

October 23, 2012

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

SHINE Medical Technologies, Inc. SMT-2012-032 Project No. 0792

Subject: Request to Withhold Information from Public Disclosure

A pre-application meeting is scheduled for November 8, 2012 between SHINE Medical Technologies, Inc. (SHINE) and the U.S. Nuclear Regulatory Commission (NRC) to discuss the SHINE organization, experience and qualifications; the content of the construction permit and operating license applications; the Target Solution Vessel (TSV) processes and supporting systems; the radioisotope production facility systems and processes; and the schedule pertinent to the SHINE construction permit and operating license applications. The purpose of this letter is to request that certain portions of the SHINE presentation materials that will be used at this meeting be withheld from public disclosure in accordance with 10 CFR 2.390.

Enclosure 1 provides the slides to be used in the closed portion of the meeting and contain proprietary information held in confidence by SHINE. SHINE requests that the NRC withhold this information from public disclosure in accordance with the requirements of 10 CFR 2.390(a)(4). Enclosure 2 provides the redacted version of the closed meeting presentation slides.

Enclosure 3 contains an appropriate affidavit supporting proprietary treatment of SHINE confidential proprietary information pursuant to 10 CFR 2.390.

There are no new regulatory commitments in this letter.

JG01 NRR

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If you have any questions regarding this letter, please contact Mr. Vann Bynum, Chief Operating Officer, at 608.210.1062.

Sincerely,

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Gregory Piefer, PhD Chief Executive Officer SHINE Medical Technologies, Inc. Enclosures: As stated

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cc: (without Enclosures)

Mr. Charles A. Castro Regional Administrator U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road Suite 210 Lisle, IL 60532-4352

Mr. Steven Lynch General Engineer Mail Stop 12D20 U.S. Nuclear Regulatory Commission Washington, DC 20555

Ms. Cheryl Rogers Supervisor, Radioactive Materials Programs Wisconsin Division of Public Health P.O. Box 2659 Madison, WI 53701-2659

Ms. Brenda Furlow General Counsel SHINE Medical Technologies 2555 Industrial Drive Monona, WI 53713 October 23, 2012 SMT-2012-032 Project No. 0792

Enclosure 3 Affidavit of Dr. Gregory Piefer



AFFIDAVIT OF GREGORY PIEFER

STATE OF WISCONSIN)

COUNTY OF DANE

I, Gregory Piefer, Chief Executive Officer of SHINE Medical Technologies, Inc. (SHINE), do hereby affirm and state:

) SS.

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- 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 disclosure. I am making this affidavit in conformance with the provisions of the NRC's regulations at 10 CFR 2.390 and in support of SHINE's request for proprietary treatment of certain confidential commercial information to be discussed during the non-public portion of the SHINE meeting with the NRC on November 8, 2012.
- 2. I have knowledge of the criteria used by SHINE in designating information as sensitive, proprietary, or confidential.
- 3. Pursuant to the provisions of paragraphs (a)(3) and (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 at the referenced non-public meeting with the NRC is owned by SHINE, its affiliates or third parties to who SHINE has an obligation to maintain its confidentiality and has been held in confidence by SHINE.
 - b. The information sought to be protected is not available to the public to the best of my knowledge and belief.
 - c. The information is of the type that would customarily be held in confidence by SHINE. The information that SHINE is requesting to be withheld from public disclosure includes trade secret, confidential 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" subject to maintaining confidentiality.

Public disclosure of these elements is likely to harm SHINE because it would allow others to understand SHINE's competitive expectations, assumptions, processes and current position.

d. The proprietary information sought to be withheld from public disclosure at the non-public portion of the referenced meeting includes; the target solution vessel processes and supporting systems, radioisotope production facility processes and systems, and the application schedule.

e. The information 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.

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

10-22-12 Date:

31/2013

Subscribed and sworn to before me, a Notary Public, in and for the county and state above named, this _______ day of October, 2012.

