



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

March 22, 2019

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 January 22, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19025A264), SHINE Medical Technologies, Inc. (SHINE) submitted an affidavit executed by James Costedio, which requested that information contained in the following enclosures of SHINE document 2019-SMT-0007 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 1, Meeting Slides for the January 29 and 30, 2019, Public Meeting Between SHINE Medical Technologies, Inc. and the U.S. Nuclear Regulatory Commission (NRC), SHINE Technology Overview, Non-Public Version

Enclosure 3, Meeting Slides for the January 29 and 30, 2019, Public Meeting Between SHINE Medical Technologies, Inc. and the NRC, SHINE Construction Planning, Non-Public Version

SHINE also requested that security-related information contained in Enclosure 1 and the following enclosure be withheld from public disclosure pursuant to 10 CFR 2.390:

Enclosure 5, Meeting Slides for the January 29 and 30, 2019, Public Meeting Between SHINE Medical Technologies, Inc. and the NRC, SHINE Identification of Safety-Related Controls, Non-Public Version

Non-proprietary versions of these enclosures, designated as Enclosures 2, 4, and 6 respectively, submitted by SHINE in the January 22, 2019, letter referenced above have been placed in the NRC Public Document Room and added to the NRC Library in ADAMS for public inspection (ADAMS Accession No. ML19025A264).

The affidavit requesting withholding of Enclosures 1 and 3, 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 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 [SHINE's] 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.

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 trade secret, commercial financial information, and commercial information, and, as such, should be withheld from public disclosure.

Therefore, the submitted information marked as proprietary in Enclosures 1 and 3, including the related meeting discussions, will be withheld from public disclosure pursuant to 10 CFR 2.390(b)(5). Information marked as security-related in Enclosures 1 and 5 will also be withheld from public disclosure pursuant to 10 CFR 2.390(d)(1).

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 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.

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

cc: See next page

SHINE Medical Technologies, Inc.

Docket No. 50-608

Jeff Bartelme
Licensing Manager
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101 E. Milwaukee Street, Suite 600
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Jeff Chamberlin
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Bill McCoy
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Alfred Lembrich
541 Miller Avenue
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Gerald and Muriel Bumgarner
1735 S Osborne Ave
Janesville, WI 53546

Test, Research and Training
Reactor Newsletter
Attention: Amber Johnson
Dept of Materials Science
and Engineering
University of Maryland
4418 Stadium Drive
College Park, MD 20742-2115

Mark Freitag
City Manager
P.O. Box 5005
Janesville, WI 53547-5005

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ADAMS Accession Nos.: ML19071A185, Withholding Ltr.; ML19025A275, Slides
 *concurring via email

NRR-084

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