

January 6, 2016

Gregory Piefer, PhD
Chief Executive Officer
SHINE Medical Technologies, Inc.
2555 Industrial Drive
Monona, WI 53713

SUBJECT: REQUEST FOR WITHHOLDING INFORMATION FROM PUBLIC
DISCLOSURE - SHINE MEDICAL TECHNOLOGIES, INC. (TAC NO. MF2307)

Dear Dr. Piefer:

By letter dated June 19, 2015 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15183A290), SHINE Medical Technologies, Inc. (SHINE), submitted an affidavit executed by Richard Vann Bynum, 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:

Enclosure 1, Response to Request for Additional Information

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-2015-033 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 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: structural configuration, primary and supporting systems of the medical isotope 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 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 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 (d)(1), 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 this 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.

Sincerely,

/RA PBoyle for/

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

cc: Jim Costedio
Licensing Manager
SHINE Medical Technologies, Inc.
2555 Industrial Drive
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Steven T. Lynch, Project Manager
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***via email**

NRR-084

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