



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

January 22, 2019

2019-SMT-0006

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

Meeting Slides for the January 29 and 30, 2019 Meeting
between SHINE Medical Technologies, Inc. and the NRC

A meeting is scheduled between SHINE Medical Technologies, Inc. (SHINE) and the NRC's Region II construction inspection staff to familiarize the staff with SHINE's medical isotope production facility technology and discuss topics related to SHINE's construction planning.

Enclosure 1 provides the non-public (proprietary) version of the SHINE meeting slides for the discussion regarding SHINE's technological overview. In addition to proprietary information, Enclosure 1 contains security-related information which was identified utilizing the guidance contained in 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 meeting slides for the discussion regarding SHINE's technological overview.

Enclosure 3 provides the non-public (proprietary) version of the SHINE meeting slides for the discussion regarding SHINE's construction planning. SHINE requests that the NRC withhold Enclosure 3 from public disclosure under 10 CFR § 2.390.

Enclosure 4 provides the public (non-proprietary) version of the SHINE meeting slides for the discussion regarding SHINE's construction planning.

Enclosure 5 provides the non-public version of the SHINE meeting slides for the discussion regarding SHINE's hazard analysis methodology and results. Enclosure 5 contains security-related information which was identified utilizing the guidance contained in RIS 2005-31. SHINE requests that the NRC withhold Enclosure 5 from public disclosure under 10 CFR § 2.390.

Enclosure 6 provides the public version of the SHINE meeting slides for the discussion regarding SHINE's hazard analysis methodology and results.

Enclosures 1 and 5 contain security-related information.
Withhold from public disclosure under 10 CFR 2.390.
Upon removal of Enclosures 1, 3, and 5, this letter is uncontrolled.

YGOI
NRR

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Enclosure 7 provides an affidavit supporting the proprietary treatment of the SHINE proprietary information contained in Enclosures 1 and 3, pursuant to 10 CFR § 2.390. SHINE requests that the NRC withhold Enclosures 1 and 3 from public disclosure under 10 CFR § 2.390. Upon removal of Enclosures 1, 3, and 5, this letter is uncontrolled.

If you have any questions, please contact me at 608/210-1735.

Very truly yours,

A handwritten signature in black ink, appearing to read "Jeff M. Bartelme", with a long horizontal flourish extending to the right.

Jeff Bartelme
Licensing Manager
SHINE Medical Technologies, Inc.
Docket No. 50-608

Enclosures

cc: Project Manager, USNRC
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health
(w/o Enclosures 1, 3, and 5)

<p>Enclosures 1 and 5 contain security-related information. Withhold from public disclosure under 10 CFR 2.390. Upon removal of Enclosures 1, 3, and 5, this letter is uncontrolled.</p>
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ENCLOSURE 7

SHINE MEDICAL TECHNOLOGIES, INC.

**MEETING SLIDES FOR THE JANUARY 29 AND 30, 2019 MEETING
BETWEEN SHINE MEDICAL TECHNOLOGIES, INC. AND THE NRC**

AFFIDAVIT OF JAMES COSTEDIO



AFFIDAVIT OF JAMES COSTEDIO

STATE OF WISCONSIN)
) ss.
COUNTY OF ROCK)

I, James Costedio, Vice President of Regulatory Affairs and Quality 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 meeting slides provided by letter 2019-SMT-0006 with enclosures. SHINE requests that the confidential information contained in Enclosures 1 and 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 Enclosures 1 and 3 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 Enclosures 1 and 3 is not available to the public to the best of my knowledge and belief.

- c. The information contained in Enclosures 1 and 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 Enclosures 1 and 3 includes, but is not limited to: structural configuration, primary and supporting systems of the medical isotope production 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 Enclosures 1 and 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 Enclosures 1 and 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 Enclosures 1 and 3 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 January 18, 2019.



James Costedio
Vice President of Regulatory Affairs and Quality
SHINE Medical Technologies, Inc.

**ENCLOSURE 1 CONTAINS PROPRIETARY INFORMATION
IN ACCORDANCE WITH 10 CFR § 2.390**

ENCLOSURE 1

SHINE MEDICAL TECHNOLOGIES, INC.

**MEETING SLIDES FOR THE JANUARY 29 AND 30, 2019 MEETING
BETWEEN SHINE MEDICAL TECHNOLOGIES, INC. AND THE NRC**

**SHINE TECHNOLOGY OVERVIEW
NON-PUBLIC VERSION**

<p>Enclosures 1 and 5 contain security-related information. Withhold from public disclosure under 10 CFR 2.390. Upon removal of Enclosures 1, 3, and 5, this letter is uncontrolled.</p>
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36 pages follow