

### THIS LETTER CONTAINS PROPRIETARY INFORMATION **IN ACCORDANCE WITH 10 CFR 2.390**

October 4, 2013

SMT-2013-034 10 CFR 50.30

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

- References: (1) SHINE Medical Technologies, Inc. letter to NRC, dated March 26, 2013. Part One of the SHINE Medical Technologies, Inc. Application for Construction Permit (ML130880226)
  - (2) SHINE Medical Technologies, Inc. letter to NRC, dated May 31, 2013, Part Two of the SHINE Medical Technologies, Inc. Application for Construction Permit (ML13172A361)
  - (3) NRC letter to SHINE Medical Technologies, Inc., dated July 3, 2013, Environmental Site Audit Regarding SHINE Medical, Inc. Proposed Radioisotope Production Facility (ML13168A562)
  - (4) NRC letter to SHINE Medical Technologies, Inc., dated September 11, 2013. Requests for Additional Information for the Environmental Review of the SHINE Radioisotope Production Facility Construction Permit Application (ML13231A041)

SHINE Medical Technologies, Inc. Application for Construction Permit Response to Environmental Requests for Additional Information

Pursuant to 10 CFR 50.30, SHINE Medical Technologies, Inc. (SHINE) submitted an application for a construction permit to construct a medical isotope facility to be located in Janesville. WI (References 1 and 2). To develop the environmental impact statement, the NRC staff transmitted an environmental site audit needs list for SHINE to discuss with the NRC during the environment site audit (Reference 3).

An environmental site audit was held during the week of July 29, 2013. On July 31, 2013, SHINE discussed the Reference (3) requested needs list with the NRC. Subsequently, the NRC staff determined additional information was required to complete the environmental review (Reference 4).

Enclosure 1 provides the non-public (proprietary) version of the SHINE response to the NRC staff's request for additional information. Enclosure 1 is being provided via optical storage media (OSM) as OSM#1. In additional to proprietary information, Enclosure 1 contains security-related information which was identified utilizing the guidance contained in Regulatory Information Summary (RIS) 2005-31. SHINE requests that the NRC withhold Enclosure 1 from public disclosure under 10 CFR 2.390.

> Enclosure 1 contains both proprietary and security-related information. Withhold from public disclosure under 10 CFR 2.390. Upon removal of Enclosure 1, this letter is uncontrolled.

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Enclosure 2 provides the public (non-proprietary) version of the SHINE response to the NRC staff's request for additional information. Enclosure 2 is provided via OSM as OSM#2.

Enclosure 3 provides an affidavit supporting the proprietary treatment of the SHINE proprietary information pursuant to 10 CFR 2.390. Enclosure 1 contains proprietary information. SHINE requests that the NRC withhold Enclosure 1 from public disclosure under 10 CFR 2.390. Upon removal of Enclosure 1, this letter is uncontrolled.

If you have any questions, please contact Mr. Jim Costedio, Licensing Manager, at 608/210-1730.

I declare under the penalty of perjury that the foregoing is true and correct. Executed on October 4, 2013.

Very truly yours,

R. Vann Bynum, Ph.D. Chief Operating Officer

SHINE Medical Technologies, Inc.

R.V. Bynum

**Docket No. 50-608** 

#### **Enclosures**

cc: Administrator, Region III, USNRC

Project Manager, USNRC

Environmental Project Manager, USNRC

Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health

Enclosure 1 contains both proprietary and security-related information.

Withhold from public disclosure under 10 CFR 2.390.

Upon removal of Enclosure 1, this letter is uncontrolled.

## ENCLOSURE 1 CONTAINS PROPRIETARY INFORMATION IN ACCORDANCE WITH 10 CFR 2.390

#### **ENCLOSURE 1**

### SHINE MEDICAL TECHNOLOGIES, INC.

## SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT RESPONSE TO ENVIRONMENTAL REQUESTS FOR ADDITIONAL INFORMATION

NON-PUBLIC VERSION (OSM#1)



Enclosure 1 contains both proprietary and security-related information.

Withhold from public disclosure under 10 CFR 2.390.

Upon removal of Enclosure 1, this letter is uncontrolled.

#### **ENCLOSURE 2**

### SHINE MEDICAL TECHNOLOGIES, INC.

## SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT RESPONSE TO ENVIRONMENTAL REQUESTS FOR ADDITIONAL INFORMATION

PUBLIC VERSION (OSM#2)



## **ENCLOSURE 3**

## SHINE MEDICAL TECHNOLOGIES, INC.

# SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT RESPONSE TO ENVIRONMENTAL REQUESTS FOR ADDITIONAL INFORMATION

**AFFIDAVIT OF RICHARD VANN BYNUM** 



### **AFFIDAVIT OF RICHARD VANN BYNUM**

STATE OF WISCONSIN	)
	) ss
COUNTY OF DANE	)

- I, Richard Vann Bynum, Chief Operating Officer of SHINE Medical Technologies, Inc. (SHINE), do hereby affirm and state:
  - 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 public disclosure. The purpose of this affidavit is to provide the information required by 10 CFR 2.390(b) in support of SHINE's request for proprietary treatment of certain confidential commercial information submitted in the SHINE response to the NRC staff's environmental requests for additional information. SHINE requests that the confidential information contained in Enclosure 1 be withheld from public disclosure in their entirety.
  - 2. I have knowledge of the criteria used by SHINE in designating information as sensitive, proprietary, or confidential.
  - 3. Pursuant to the provisions of paragraph (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 contained in Enclosure 1 of SMT-2013-034 is owned by SHINE, its affiliates or third parties to whom SHINE has an obligation to maintain its confidentiality. This information is and has been held in confidence by SHINE.
    - b. The information sought to be protected in Enclosure 1 is not available to the public to the best of my knowledge and belief.

- c. The information contained in Enclosure 1 is of the type that is customarily held in confidence by SHINE, and there is a rational basis for doing so. The information that SHINE is requesting to be withheld from public disclosure includes trade secret, commercial information or information that is subject to export controls. SHINE limits access to these elements to those with a "need to know," and subject to maintaining confidentiality.
- d. The proprietary information sought to be withheld from public disclosure in Enclosure 1 includes, but is not limited to: primary and supporting systems of the medical isotope facility and process details. This would include information regarding the types and quantities of materials stored on site. Public disclosure of the information in Enclosure 1 would create substantial harm to SHINE because it would reveal trade secrets owned by SHINE, its affiliates or third parties to whom SHINE has an obligation to maintain its confidentiality.
- e. The information contained in Enclosure 1 of letter SMT-2013-034 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. The information is properly marked.

I declare under the penalty of perjury that the foregoing is true and correct. Executed on October 4, 2013.

Richard Vann Byoum, Ph.D.

COO - SHINE Medical Technologies, Inc.