



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

March 23, 2015

SMT-2015-008
10 CFR 50.30

50-608

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

References: See Below

SHINE Medical Technologies, Inc. Application for Construction Permit
Response to Request for Additional Information 11.1-9

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). Via Reference (3), the NRC staff determined that additional information was required to enable the staff's continued review of the SHINE construction permit application. SHINE responded to the NRC staff's requests via References (4) and (5).

In the course of reviewing the SHINE responses submitted via Reference (4), the NRC staff determined that additional information was required (Reference 6) to complete the review of the SHINE construction permit application. SHINE responded to the NRC staff's additional requests via Reference (7), with the exception of Request for Additional Information (RAI) 11.1-9.

Enclosure 1 provides the SHINE response to RAI 11.1-9. Enclosure 1 is being provided via optical storage media (OSM) as OSM#1.

Enclosure 2 provides a non-public (proprietary) revision to the SHINE Preliminary Safety Analysis Report (PSAR), incorporating changes based on the SHINE response to RAI 11.1-9. Enclosure 2 is provided via OSM as OSM#2. In addition to proprietary information, Enclosure 2 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 2 from public disclosure under 10 CFR 2.390.

Enclosure 3 provides a public (non-proprietary) revision to the SHINE PSAR, incorporating changes based on the SHINE response to RAI 11.1-9. Enclosure 3 is provided via OSM as OSM#3.

Enclosure 2 contains both ~~proprietary and security-related information.~~
~~Withhold from public disclosure under 10 CFR 2.390.~~
Upon removal of Enclosure 2, this letter is uncontrolled.

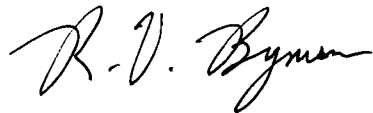
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Enclosure 4 provides an affidavit supporting the proprietary treatment of the SHINE proprietary information pursuant to 10 CFR 2.390. Enclosure 2 contains information proprietary to SHINE. Upon removal of Enclosure 2, this letter is uncontrolled.

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 March 23, 2015.

Very truly yours,



R. Vann Bynum, Ph.D.
Chief Operating Officer
SHINE Medical Technologies, Inc.
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
(w/o Enclosure 2)

Enclosure 2 contains both ~~proprietary and security-related information.~~
~~Withhold from public disclosure under 10 CFR 2.390.~~
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- 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 (ML13172A324)
 - (3) NRC letter to SHINE Medical Technologies, Inc., dated September 19, 2014, SHINE Medical Technologies, Inc. – Request for Additional Information Regarding Application for Construction Permit (TAC Nos. MF2305, MF2307, and MF2308) (ML14195A159)
 - (4) SHINE Medical Technologies, Inc. letter to NRC, dated October 15, 2014, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information (ML14296A190)
 - (5) SHINE Medical Technologies, Inc. letter to NRC, dated December 3, 2014, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information (ML14356A528)
 - (6) NRC letter to SHINE Medical Technologies, Inc., dated January 8, 2015, SHINE Medical Technologies, Inc. – Request for Additional Information Regarding Application for Construction Permit (TAC Nos. MF2305, MF2307, and MF2308) (ML15005A407)
 - (7) SHINE Medical Technologies, Inc. letter to NRC, dated February 6, 2015, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information

Enclosure 2 contains both ~~proprietary and security-related information.~~
~~Withhold from public disclosure under 10 CFR 2.390.~~
Upon removal of Enclosure 2, this letter is uncontrolled.

ENCLOSURE 1

SHINE MEDICAL TECHNOLOGIES, INC.

**SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT
RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION 11.1-9**

**SHINE RESPONSE TO RAI 11.1-9
(OSM#1)**



**ENCLOSURE 2 CONTAINS ~~PROPRIETARY INFORMATION~~
~~IN ACCORDANCE WITH 10 CFR 2.390~~**

ENCLOSURE 2

SHINE MEDICAL TECHNOLOGIES, INC.

**SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT
RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION 11.1-9**

**PRELIMINARY SAFETY ANALYSIS REPORT
NON-PUBLIC VERSION
(OSM#2)**



Enclosure 2 contains both ~~proprietary and security-related information.~~
~~Withhold from public disclosure under 10 CFR 2.390.~~
Upon removal of Enclosure 2, this letter is uncontrolled.

ENCLOSURE 3

SHINE MEDICAL TECHNOLOGIES, INC.

**SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT
RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION 11.1-9**

**PRELIMINARY SAFETY ANALYSIS REPORT
PUBLIC VERSION
(OSM#3)**



ENCLOSURE 4

SHINE MEDICAL TECHNOLOGIES, INC.

**SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT
RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION 11.1-9**

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 and financial information submitted in the SHINE response to the NRC staff's requests for additional information transmitted by letter SMT-2015-008 with enclosures. SHINE requests that the confidential information contained in Enclosure 2 be withheld from public disclosure in its 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 2 of SMT-2015-008 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 2 is not available to the public to the best of my knowledge and belief.

- c. The information contained in Enclosure 2 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 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,” and subject to maintaining confidentiality.
- d. The proprietary information sought to be withheld from public disclosure in Enclosure 2 includes, but is not limited to: structural configuration, primary and supporting systems of the medical isotope facility, process and system locations, and process details. This would include information regarding the types, quantities, and locations of materials stored on site as would be referenced in facility configuration drawings. Public disclosure of the information in Enclosure 2 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 2 of SMT-2015-008 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 March 23, 2015.



Richard Vann Gynum, Ph.D.
COO – SHINE Medical Technologies, Inc.