The beam is accelerated by an electrostatic accelerator.
3. The beam passes through the differential pumping sections which serve to keep the accelerator at its working pressure, while maintaining sufficient target gas pressure to produce high neutron yield.
4. The gas target chamber is filled with tritium gas. When the accelerated deuterium ions enter the target chamber, they impact the tritium gas, resulting in nuclear reactions which create neutrons.
5. The neutrons enter a multiplier layer which increases the source neutron population by 2-3 times before entering the target solution vessel (TSV)
6. After multiplication, the neutrons enter the Low Enriched Uranium (LEU) target solution vessel causing ^{235}U therein to fission, creating more neutrons and fission products, including ^{99}Mo. ^{99}Mo accumulates in the solution during the irradiation cycle. The TSV is operated as a subcritical process (k_{eff} < 1.00) at all times.
7. The LEU target vessel is surrounded by a light water pool which reflects neutrons back into the solution vessel, cools the system, and absorbs radiation produced by the device.

8. After several days of irradiation, the solution is removed from the LEU target vessel and ^{99}Mo is separated, purified, tested, and packaged for shipment to ^{99m}Tc generator manufacturers.
9. The LEU target solution is returned to the TSV for another irradiation.

Figure 1
The Subcritical Hybrid Intense Neutron Emitter (SHINE)

