SHINE Medical Technologies

99902034

THIS LETTER CONTAINS PROPRIETARY AND EXPORT CONTROLLED INFORMATION IN ACCORDANCE WITH 10 CFR § 2.390

February 24, 2020 2020-SMT-0020

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

References: (1) U.S. Nuclear Regulatory Commission, "SHINE Medical Technologies, LLC Public Meeting on Operating License Application," Public Meeting Announcement, February 21, 2020 (ML20052G475)

Meeting Slides for the March 4 and 5, 2020 Public Meeting between SHINE Medical Technologies, LLC and the NRC

A meeting is scheduled between SHINE Medical Technologies, LLC (SHINE) and the NRC staff (Reference 1) to discuss technical topics related to the SHINE operating license application.

The enclosed meeting slides and supplemental information contain information which SHINE requests to be withheld from public disclosure, including proprietary information in accordance with 10 CFR 2.390(a)(4), export controlled information (ECI) in accordance with 10 CFR 2.390(a)(3), and security-related information (SRI) in accordance 10 CFR 2.390(d). SRI was identified utilizing the guidance contained in Regulatory Issue Summary (RIS) 2005-31, Revision 1. The meeting slides and supplemental information are provided via optical storage media (OSM).

Enclosure 1 provides the non-public version of the SHINE meeting slides for the discussion regarding design changes to the tritium purification system (TPS). Enclosure 1 contains proprietary information, a subset of which has been determined to be ECI, as well as SRI. Due to the proprietary nature of the discussion, SHINE requests the NRC close a portion of the meeting session regarding design changes to the TPS to the public and withhold Enclosure 1 from public disclosure under 10 CFR 2.390.

Enclosure 2 provides the public version of the SHINE meeting slides for the discussion regarding design changes to the TPS.

Enclosure 3 provides the non-public version of the SHINE meeting slides for the discussion regarding the SHINE safety analysis methodology. Enclosure 3 contains proprietary information, a subset of which has been determined to be ECI, as well as SRI. Due to the proprietary nature of the discussion, SHINE requests the NRC close a portion the meeting session regarding the SHINE safety analysis methodology to the public and withhold Enclosure 3 from public disclosure under 10 CFR 2.390.

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NRR

Enclosures 1 and 3 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.

Enclosure 4 provides the public version of the SHINE meeting slides for the discussion regarding the SHINE safety analysis methodology.

Enclosure 5 provides the non-public version of the draft SHINE safety analysis approach as supplemental information to support the discussion of the SHINE safety analysis. SHINE will incorporate the safety analysis approach into the SHINE Safety Analysis Report following the discussion with the NRC Staff. SHINE is not seeking NRC review and approval of the enclosed SHINE safety analysis approach. The SHINE licensing basis accident analysis, including methodology, is described in Chapter 13 of the Final Safety Analysis Report (FSAR). Enclosure 5 contains proprietary information, a subset of which has been determined to be ECI. SHINE requests the NRC withhold Enclosure 5 from public disclosure under 10 CFR 2.390.

Enclosure 6 provides the public version of the draft SHINE safety analysis approach.

Enclosure 7 provides an affidavit supporting the proprietary treatment of the SHINE proprietary information contained in Enclosures 1, 3, and 5 and the proprietary nature of the discussion surrounding the content of the meeting slides for the subject meeting sessions, pursuant to 10 CFR 2.390. SHINE requests that the NRC withhold Enclosures 1, 3, and 5 from public disclosure, in their entirety, and close the related meeting sessions to the public, under 10 CFR 2.390. Upon removal of Enclosures 1, 3, and 5, this letter is uncontrolled.

If you have any questions, please contact Mr. Jeff Bartelme, Director of Licensing, at 608/210-1735.

Very truly yours,

James Costedio
Vice President of Regulatory Affairs and Quality
SHINE Medical Technologies, LLC
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)

ENCLOSURE 7

SHINE MEDICAL TECHNOLOGIES, LLC

MEETING SLIDES FOR THE MARCH 4 AND 5, 2020 PUBLIC MEETING BETWEEN SHINE MEDICAL TECHNOLOGIES, LLC AND THE NRC

AFFIDAVIT OF JAMES COSTEDIO

2 pages follow

SHINE® Medical Technologies

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, LLC (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 2020-SMT-0020 with enclosures and the related meeting discussion. SHINE requests that the confidential information contained in Enclosures 1, 3, and 5, and the related meeting discussion, 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, 3, and 5, and the related meeting discussion, 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, 3, and 5, and the related meeting discussion, is not available to the public to the best of my knowledge and belief.

c. The information contained in Enclosures 1, 3, and 5, and the related meeting discussion, 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, 3, and 5, and the related meeting discussion, 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, 3, and 5, and the related meeting discussion, 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, 3, and 5, and the related meeting discussion, 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, 3, and 5, and the related meeting discussion, 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 February 24, 2020.

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