



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

October 22, 2021

Dr. Gregory Piefer
Chief Executive Officer
SHINE Medical Technologies, LLC
101 East Milwaukee Street, Suite 600
Janesville, WI 53545

SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – REQUEST FOR ADDITIONAL INFORMATION RELATED TO OPERATOR TRAINING AND REQUALIFICATION PROGRAM (EPID NO. L-2019-NEW-0004)

Dear Dr. Piefer:

By letter dated July 17, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19211C044), as supplemented by letters dated November 14, 2019 (ADAMS Accession No. ML19337A275), March 27, 2020 (ADAMS Accession No. ML20105A295), August 28, 2020 (ADAMS Accession No. ML20255A027), November 13, 2020 (ADAMS Accession No. ML20325A026), December 10, 2020 (ADAMS Package Accession No. ML20357A084), December 15, 2020 (ADAMS Package Accession No. ML21011A264), and March 23, 2021 (ADAMS Accession No. ML21095A235), SHINE Medical Technologies, LLC (SHINE) submitted to the U.S. Nuclear Regulatory Commission (NRC) an operating license application for its proposed SHINE Medical Isotope Production Facility in accordance with the requirements contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities."

During the NRC staff's review of SHINE's operating license application, questions have arisen for which additional information is needed. The enclosed request for additional information (RAI) identifies information needed for the NRC staff to continue its review of the SHINE final safety analysis report, submitted in connection with the operating license application, and prepare a safety evaluation report. The specific technical area of the SHINE operating license application covered by this RAI is the operator training and requalification program.

It is requested that SHINE provide responses to the enclosed RAI within 30 days from the date of this letter. To facilitate a timely and complete response to the enclosed RAI, the NRC staff is available to meet with SHINE to clarify the scope of information and level of detail expected to be included in the RAI response and corresponding final safety analysis report update. SHINE may coordinate the scheduling and agendas for any such meetings with the responsible project manager assigned to this project.

In accordance with 10 CFR 50.30(b), "Oath or affirmation," SHINE must execute its response in a signed original document under oath or affirmation. The response must be submitted in accordance with 10 CFR 50.4, "Written communications." Information included in the response that is considered sensitive or proprietary, that SHINE seeks to have withheld from the public, must be marked in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." Any information related to safeguards should be submitted in accordance with

10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements." Following receipt of the additional information, the NRC staff will continue its evaluation of the subject chapters and technical areas of the SHINE operating license application.

As the NRC staff continues its review of SHINE's operating license application, additional RAIs for other chapters and technical areas may be developed. The NRC staff will transmit any further questions to SHINE under separate correspondence.

If SHINE has any questions, or needs additional time to respond to this request, please contact me at 301-415-1524, or by electronic mail at Steven.Lynch@nrc.gov.

Sincerely,



Signed by Lynch, Steven
on 10/22/21

Steven T. Lynch, Senior Project Manager
Non-Power Production and Utilization Facility
Licensing Branch
Division of Advanced Reactors and Non-Power
Production and Utilization Facilities
Office of Nuclear Reactor Regulation

Docket No. 50-608
Construction Permit No. CPMIF-001

Enclosure:
As stated

cc: See next page

SHINE Medical Technologies, LLC

Docket No. 50-608

cc:

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Test, Research and Training
Reactor Newsletter
Attention: Amber Johnson
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SUBJECT: SHINE MEDICAL TECHNOLOGIES, LLC – REQUEST FOR ADDITIONAL INFORMATION RELATED TO OPERATOR TRAINING AND REQUALIFICATION (EPID NO. L-2019-NEW-0004) DATED: OCTOBER 22, 2021

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NRR-088

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OFFICE OF NUCLEAR REACTOR REGULATION
REQUEST FOR ADDITIONAL INFORMATION
REGARDING OPERATING LICENSE APPLICATION FOR
SHINE MEDICAL TECHNOLOGIES, LLC
CONSTRUCTION PERMIT NO. CPMIF-001
SHINE MEDICAL ISOTOPE PRODUCTION FACILITY
DOCKET NO. 50-608

By letter dated July 17, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19211C044), as supplemented by letters dated November 14, 2019 (ADAMS Accession No. ML19337A275), March 27, 2020 (ADAMS Accession No. ML20105A295), August 28, 2020 (ADAMS Accession No. ML20255A027), November 13, 2020 (ADAMS Accession No. ML20325A026), December 10, 2020 (ADAMS Package Accession No. ML20357A084), December 15, 2020 (ADAMS Package Accession No. ML21011A264), and March 23, 2021 (ADAMS Accession No. ML21095A235), SHINE Medical Technologies, LLC (SHINE) submitted to the U.S. Nuclear Regulatory Commission (NRC) an operating license application for its proposed SHINE Medical Isotope Production Facility in accordance with the requirements contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities."

During the NRC staff's review of SHINE's operating license application, questions have arisen for which additional information is needed. This request for additional information (RAI) identifies information needed for the NRC staff to continue its review of the SHINE final safety analysis report (FSAR), submitted in connection with the operating license application, and prepare a safety evaluation report. The specific technical area of the SHINE operating license application covered by this RAI is the operator training and requalification program.