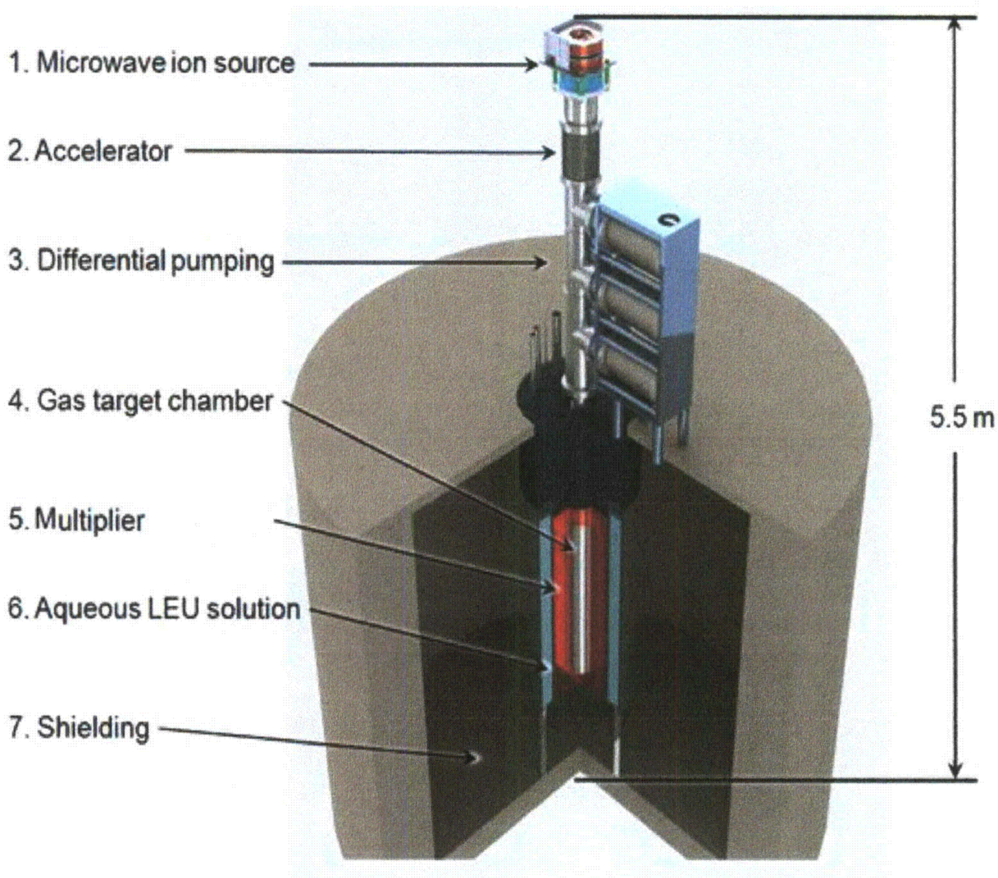
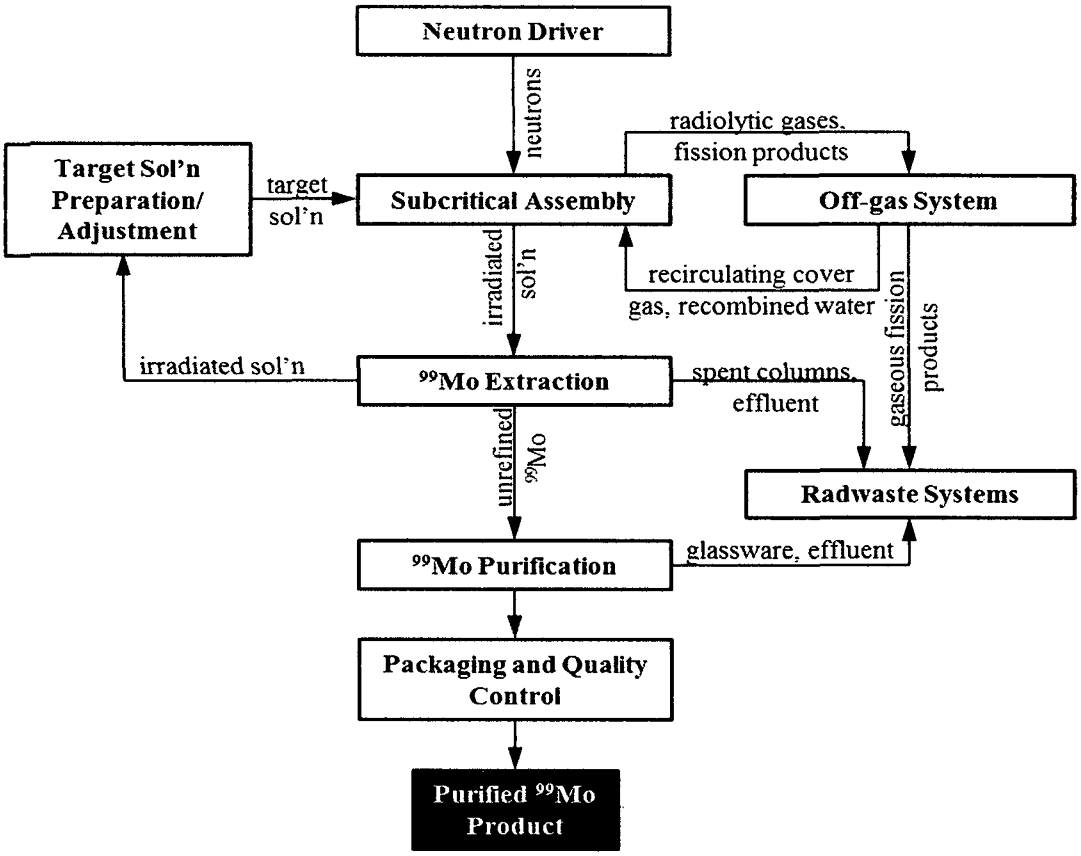


Figure 2 provides the process flow diagram for the SHINE production system.

Figure 2
Flow diagram showing the SHINE ^{99}Mo production process



Plutonium production:

10 CFR 50.2, "Definitions", states:

> *Special nuclear material* means (1) plutonium, uranium-233, uranium enriched in the isotope-233 or in the isotope-235, and any other material which the Commission, pursuant to the provisions of section 51 of the act, determines to be special nuclear material, but does not include source material; or (2) any material artificially enriched by any of the foregoing, but does not include source material.

