SHINE™
Medical Technologies

July 27, 2011

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-001

SHINE Medical Technologies, Inc.
Project 0792
SMT-2011-010

Subject: Response to NRC Regulatory Issue Summary 2011-006, Pre-application Communication and Voluntary Submittal of Schedule for Future Molybdenum-99 Facility Licensing Actions for NRC Review

References:

1) G. Piefer (SHINE Medical Technologies, Inc.) to J. Kinnemann (NRC), SMT-2011-001, "Notice of Intent to Submit License Application, Request for Regulatory Interpretations, and Request for Public Meetings", dated February 14, 2011 (ML110490138)

2) G. Piefer (SHINE Medical Technologies, Inc.) to J. Kinnemann (NRC), SMT-2011-003, "Updated Request for Regulatory Interpretations", dated May 3, 2011 (ML11138A220)

The purpose of this letter is to provide responses to the questions posed in Regulatory Information Summary (RIS) 2011-006. SHINE Medical Technologies, Inc. (SHINE) recognizes the benefits of frequent and open communication with the NRC Staff regarding scheduling for licensing activities. The responses to the RIS questions are included in the body of this letter and are based on the current maturity of the regulatory and licensing framework for medical isotope production facilities, SHINE project plan, and facility design.

In the responses to some RIS questions, specific schedule information cannot be provided at this time. This is due, in part, to dependency on project funding from external organizations. SHINE anticipates that greater clarity can be provided relative to licensing action document submittals in the fourth quarter of calendar year 2011. SHINE will provide an update response to the anticipated licensing action document submittals by November 30, 2011. The only new commitment in this letter is to provide an updated licensing action submittal schedule to the NRC by November 30, 2011.

The responses to the RIS questions are as follows:

Design and Licensing Submittal Information

(1) How many applications will be submitted to the NRC? When (month and year) will the NRC receive these application(s) for review? What NRC licensing

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actions will the application(s) request? What are the project milestones for the applicant and the NRC (i.e., review length)?

Response:

SHINE intends to submit two applications to construct and operate the SHINE facility. One will be for a construction permit and one will be for the operating license. Currently, SHINE intends to submit the construction permit application in the first half of calendar year 2012. The submittal schedule is dependent on a number of variables at this time and a specific month for the construction permit application submittal cannot be provided. The subsequent submittal of the operating license application is contingent on the same variables. SHINE will provide updates to the submittal schedules by November 30, 2011 for both submittals. The SHINE schedule for the construction license application NRC review duration expects the NRC license application review to be completed within twelve months of construction license application receipt and necessary remaining licensing process steps within the following 90 days.

(2) Under which part(s) of 10 CFR will the application(s) seek licenses? In particular, will license applications for processing facilities be submitted under 10 CFR Part 50 for consideration as a production facility or under 10 CFR Part 70 as a processing facility? Will an exemption from any part of the regulations be sought? If so, has the applicant accounted for the increase in time for the licensing process (a possible six month increase in time should be allotted).

Response:

At this time, and as identified in Reference 2, SHINE intends to pursue licensing the facility under 10 CFR 50 as a production facility. SHINE recognizes that the proposed regulatory framework for licensing the facility will be based on NUREG-1537, Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors. However, this regulatory guidance is currently being supplemented by the Staff in order to better address medical isotope production facilities. When the supplementary guidance is issued for NUREG-1537, SHINE will reassess the regulatory framework and licensing path for licensing the facility. Therefore, at this time, there are no identified exemptions to current regulations envisioned for the applications. Exemption requests may be possible based on future regulations or if the regulatory framework and licensing path supplemental guidance is not appropriate or relevant for our technological approach. Our goal is to work with NRC to protect the health and safety of workers, the public and the environment through the NRC's licensing tools that best match our approach.

(3) Has a location been selected for each proposed unit at the site? If so, please describe.

Response:

A final site location has not yet been selected for the SHINE facility. Numerous sites are under consideration and a preferred site selection is anticipated to occur in August 2011. SHINE is evaluating the number of production units that will be located at the site. Although a final determination of production units has not been made, presently six different production devices are proposed to be located in a central facility within the site boundary.

(4) When will the environmental report be submitted for review?

Response:

SHINE intends to submit a complete environmental report for both the construction permit and operating license coincident with the construction permit application. The environmental report will address the necessary informational needs for the construction and operating phases of the SHINE facility. The submittal timing of the construction permit application is addressed in Question (1).

(5) What design will be used for each facility? What is the current status of the development of this design? Please provide a schedule for completing the design.

Response:

The design of the SHINE facility will be based on particle accelerator-based technology. The accelerator production device will produce a deuterium ion beam with a nominal total current of 50 mA that is accelerated to approximately 300 keV. The beam passes through differential pumping sections that provide the accelerator working pressure, while maintaining sufficient target gas pressure for a high yield. The gas target chamber is filled with tritium gas, which interacts with the accelerated deuterium ions and produces neutrons. The neutrons are then moderated and multiplied in a layer of beryllium (or other multiplying medium), thus increasing the available population of neutrons for fission. These neutrons enter the low-enriched uranium solution causing subcritical fission to occur from which molybdenum-99 is produced as a fission yield. After several days of irradiation, the solution is removed from the low-enriched uranium target solution vessel and the molybdenum-99 is separated, purified, tested, packaged and shipped to technetium-99(m) generator manufacturers.

A pre-conceptual design of the facility has been completed, and SHINE is preparing to enter the conceptual design phase of the project. The facility design schedule is dependent on a number of variables at this time and a specific month for facility design completion cannot be provided at this time. SHINE will provide an update to the facility design schedule by November 30,

2011.

(6) Are there vendors or consultants assisting in the preparation of the application(s)? If so, please describe their roles and responsibilities in the design and licensing activities.

Response:

Vendors, consultants and other external companies are participating in the design and licensing activities of SHINE. Some of the project partners can be found at http://www.shinemed.com/team.php

(7) What actions, if any, have you taken or propose to take regarding 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," license for possession of byproduct material (or a State byproduct materials license if in an Agreement State)?

Response:

SHINE has previously requested that the NRC provide clarification of the interface and roles and responsibilities for both the NRC and an Agreement State when licensing a facility under 10 CFR 50 (References 1 and 2). To date, the NRC has not provided a response to the clarification request in the identified references. After the NRC responds to with the requested information, or otherwise provides docketed information related to the question, SHINE will be better positioned to address this issue.

White Papers and Technical/Topical Reports

1. Are there current plans to submit for review and approval white papers or technical/topical reports related to design features, policy resolution, or technical issues? Please provide a schedule for submitting future anticipated reports.

Response:

At this time, there are no plans to submit for review and approval white papers or technical/topical reports related to design features, policy resolution or technical issues beyond what has been submitted to the NRC in References 1 and 2. SHINE will consider submitting white papers that would be helpful to NRC Staff regarding improved understanding of our technological basis and operational objectives.

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

Sincerely,

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