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Notary Public in a PAT Wisconsi Nota 8 State q/WiConstanission xpires

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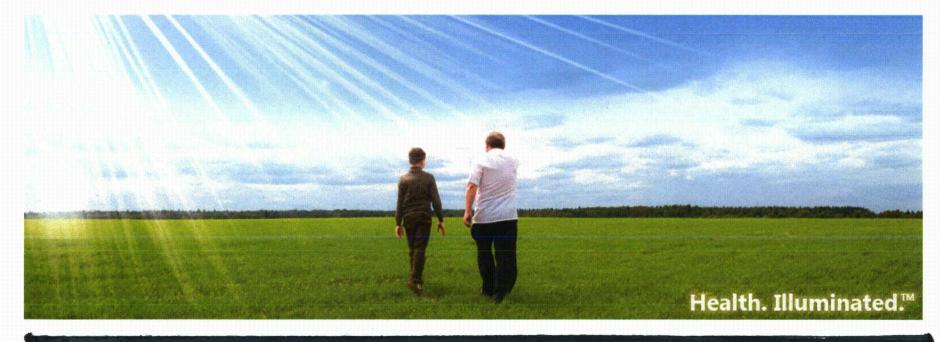
October 23, 2012 SMT-2012-032 Project No. 0792

Enclosure 2 Closed Meeting Slides (Redacted)



Who is SHINE Medical Technologies?

November 8, 2012



An impressive suite of organizations created SHINE



We have sought out the best





Sargent & Lundy









Argonne, Los Alamos, and Savannah River National Laboratories

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Irradiation Facility Design and Operational Overview

NRC/SHINE Pre-Application Meeting Rockville, MD November 8, 2012



Questions?

Eric N. Van Abel Nuclear Systems Engineer SHINE Medical Technologies, Inc. 877-512-6554 eric.vanabel@shinemed.com



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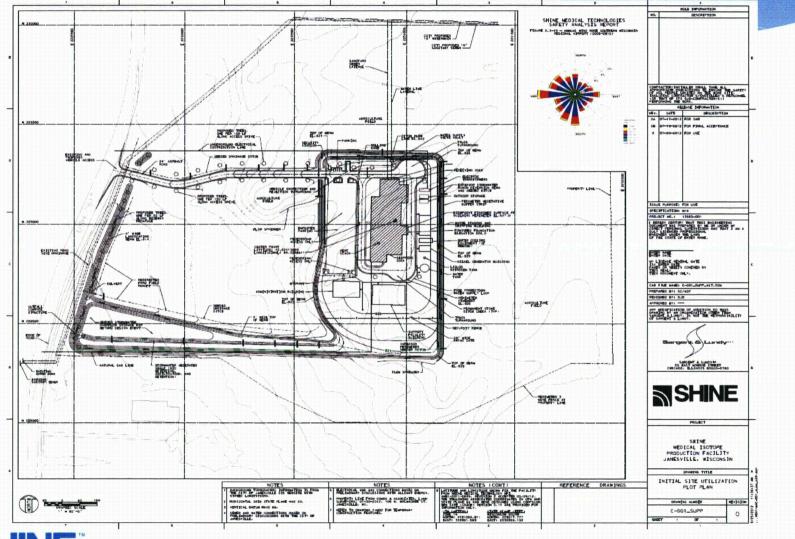
Mo-99 Production Facility Design and Processing Overview

NRC/SHINE Pre-Application Meeting Rockville, MD November 8, 2012



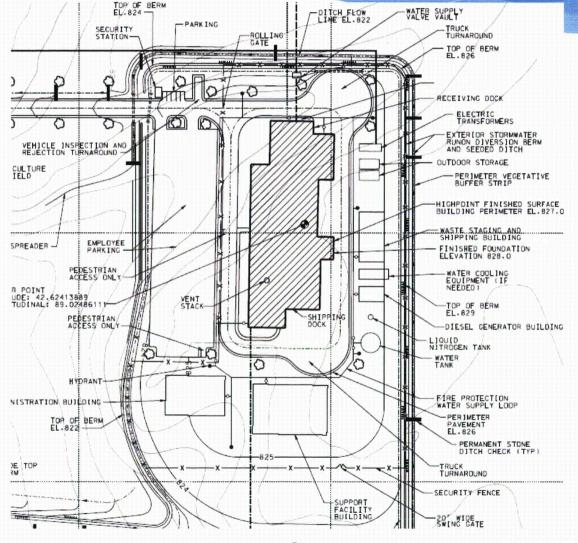
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Site Utilization Plot Plan





Site Utilization Plot Plan (zoom)





Questions?

Mike Washer, P.E. Principal Process Engineer SHINE Medical Technologies, Inc. 877-512-6554 michael.washer@merrick.com

