

May 21, 2015

Richard Vann Bynum, PhD
Chief Operating Officer
SHINE Medical Technologies, Inc.
2555 Industrial Drive
Monona, WI 53713

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

Dear Dr. Bynum:

By letter dated March 26, 2013 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML13088A192) SHINE Medical Technologies, Inc. (SHINE), submitted an affidavit executed by yourself, which requested that information contained in the following document be withheld from public disclosure pursuant to the Title 10 of the *Code of Federal Regulations* (10 CFR), Section 2.390:

Enclosure 1, SHINE Preliminary Safety Analysis Report Chapters 2 and 19
Enclosure 3, SHINE General and Financial Information

The affidavit stated that the submitted information should be considered exempt from mandatory public disclosure for the following reasons:

The information sought to be withheld from public disclosure contained in Enclosure 1 and Enclosure 3[...] 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.

The information sought to be protected in Enclosure 1 and Enclosure 3 is not available to the public to the best of my knowledge and belief.

The information contained in Enclosure 1 and Enclosure 3 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.

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.

Public disclosure of the information in Enclosure 3 would create substantial harm to SHINE because it would reveal valuable business information regarding SHINE's competitive expectations, assumptions, processes, and current position.

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 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/

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

Project No. 0792

cc: Jim Costedio
Licensing Manager
SHINE Medical Technologies, Inc.
2555 Industrial Drive
Monona, WI 5373

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.

Public disclosure of the information in Enclosure 3 would create substantial harm to SHINE because it would reveal valuable business information regarding SHINE's competitive expectations, assumptions, processes, and current position.

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

Project No. 0792

cc: Jim Costedio
Licensing Manager
SHINE Medical Technologies, Inc.
2555 Industrial Drive
Monona, WI 5373

DISTRIBUTION:

PUBLIC
RTR r/f
RidsAcrsAcnw_MailCTR Resource

LTran, NRR
SLynch, NRR
AAdams, NRR

RidsNrrDprPrta
RidsNrrDpr
RidsNrrDprPrtb RidsOgcRp Resource

ADAMS Accession No: ML15140720 *via email NRR-084

OFFICE	NRR/PRLB/PM	NRR/PRLB/BC	NRR/PRLB/PM
NAME	SLynch	AAdams	SLynch
DATE	05/21/2015	05/21/2015	05/21/2015

OFFICIAL RECORD COPY