

August 27, 2015

Richard Vann Bynum, PhD
Chief Operating 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. Bynum:

By letter dated May 21, 2015 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15161A343), SHINE Medical Technologies, Inc. (SHINE), submitted an affidavit executed by yourself, which requested that information contained in the following documents be withheld from public disclosure pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR), Section 2.390:

Enclosure 2, Summary of SHINE Preliminary Safety Analysis Report Revisions
Enclosure 4, Revision to SHINE Preliminary Safety Analysis Report

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 and 4 [...] 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 and 4 is not available to the public to the best of my knowledge and belief.
- c. The information contained in Enclosures 2 and 4 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 and 4 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 Enclosures 2 and 4 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 and 4 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 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 there is insufficient justification to withhold certain information contained in Enclosure 4. Certain information in Enclosure 4 is publicly available and, therefore, not considered proprietary commercial information. Therefore, as discussed with and agreed upon by you, certain information in Enclosure 4 will not be withheld from public disclosure.

NRC staff has determined that the remainder of the information sought to be withheld in Enclosures 2 and 4 contains proprietary commercial information and should be withheld from public disclosure. Therefore, this submitted information marked as proprietary will be withheld from public disclosure pursuant to 10 CFR 2.390(b)(5) and (d)(1).

Enclosures 3 and 5 of your letter dated May 21, 2015 (redacted versions of Enclosures 2 and 4), have been placed in ADAMS under Package Nos. ML15161A336 and ML15161A201, respectively.

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.

R. Vann Bynum

- 3 -

If you have any questions regarding this matter, I may be reached at (301) 415-1524.

Sincerely,

/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

cc: Mr. Jim Costedio
Licensing Manager
SHINE Medical Technologies, Inc.
2555 Industrial Drive
Monona, WI 53713

R. Vann Bynum

- 3 -

If you have any questions regarding this matter, I may be reached at (301) 415-1524.

Sincerely,

/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

cc: Mr. Jim Costedio
Licensing Manager
SHINE Medical Technologies, Inc.
2555 Industrial Drive
Monona, WI 53713

DISTRIBUTION:

PUBLIC	LTran	RidsNrrDprPrta
RTR r/f	SLynch	RidsNrrDpr
RidsAcrsAcnw_MailCTR	AAdams	RidsNrrDprPrtb
RidsOgcMailCenter	MMoser	PIsaac

ADAMS Accession No. ML15219A182

***via email**

NRR-084

OFFICE	NRR/PRLB/PM	NRR/DPR/LA	NRR/PRLB/BC	NRR/PRLB/PM
NAME	SLynch	ABaxter	AAdams	SLynch
DATE	08/17/2015	08/17/2015	08/27/2015	08/27/2015

OFFICIAL RECORD COPY