The nuclear process to be employed by SHINE will produce plutonium which is defined as a special nuclear material. The production of plutonium is a physical result of using low enriched uranium (LEU), natural uranium (NU), or depleted uranium (DU) in the Target Solution Vessel in the presence of neutrons. The production of plutonium in a neutron-capture reaction with ^{238}U is a matter of elementary nuclear physics. As in the case of all civilian power, research, or test reactors that contain ^{238}U, neutrons are captured by the ^{238}U and ^{239}U is produced. After a relatively short decay chain from ^{239}U to ^{239}Np, further radioactive decay of ^{239}Np produces ^{239}Pu. ^{239}Pu can also absorb a neutron and become ^{240}Pu. SHINE production of plutonium from a nuclear interaction perspective is indistinguishable from the processes that produce plutonium in civilian power, research, and test reactors that contain ^{238}U in their fuel.

The production of neutrons by a particle accelerator is also not new or novel. Particle accelerator technology has been employed to produce neutrons in commercial and medical applications for many years. These applications include, but are not limited to; petroleum and uranium exploration, coal quality analysis, body composition measurement, explosives detection and identification, neutron radiography and nuclear waste assay.

Question 2:

This question asks for accurate projections of the amounts of materials that will be produced in the process. Since the design of the SHINE facility is in its early stages, this question cannot be answered precisely, but calculations can be performed to determine the amount of plutonium that is expected to be produced on a cumulative basis and the results are presented below:

The SHINE fission process system, known as the Target Solution Vessel (TSV) will operate as a subcritical process, and relies on the same physical principles as does a civilian nuclear power reactor, including the fission of ^{235}U and the production of plutonium where LEU, NU, or DU may be located. Along with plutonium, the entire spectrum of fission products will be produced in the TSV just as in nuclear power reactor fuel. In addition, the system that reconditions the fuel solution does not use any unique materials or processes.

SHINE intends to possess plutonium amounts that will be less than the amounts specified in 10 CFR 73 for a *formula quantity*. The SHINE possession limits for plutonium meet the stipulations of 10 CFR 73 for *special nuclear material of moderate strategic significance*. SHINE has performed preliminary calculations that estimate the amount of plutonium that will be produced using the methods identified below.

Two different methodologies were used to predict the plutonium production rates in the SHINE facility. The first method was through the use of the Monte Carlo code MCNP5 (v1.51). The second method was by using the code ORIGEN2.2 for transmutation and burn up calculations (with initial flux data from MCNP5). The results of these methodologies are normalized for the expected output of the SHINE facility (3000 6-day curies of ^{99}Mo per week, accounting for process and decay losses with constant operation for 52 weeks per year for the 30 year lifetime of the facility). The results from these calculations identify the total plutonium production from the facility to be between 1900 and 2250 grams of plutonium. It is to be emphasized that the calculated plutonium production is at the end of 30 years of facility operation at constant output. This quantity will be reduced by disposal of target solution and by realistic out-of-service times. Therefore there is every expectation that the amount of plutonium possessed by the SHINE facility at the end of 30 years of operation will meet the definition of *special nuclear material of moderate strategic significance*.

In addition, the Department of Energy (DOE) regulations make a clear case for not classifying any SHINE information as Restricted Data:

The Department of Energy regulates the classification of information under 10 CFR 1045; "Nuclear Classification and Declassification". The definition of Restricted Data from 10 CFR 1045.3 is as follows:

> *Restricted Data (RD)* means a kind of classified information that consists of all data concerning the following, but not including data declassified or removed from the RD category pursuant to section 142 of the Atomic Energy Act:
>
> (1) Design, manufacture, or utilization of atomic weapons;
> (2) Production of special nuclear material; or

(3) Use of special nuclear material in the production of energy.

The regulations that cover Restricted Data are contained in 10 CFR Part 1045, Subpart B; "Identification of Restricted Data and Formerly Restricted Data Information". The specific sections of interest are 10 CFR 1045.15 and 1045.16.

In 10 CFR 1045.15, "Classification and Declassification Presumptions", item (d) lists the information in 14 areas that is presumed to be unclassified. The information areas that apply to the SHINE facility are:

- Basic science including mathematics, chemistry, physics, and engineering
- Civilian power reactors, including nuclear fuel cycle information
- Source materials
- Physical and chemical properties of uranium and plutonium
- Nuclear fuel reprocessing technology and reactor products
- Any information solely relating to the public and worker health and safety or to environmental quality

These applicable presumptions indicate that all information relating to the SHINE facility should not be classified.