



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

May 2, 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-2018-LLM-0154)

Dear Dr. Piefer:

By letter dated March 8, 2019 (Agencywide Documents Access and Management System Accession No. ML19071A055), SHINE Medical Technologies, Inc. (SHINE) submitted an affidavit (ADAMS Accession No. ML19071A056) executed by James Costedio, which requested that information contained in the following document be withheld from public disclosure pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR), Section 2.390:

SHINE Medical Technologies, Inc. Application for Order Approving Indirect
Transfer of Control of Construction Permit Response to Request for Additional
Information (Enclosure 1 of 2019-SMT-0015)

The affidavit 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 Enclosure 1 of 2019-SMT-0015 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 Enclosure 1 is not available to the public to the best of my knowledge and belief.
- 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 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. Public disclosure of the information in Enclosure 1 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.

- e. The information contained in Enclosure 1 of 2019-SMT-0015 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 U.S. Nuclear Regulatory Commission (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 sought to be withheld contains proprietary commercial information and should be withheld from public disclosure.

Therefore, the submitted information marked as proprietary, 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 may have cause to review this determination in the future, for example, if the scope of a Freedom of Information Act request includes your information. In all review situations, if the NRC staff 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

cc:

Jeff Bartelme
Licensing Manager
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Janesville, WI 53545

Jeff Chamberlin
National Nuclear Security Administration,
NA-231
U.S. Department of Energy
1000 Independence Ave SW
Washington, DC 20585

Mark Paulson, Supervisor
Radiation Protection Section
Wisconsin Department of Health Services
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Madison, WI 53701-2659

Test, Research and Training
Reactor Newsletter
Attention: Amber Johnson
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4418 Stadium Dr.
College Park, MD 20742-2115

Mark Freitag
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541 Miller Avenue
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1735 S Osborne Ave
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ADAMS Accession Nos.: ML19102A348 Ltr.; ML19102A321 Pkg. *concurred via email NRR-106

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