



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

August 17, 2018

Gregory Piefer, Ph.D.  
Chief Executive Officer  
SHINE Medical Technologies, Inc.  
101 E. Milwaukee Street, Suite 600  
Janesville, WI 53545

SUBJECT: SHINE MEDICAL TECHNOLOGIES, INC. - REQUEST FOR WITHHOLDING  
INFORMATION FROM PUBLIC DISCLOSURE (EPID NO. L-2017-PMP-0014)

Dear Dr. Piefer:

By letter dated July 2, 2018 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML18187A216), SHINE Medical Technologies, Inc. (SHINE) submitted an affidavit executed by James Costedio, which requested that information contained in the following enclosures of SHINE document 2018-SMT-0054 and associated meeting discussions be withheld from public disclosure pursuant to the Title 10 of the *Code of Federal Regulations* (10 CFR), Section 2.390:

Enclosure 2, Resubmittal of Meeting Slides for the June 28, 2018 Public Meeting Between SHINE Medical Technologies, Inc. and the NRC, Process Vessel Vent System Design, Non-Public Version

Enclosure 4, Resubmittal of Meeting Slides for the June 28, 2018 Public Meeting Between SHINE Medical Technologies, Inc. and the NRC, Safety-Related Instrumentation and Control (I&C) Overview, Non-Public Version

Nonproprietary versions of these enclosures, designated as Enclosures 3 and 5, respectively, submitted by SHINE in the July 2, 2018, letter referenced above have been placed in the U.S. Nuclear Regulatory Commission's (NRC's) Public Document Room and added to the NRC Library in ADAMS for public inspection (ADAMS Accession No. ML18187A216).

The affidavit requesting withholding of Enclosures 2 and 4, and the related meeting discussions, stated that the submitted information should be considered exempt from mandatory public disclosure for the following reasons:

- a. The information sought to be withheld from public disclosure contained in Enclosures 2 and 4, 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 2 and 4, 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 2 and 4, 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 individuals with a "need to know," and subject to maintaining confidentiality.
- d. The proprietary information sought to be withheld from public disclosure in Enclosures 2 and 4, 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 2 and 4 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 2 and 4, 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.

The NRC staff has reviewed SHINE's submittal in accordance with the requirements of 10 CFR 2.390 and, on the basis of the statements in the affidavit, has determined that the submitted information and associated meeting discussions sought to be withheld contains proprietary commercial information and should be withheld from public disclosure.

Therefore, the submitted information marked as proprietary and the related meeting discussions, will be withheld from public disclosure pursuant to 10 CFR 2.390(b)(5) and Section 103(b) of the Atomic Energy Act of 1954, as amended.

Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, the NRC staff may send copies of this information to its consultants working in this area. The NRC staff will, of course, ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding information from public inspection should change in the future such that the information could then be made available for public inspection, SHINE should promptly notify the NRC. SHINE also should understand that the NRC staff may have cause to review this determination in the future, for example, if the scope of a Freedom of Information Act request includes SHINE's information. In all review situations, if the NRC makes a determination adverse to the above, SHINE will be notified in advance of any public disclosure.

If you have any questions regarding this matter, I may be reached at (301) 415-1524, or by electronic mail at [Steven.Lynch@nrc.gov](mailto:Steven.Lynch@nrc.gov).

Sincerely,

**/RA/**

Steven T. Lynch, Project Manager  
Research and Test Reactors Licensing Branch  
Division of Licensing Projects  
Office of Nuclear Reactor Regulation

Docket No. 50-608

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DATE: AUGUST 17, 2018

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ADAMS Accession Nos.: ML18221A453, Pkg; ML18178A651, Notice; ML18221A454, Mtg. Summary;  
ML18221A455, Withholding Ltr.; ML18187A216, Slides \*concurred via email

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