



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

50-608

October 15, 2014

SMT-2014-033  
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 (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)

SHINE Medical Technologies, Inc. Application for Construction Permit  
Response to Request 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). 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.

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 addition 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 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.

<p>Enclosures 1 and 3 contain both proprietary and security-related information. Withhold from public disclosure under 10 CFR 2.390. Upon removal of Enclosures 1 and 3, this letter is uncontrolled.</p>
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Enclosure 3 provides a non-public (proprietary) revision to the SHINE Preliminary Safety Analysis Report (PSAR), incorporating changes based on the SHINE Response to RAI 3.5-1 (Reference 3). Enclosure 3 is provided via OSM as OSM#3. In addition to proprietary information, Enclosure 3 contains security-related information which was identified utilizing the guidance contained in RIS 2005-31. SHINE requests that the NRC withhold Enclosure 3 from public disclosure under 10 CFR 2.390.

Enclosure 4 provides a public (non-proprietary) revision to the SHINE PSAR, incorporating changes based on the SHINE Response to RAI 3.5-1. Enclosure 4 is provided via OSM as OSM#4.

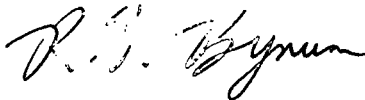
Enclosure 5 provides an affidavit supporting the proprietary treatment of the SHINE proprietary information pursuant to 10 CFR 2.390. Enclosures 1 and 3 contain information proprietary to SHINE. Upon removal of Enclosures 1 and 3, this letter is uncontrolled.

Enclosure 6 provides the schedule for submittal of the remaining SHINE Responses to the requests for additional information.

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 15, 2014.

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 Enclosures 1 and 3)

<p>Enclosures 1 and 3 contain both proprietary and security-related information. Withhold from public disclosure under 10 CFR 2.390. Upon removal of Enclosures 1 and 3, this letter is uncontrolled.</p>
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**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 REQUEST 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 Enclosures 1 and 3, this letter is uncontrolled.

**ENCLOSURE 2**

**SHINE MEDICAL TECHNOLOGIES, INC.**

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

**PUBLIC VERSION  
(OSM#2)**



**ENCLOSURE 3 CONTAINS PROPRIETARY INFORMATION  
IN ACCORDANCE WITH 10 CFR 2.390**

**ENCLOSURE 3**

**SHINE MEDICAL TECHNOLOGIES, INC.**

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

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



Enclosure 3 contains both proprietary and security-related information.  
Withhold from public disclosure under 10 CFR 2.390.  
Upon removal of Enclosures 1 and 3, this letter is uncontrolled.

**ENCLOSURE 4**

**SHINE MEDICAL TECHNOLOGIES, INC.**

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

**PRELIMINARY SAFETY ANALYSIS REPORT  
PUBLIC VERSION  
(OSM#4)**



**ENCLOSURE 5**

**SHINE MEDICAL TECHNOLOGIES, INC.**

**SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT  
RESPONSE TO REQUEST 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 and financial information submitted in the SHINE response to the NRC staff's requests for additional information transmitted by letter SMT-2014-033 with enclosures. SHINE requests that the confidential information contained in Enclosure 1 and Enclosure 3 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 and Enclosure 3 of SMT-2014-033 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 and Enclosure 3 is not available to the public to the best of my knowledge and belief.

- c. The information contained in Enclosure 1 and Enclosure 3 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 1 and Enclosure 3 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 1 and Enclosure 3 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. Public disclosure of the information in Enclosure 1 and Enclosure 3 would create substantial harm to SHINE because it would reveal valuable business information regarding SHINE's competitive expectations, assumptions, processes, and current position. Its use by a competitor could substantially improve their competitive position in the design, manufacture, shipment, installation, assurance of quality, or licensing of a similar product.
- f. The information contained in Enclosure 1 and Enclosure 3 of SMT-2014-033 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 15, 2014.



