

July 14, 2017

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

Dear Dr. Piefer:

By letter dated March 17, 2017 (Agencywide Documents Access and Management System Accession No. ML17079A476), SHINE Medical Technologies, Inc. (SHINE) submitted an affidavit executed by James Costedio, which requested that information contained in the following document included in SHINE's submittal be withheld from public disclosure pursuant to the Title 10 of the *Code of Federal Regulations* (10 CFR), Section 2.390:

Enclosure 1 of SHINE Medical Technologies, Inc. Request for Confirmation
Related to Proposed Demonstration Project (SMT-2017-009), SHINE Evaluation
of the Proposed Demonstration Project (Non-Public)

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 SMT-2017-009 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 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 Enclosure 1, includes, but is not limited to: primary and supporting systems of the medical isotope facility and process details. Public disclosure of the information in Enclosure 1 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.

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) as well as 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,

/Duane Hardesty Acting for RA/

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

Docket No. 50-608

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