

March 1, 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. – REVIEW OF SAFEGUARDS
INFORMATION PROTECTION PROGRAM (TAC NO. MF9090)

Dear Dr. Piefer:

By letter dated December 20, 2016 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML16364A091), SHINE Medical Technologies, Inc. (SHINE) submitted its Safeguards Information (SGI) Protection Program procedures for U.S. Nuclear Regulatory Commission (NRC) review.

By letter dated February 6, 2017 (ADAMS Accession No. ML17031A443), the NRC staff issued a letter requesting additional information to complete its review. This information was necessary to demonstrate SHINE's compliance with the regulations contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 73, "Physical Protection of Plants and Materials," and 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." By letter dated February 7, 2017 (ADAMS Accession No. ML17040A138), SHINE responded to this request for information, including necessary revisions to its SGI Protection Program procedures.

Based upon its review of SHINE's SGI Protection Program procedures, as revised, the NRC staff has determined that SHINE has provided sufficient assurance that it will protect SGI that it produces, receives, or acquires from unauthorized disclosure in accordance with the requirements of 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements," and 10 CFR 73.22, "Protection of Safeguards Information: Specific Requirements."

The implementation of SHINE's SGI Protection Program procedures relates solely to safeguards matters and does not involve any significant construction impacts. Accordingly, this action meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22, "Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review," specifically, it meets the categorical exclusion in 10 CFR 51.22(c)(12).

Pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the implementation of SHINE's SGI Protection Program procedures.

If you have any questions, please contact Steven Lynch at 301-415-1524, or by electronic mail at Steven.Lynch@nrc.gov.

Sincerely,

/RA Duane Hardesty Acting For/

Alexander Adams, Jr., Chief
Research and Test Reactors Licensing Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Docket No. 50-608

cc: See next page

SHINE Medical Technologies, Inc.

Docket No. 50-608

cc:

Jeff Batelme
Licensing Manager
SHINE Medical Technologies, Inc.
101 E. Milwaukee Street, Suite 600
Janesville, WI 53545

Jeff Chamberlin
National Nuclear Security
Administration NA-231
U.S. Department of Energy
1000 Independence Ave SW
Washington, DC 20585

Mark Paulson
Supervisor
Radiation Protection Section
Wisconsin Department of Health Services
P.O. Box 2659
Madison, WI 53701-2659

TRTR Newsletter
University of Florida
Department of Nuclear
Engineering Sciences
202 Nuclear Sciences Center
Gainesville, FL 32611

Mark Freitag
City Manager
P.O. Box 5005
Janesville, WI 53547-5005

Bill McCoy
1326 Putnam Avenue
Janesville, WI 53546

Alfred Lembrich
541 Miller Avenue
Janesville, WI 53548

Gerald and Muriel Bumgarner
1735 S Osborne Ave
Janesville, WI 53546

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