



**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 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 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.

ADD
NRR

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IN ACCORDANCE WITH 10 CFR 2.390**

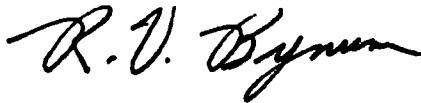
Enclosure 2 provides the public (non-proprietary) version of the SHINE response to the NRC staff's request for additional information. Enclosure 2 is provided via OSM as OSM#2.

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.
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

<p>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.</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 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

2 pages follow

- 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 Byrum, Ph.D.
COO – SHINE Medical Technologies, Inc.