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

**ENCLOSURE 6**

**SHINE MEDICAL TECHNOLOGIES, INC.**

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

**SCHEDULE FOR SUBMITTAL OF REMAINING RAI RESPONSES**

Request Number	Submittal Date	Request Number	Submittal Date	Request Number	Submittal Date
RAI 2.4-2	December 18, 2014	RAI 5a2.2-1	December 18, 2014	RAI 9a2.1-1(a)	November 18, 2014
RAI 2.4-3	December 18, 2014	RAI 5a2.2-3	December 18, 2014	RAI 9a2.1-1(b)	December 18, 2014
RAI 2.4-4	December 18, 2014	RAI 6a2.1-1(a)	December 18, 2014	RAI 9a2.1-2	December 18, 2014
RAI 2.4-5	December 18, 2014	RAI 6a2.1-1(b)	November 18, 2014	RAI 9a2.3-1	December 18, 2014
RAI 2.5-1	December 18, 2014	RAI 6a2.2-1	December 18, 2014	RAI 9a2.3-2	December 18, 2014
RAI 2.5-2	December 18, 2014	RAI 6a2.2-3	December 18, 2014	RAI 9a2.3-3	December 18, 2014
RAI 2.5-4	December 18, 2014	RAI 6a2.2-4	December 18, 2014	RAI 9a2.3-4	December 18, 2014
RAI 2.5-5	December 18, 2014	RAI 6a2.2-7	December 18, 2014	RAI 9a2.3-5	December 18, 2014
RAI 2.5-6	December 18, 2014	RAI 6a2.2-9	December 18, 2014	RAI 9a2.3-6	November 18, 2014
RAI 3.2-1	December 18, 2014	RAI 6a2.2-11	November 18, 2014	RAI 9a2.3-7	December 18, 2014
RAI 3.3-1	December 18, 2014	RAI 6b.1-1(a)	December 18, 2014	RAI 9b.7-1	December 18, 2014
RAI 3.4-1	December 18, 2014	RAI 6b.1-1(b)	November 18, 2014	RAI 9b.7-2	December 18, 2014
RAI 3.4-2	December 18, 2014	RAI 6b.2-1	December 18, 2014	RAI 11.1-1	November 18, 2014
RAI 3.4-3	December 18, 2014	RAI 6b.2-6	November 18, 2014	RAI 11.1-4	December 18, 2014
RAI 3.4-4	December 18, 2014	RAI 6b.3-1	December 18, 2014	RAI 11.1-6	December 18, 2014
RAI 3.4-5	December 18, 2014	RAI 6b.3-2	December 18, 2014	RAI 11.2-1(a)	November 18, 2014
RAI 3.4-7	December 18, 2014	RAI 6b.3-4	December 18, 2014	RAI 11.2-1(b)	December 18, 2014
RAI 3.5-3	December 18, 2014	RAI 6b.3-5	December 18, 2014	RAI 11.2-1(c)	December 18, 2014
RAI 3.5-5	December 18, 2014	RAI 6b.3-6	December 18, 2014	RAI 11.2-2	December 18, 2014
RAI 4a2.2-5	December 18, 2014	RAI 6b.3-7	December 18, 2014	RAI 11.2-4	December 18, 2014
RAI 4a2.2-8	November 18, 2014	RAI 6b.3-8	December 18, 2014	RAI 11.2-5	December 18, 2014
RAI 4a2.2-9	November 18, 2014	RAI 6b.3-9	December 18, 2014	RAI 12.7-12	December 18, 2014
RAI 4a2.3-1(3)	November 18, 2014	RAI 6b.3-10	December 18, 2014	RAI 13a2-G	December 18, 2014
RAI 4a2.4-1	December 18, 2014	RAI 6b.3-11	December 18, 2014	RAI 13a2.1-3	December 18, 2014
RAI 4a2.4-2	December 18, 2014	RAI 6b.3-13	December 18, 2014	RAI 13a2.1-4	November 18, 2014
RAI 4a2.5-1	November 18, 2014	RAI 6b.3-14	December 18, 2014	RAI 13a2.1-5	November 18, 2014
RAI 4a2.6-3	December 18, 2014	RAI 6b.3-15	December 18, 2014	RAI 13a2.1-6	December 18, 2014
RAI 4a2.6-4	December 18, 2014	RAI 6b.3-16	December 18, 2014	RAI 13a2.1-7	December 18, 2014
RAI 4a2.6-5	November 18, 2014	RAI 6b.3-17	December 18, 2014	RAI 13a2.1-8	December 18, 2014
RAI 4a2.6-6	December 18, 2014	RAI 6b.3-18	December 18, 2014	RAI 13a2.2-1	December 18, 2014
RAI 4a2.6-8	December 18, 2014	RAI 6b.3-19	December 18, 2014	RAI 13a2.2-3	December 18, 2014
RAI 4a2.6-9	December 18, 2014	RAI 6b.3-20	December 18, 2014	RAI 13a2.2-4	December 18, 2014
RAI 4a2.7-1	December 18, 2014	RAI 6b.3-21	December 18, 2014	RAI 13b.1-1	December 18, 2014
RAI 4a2.8-1	December 18, 2014	RAI 6b.3-22	December 18, 2014	RAI 13b.1-2	December 18, 2014
RAI 4a2.8-2	November 18, 2014	RAI 7a2.2-1	December 18, 2014	RAI 13b.2	December 18, 2014
RAI 4a2.8-4	December 18, 2014	RAI 7a2.3-1	December 18, 2014		
RAI 4a2.8-5	December 18, 2014	RAI 8a2.2-1	December 18, 2014		