

November 30, 2011

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

SHINE Medical Technologies, Inc. Project 0792 SMT-2011-029

Subject: Updated 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

Reference: G. Piefer (SHINE Medical Technologies, Inc.) to U.S. Nuclear Regulatory Commission (NRC), SMT-2011-010, "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", dated July 27, 2011 (ML11234A031)

The purpose of this letter is to provide an updated response to the questions posed in Regulatory Information Summary (RIS) 2011-006. The original responses to this RIS were submitted by SHINE Medical Technologies, Inc. (SHINE) in the referenced letter, which also included a commitment to provide an updated response by November 30, 2011. The updated response to the RIS questions follows and is based on the current maturity of the regulatory and licensing framework for medical isotope production facilities, the SHINE project plan, and the facility design.

The only update that can be provided at this time pertains to the scheduled submittal date of the construction permit application. At this time, SHINE intends to submit the construction permit application in the second half of calendar year 2012. The actual submittal schedule is dependent on a number of variables; therefore, a specific month for the construction permit application submittal cannot be provided.

SHINE anticipates that greater clarity can be provided relative to licensing action document submittals in the second quarter of calendar year 2012. SHINE will provide an updated response to the anticipated licensing action document submittals by May 31, 2012 or in response to a similar RIS information request issued by the NRC in calendar year 2012. The only new commitment in this letter is to provide an updated licensing action submittal schedule to the NRC by May 31, 2012 or to submit a response to a similar RIS information request in calendar year 2012.

YGOI

Add: M. Voth

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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.

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