



February 24, 2011

Mr. Dennis G. Smith  
Department Secretary  
State of Wisconsin  
Department of Health Services  
1 West Wilson Street  
Madison, WI 53703

**SHINE Medical Technologies, Inc.**  
**SMT-2011-002**

**Subject: Notice of Intent to Submit License Application  
and Request for Regulatory Interpretations**

Reference: 1) Dr. Greg Piefer (SHINE Medical Technologies, Inc.) to Mr. John Kinnemann (U.S. Nuclear Regulatory Commission), SMT-2011-001, "Notice of Intent to Submit License Application, Request for Regulatory Interpretations, and Request for Public Meetings", dated February 14, 2011

Dear Secretary Smith:

The purposes of this letter are to identify that SHINE Medical Technologies, Inc. (SHINE) intends to submit license applications to the U.S. Nuclear Regulatory Commission (NRC) and to the State of Wisconsin to license a particle accelerator-driven sub-critical fission process technology and facility to domestically produce molybdenum 99 and other isotopes of commercial interest and to request State of Wisconsin Department of Health Services (DHS) Staff review and interpretation of certain identified regulatory issues.

In Reference 1, SHINE submitted a letter of intent to submit a license application to the NRC. Additionally, in Reference 1, SHINE identified a number of regulatory and licensing items where we believe further discussion is needed with the NRC Staff to ensure that consensus is gained relative to the licensing path for the SHINE technology and facility. To facilitate the discussion with the NRC Staff, we have requested two public meetings to discuss the areas of interest. Since the State of Wisconsin is an Agreement State, one of our areas of interest is the regulatory authority for the various aspects of the process and facility, since we plan to have possession licenses for source, byproduct and special nuclear material. We would like to ensure that the State of Wisconsin DHS Staff has the opportunity to remain engaged in our discussions with the NRC Staff for these questions that relate to the lines of responsibility for the licensing and regulation between the NRC and the State of Wisconsin. Additionally, we request that the DHS staff provide their interpretation of the relevant DHS regulations for licensing the SHINE technology and facility. We will maintain communications and

dialogue with the DHS Staff during their review period to address any questions related to the technology, facility or planned possession amounts of source, byproduct and special nuclear material.

The following issue regarding roles and responsibilities is excerpted from Reference 1:

**Agreement State Interaction and Responsibility**

We understand that there are delegated licensing and regulatory authorities for Agreement States as provided for by the Atomic Energy Act and its subsequent amendments. Since the SHINE technology and facility will include various parts of the Code of Federal Regulations, of which some may be the responsibility of an Agreement State, we are interested in discussions related to the roles and responsibilities of both the U.S. Nuclear Regulatory Commission and the Agreement State. The proposed SHINE Technologies process and facility will use a particle accelerator and have source, byproduct and special nuclear material. We understand that the Agreement State will retain responsibility for regulatory authority for the particle accelerator and its associated radiological protection requirements. The amount of special nuclear material we plan to possess will exceed the amount by which the Agreement States are authorized to regulate, so the potential exists for multiple regulators to have regulatory and licensing responsibilities for the SHINE project. We would like to engage the Staff in discussions regarding the roles and responsibilities for licensing the SHINE technology and facility in an Agreement State setting and gain understanding and consensus regarding the scope of the NRC regulatory and licensing authority. We request the Staff to review the NRC role and responsibility for licensing the SHINE technology and facility in advance of the follow-up public meeting.

In conjunction with the NRC discussion items, we request that the following items be considered and a response provided by the DHS Staff:

**Source, Byproduct and Special Nuclear Material**

We plan to obtain an NRC possession license for an amount of special nuclear material that exceeds the amount that is allowed to be regulated by an Agreement State and, as a result, the regulatory authority will remain with the NRC under 10 CFR 70. Pending the outcome of our discussions with the NRC Staff, we may also be considered a "Production facility" within the definition included in 10 CFR 50.2, due to processing irradiated material containing special nuclear material. Article II of the Agreement between the State of Wisconsin and the NRC states that the authority and responsibility for the regulation of the construction and operation of any production facility is retained by the NRC. Thus, if the SHINE facility is determined to be a production facility, we believe the regulatory authority for this portion of the facility licensing and operation will not reside with the State of Wisconsin. However, SHINE will also have a possession license for source and byproduct material which are regulated under DHS regulations as an Agreement State. DHS 157.02, Applicability, Item (1) states:

Except as specified, this chapter applies to all persons who receive, possess, use, transfer, own or acquire any source of radiation, except that nothing in this

chapter shall apply to any person subject to regulation by the U.S. nuclear regulatory commission.

It is not clear that DHS will be responsible for the licensing and regulatory oversight of our source and byproduct material and SHINE requests the DHS Staff confirm that the responsibility for the source and byproduct material falls under NRC authority in accordance with the Agreement State language.

### **Accelerator**

The SHINE technology and facility will employ accelerator technology. We believe the DHS will retain responsibility for the shielding plan review and approval associated with the particle accelerator. Subchapter VIII of DHS 157 is the stated regulation for accelerators; however, we find this regulation is oriented to health-related radiographic and therapeutic radiation systems and not towards particle accelerators. Except for shielding plan review, the application of the various parts of this subchapter of the regulation to our technology and facility is unclear. We believe the DHS will regulate the radiation aspects associated with the accelerator, approve the shielding plan and not apply other health-related radiographic and therapeutic radiation system regulations in subchapter VIII. We request the DHS Staff confirm this interpretation of the applicability of subchapter VIII to the SHINE technology and facility, including responsibility for the review and approval of the shielding plan for the particle accelerator.

SHINE plans to submit the application to the NRC before the end of calendar year 2011 and the application to the State of Wisconsin by the end of the first quarter of 2012. SHINE looks forward to maintaining communications and interactions with the DHS Staff on these important topics.

Written communications related to the SHINE project should be addressed as follows:

Dr. Gregory Piefer, PhD  
CEO – SHINE Medical Technologies, Inc.  
8123 Forsythia Street Suite 140  
Madison, WI 53562

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

Sincerely,



Dr. Gregory Piefer, PhD  
CEO – SHINE Medical Technologies, Inc.

**SHINE Medical Technologies, Inc.**

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