

August 28, 2013

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

SUBJECT: SHINE MEDICAL TECHNOLOGIES, INC. – STATUS OF THE ACCEPTANCE  
REVIEW OF PART TWO OF THE APPLICATION FOR CONSTRUCTION PERMIT  
(TAC NO. MF2307)

Dear Dr. Bynum:

By letter dated May 31, 2013 (SMT-2013-023, Agencywide Documents Access and Management System (ADAMS) Accession No. ML13172A361), SHINE Medical Technologies, Inc. (SHINE), submitted the second and final part of its two-part application for a construction permit. If granted, the construction permit would allow SHINE to construct a medical radioisotope production facility to be located in Janesville, Wisconsin.

SHINE submitted part one of the construction permit application by letter dated March 26, 2013 (ADAMS Accession No. ML13088A192). The U.S. Nuclear Regulatory Commission (NRC) staff acknowledged receipt of this partial application for a construction permit under Title 10 of the Code of Federal Regulations (10 CFR), Part 50, "Domestic Licensing of Production and Utilization Facilities," in the Federal Register (FR) (78 FR 29390) on May 20, 2013. An exemption from certain requirements of 10 CFR 2.101(a)(5) granted by the Commission on March 20, 2013 (ADAMS Accession No. ML13072B195), in response to a letter from SHINE dated February 18, 2013 (ADAMS Accession No. ML13051A007), allowed SHINE to submit its construction permit application in two parts. Specifically, the exemption allowed SHINE to submit a portion of its application for a construction permit up to six months prior to the remainder of the application regardless of whether or not an environmental impact statement or a supplement to an environmental impact statement is prepared during the review of its application. In accordance with 10 CFR 2.101(a)(5), SHINE submitted the following in part one of its construction permit application:

- the description and safety assessment of the site required by 10 CFR 50.34(a)(1)
- the environmental report required by 10 CFR 50.30(f)
- the filing fee information required by 10 CFR 50.30(e) and 10 CFR 170.21
- the general information required by 10 CFR 50.33
- the agreement limiting access to classified information required by 10 CFR 50.37

As stated in your March 26, 2013, letter, part two of SHINE's application for a construction permit was to contain the remainder of the preliminary safety analysis report (PSAR) required by 10 CFR 50.34(a) and would be submitted in accordance with the requirements of 10 CFR 2.101(a)(5).

R. Bynum

- 2 -

NRC staff is nearing completion of its acceptance review of part two of SHINE's application for a construction permit and has identified an apparent deficiency in the application. Specifically, SHINE did not provide a discussion of preliminary plans for coping with emergencies, as required by 10 CFR 50.34(a)(10). Requirements for this plan are set forth in Appendix E to 10 CFR Part 50, "Emergency Planning and Preparedness for Production and Utilization Facilities."

Meeting regulatory requirements, with respect to the information necessary to be submitted to support a construction permit application, as outlined in applicable NRC regulations, is the principal focus of the NRC staff's acceptance review. If required information is not submitted, SHINE's application for a construction permit will be considered incomplete and unacceptable for docketing. Therefore, the NRC staff requests that SHINE provide a preliminary plan for coping with emergencies, as required by 10 CFR 50.34(a)(10), within 30 days of the date of this letter.

Should SHINE be unable to provide this information within the 30-day timeframe, the staff will consider the application incomplete and unacceptable for docketing. In the event that such a determination is made, SHINE will be notified of the decision and be provided the opportunity to withdraw, supplement, or resubmit its application for a construction permit. Part two of SHINE's application for a construction permit will be accepted for docketing and a detailed technical review only when the NRC staff has determined that the tendered application includes all information required by applicable regulatory requirements.

If you have any questions, please contact Steven Lynch at [Steven.Lynch@nrc.gov](mailto:Steven.Lynch@nrc.gov) or 301-415-1524.

Sincerely,

*/RA/*

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

cc:

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

Cindy Atkins-Duffin, Ph.D.  
Senior Policy Analyst  
Office of Science and Technology Policy  
Executive Office Building  
1650 Pennsylvania Avenue  
Washington, D.C. 20503

Joan Dix  
National Nuclear Security Administration,  
NA-212  
U.S. Department of Energy  
1000 Independence Ave SW  
Washington, DC 20585

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

Amanda Cushman  
Environmental Analysis and Review  
Specialist  
State of Wisconsin  
Department of Natural Resources  
3911 Fish Hatchery Road  
Fitchburg, WI 53711

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

Jacob Winzenz  
Acting 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

NRC staff is nearing completion of its acceptance review of part two of SHINE's application for a construction permit and has identified an apparent deficiency in the application. Specifically, SHINE did not provide a discussion of preliminary plans for coping with emergencies, as required by 10 CFR 50.34(a)(10). Requirements for this plan are set forth in Appendix E to 10 CFR Part 50, "Emergency Planning and Preparedness for Production and Utilization Facilities."

Meeting regulatory requirements, with respect to the information necessary to be submitted to support a construction permit application, as outlined in applicable NRC regulations, is the principal focus of the NRC staff's acceptance review. If required information is not submitted, SHINE's application for a construction permit will be considered incomplete and unacceptable for docketing. Therefore, the NRC staff requests that SHINE provide a preliminary plan for coping with emergencies, as required by 10 CFR 50.34(a)(10), within 30 days of the date of this letter.

Should SHINE be unable to provide this information within the 30-day timeframe, the staff will consider the application incomplete and unacceptable for docketing. In the event that such a determination is made, SHINE will be notified of the decision and be provided the opportunity to withdraw, supplement, or resubmit its application for a construction permit. Part two of SHINE's application for a construction permit will be accepted for docketing and a detailed technical review only when the NRC staff has determined that the tendered application includes all information required by applicable regulatory requirements.

If you have any questions, please contact Steven Lynch at [Steven.Lynch@nrc.gov](mailto:Steven.Lynch@nrc.gov) or 301-415-1524.

Sincerely,

/RA/

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

DISTRIBUTION:

Public	DHowe, FSME	MVoth, NRR	DFisher, RII
RTR r/f	PSilva, NMSS	SLynch, NRR	JLynch, RIII
RidsNrrDpr	MAdams, NMSS	MBlumberg, NRR	CFrazier, RIII
RidsNrrDprPrta	MWong, NRR	PBlechman, NRR	SPrice, OGC
RidsNrrDprPrtb	MMoser, NRR	DBarss, NSIR	MYoung, OGC
RidsAcrsAcnw_MailCTR Resource	AAdams, NRR	ASapountzis, NSIR	RSkarda, RES
RidsOgcRp Resource	LTran, NRR	JFisher, RII	MConley, OPA

**ADAMS Accession No.: ML13233A356**

\*concurrence via e-mail **NRR-106**

OFFICE	NRR/DPR/PRLB/PM	NRR/DPR/PRLB/LA	OGC	NRR/PRLB/BC
NAME	SLynch	PBlechman	SPrice*	AAdams
DATE	8/21/13	8/21/13	8/28/13	8/28/13

OFFICIAL RECORD COPY