

June 18, 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 May 16, 2018 (Agencywide Documents Access and Management System Accession No. ML18138A291), 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-0032 be withheld from public disclosure pursuant to the Title 10 of the *Code of Federal Regulations* (10 CFR), Section 2.390:

Enclosure 2, Meeting Slides for the May 23 and 24, 2018 Public Meeting
Between SHINE Medical Technologies, Inc. and the NRC, Construction Planning
(Non-Public Portion)

Enclosure 4, Meeting Slides for the May 23 and 24, 2018 Public Meeting
Between SHINE Medical Technologies, Inc. and the NRC, SHINE Hazard
Analysis

Enclosure 5, Meeting Slides for the May 23 and 24, 2018 Public Meeting
Between SHINE Medical Technologies, Inc. and the NRC, Structural Design of
the SHINE Medical Isotope Production Facility Building

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 Enclosures 2, 4, and 5 of 2018-SMT-0032 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, 4, and 5 of 2018-SMT-0032 is not available to the public to the best of my knowledge and belief.
- c. The information contained in Enclosures 2, 4, and 5 of 2018-SMT-0032 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, 4, and 5 of 2018-SMT-0032 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, 4, and 5 of 2018-SMT-0032 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, 4, and 5 of 2018-SMT-0032 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 U.S. Nuclear Regulatory Commission (NRC) staff has reviewed your 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, we may send copies of this information to our consultants working in this area. We 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, you should promptly notify the NRC. You 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 makes a determination adverse to the above, you 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

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**ADAMS Accession Nos.: Pkg: ML18162A136, Notice: ML18131A371, Mtg. Summary:
ML18162A138; Withholding Letter.; ML18162A140; Slides: ML18138A291 *concurred via email**

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