Applicable Regulatory Requirements and Guidance Documents

The NRC staff is reviewing the SHINE operating license application, which describes the SHINE irradiation facility, including the irradiation units, and radioisotope production facility, using the applicable regulations, as well as the guidance contained in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (ADAMS Accession No. ML042430055), and NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (ADAMS Accession No. ML042430048). The NRC staff is also using the "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ADAMS Accession No. ML12156A069), and "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ADAMS

Enclosure

Accession No. ML12156A075). As applicable, additional guidance cited in SHINE's FSAR or referenced in NUREG-1537, Parts 1 and 2, or the ISG Augmenting NUREG-1537, Parts 1 and 2, has been utilized in the review of the SHINE operating license application.

For the purposes of this review, the term "reactor," as it appears in NUREG-1537, the ISG Augmenting NUREG-1537, and other relevant guidance can be interpreted to refer to SHINE's "irradiation unit," "irradiation facility," or "radioisotope production facility," as appropriate within the context of the application and corresponding with the technology described by SHINE in its application. Similarly, for the purposes of this review, the term "reactor fuel," as it appears in the relevant guidance listed above, may be interpreted to refer to SHINE's "target solution."

Operator Training and Requalification

The following regulatory requirement is applicable to RAI OTR-1 through OTR-5:

Paragraph (b)(8) of 10 CFR 50.34, "Contents of applications; technical information," states, in relevant part, that the FSAR supporting an application for an operating license shall include "[a] description and plans for implementation of an operator requalification program." The operator requalification program must as a minimum, meet the requirements for those programs contained in 10 CFR 55.59, "Requalification." Paragraph (c) of 10 CFR 55.59 states, in relevant part, that "[a] facility licensee shall have a requalification program reviewed and approved by the Commission...." Paragraph (i-1) of 10 CFR 50.54, "Conditions of licenses," states, in relevant part, that an operator requalification program shall be in effect within three months after the issuance of an operating license.

RAI OTR-1 Paragraph (c)(3)(iv) of 10 CFR 55.59 requires the requalification program to include on-the-job training such that each licensed operator reviews the contents of all abnormal and emergency procedures on a regularly scheduled basis.

While SHINE has identified the requirement for the reviews of abnormal and emergency procedure reviews on an annual basis in Table 4-1, "Continuing Training Program Requirements," of its Licensed Operator Continuing Training Program (ADAMS Accession No. ML19211C141), SHINE has not defined what time period constitutes annual periodicity. Further, SHINE has also not defined the periodicity for quarterly and biennial time periods set for other continuing training program requirements.

Update the SHINE Licensed Operator Continuing Training Program to define what constitutes periodicity for annual, quarterly, and biennial time periods for continuing training program requirements.

This information is necessary for the NRC staff to determine that SHINE has established an adequate periodicity of program requirements, as required by 10 CFR 55.59.

RAI OTR-2 Section 1.1, "Purpose," of SHINE's Licensed Operator Continuing Training Program states, in relevant part, that "[t]his program establishes a continuing training program for personnel performing, verifying, or managing licensed operator activities to ensure that suitable proficiency is achieved and maintained, satisfying the requirements of 10 CFR 55.59 and in accordance with ANSI/ANS-15.4-2016, "Selection and Training of Personnel for Research Reactors."

Section 8, "Fitness for duty," of American National Standard Institute/American Nuclear Society (ANSI/ANS)-15.4-2016 describes elements of a drug and alcohol testing program to be incorporated into licensee training programs. The NRC staff could not identify any docketed information describing SHINE's approach to drug and alcohol testing.

Update the SHINE Licensed Operator Continuing Training Program and Licensed Operator Initial Training Program (ADAMS Accession

No. ML19211C144), as appropriate, to describe the drug and alcohol testing program that will be implemented or utilized for licensed operators.

This information is necessary for the NRC staff to understand how SHINE is implementing its commitment to use ANSI/ANS-15.4-2016 and determine that SHINE meets the requirement of 10 CFR 50.34(b)(8) to include “[a] description and plans for implementation of an operator requalification program.”

RAI OTR-3 Paragraph (e) of 10 CFR 55.53, “Conditions of licenses,” requires, in order to maintain active status, a licensed operator to actively perform the functions for a specified number of hours per calendar quarter. Paragraph (f) of 10 CFR 55.53, requires, in order to restore active status, a licensed operator to perform a minimum amount of hours of licensed duties under the direction of another operator. While SHINE’s application states that the requalification program describes the essential training required to maintain a license in active status, it does not discuss operator proficiency in sufficient detail.

Additionally, SHINE has described in Table 4-1 of its Licensed Operator Continuing Training Program that licensed operators are to perform four hours of licensed duties on a quarterly basis, consistent with the requirement for research and test reactors in 10 CFR 55.53(e). Additionally, SHINE states in Section 4, “Program Requirements,” of its Licensed Operator Continuing Training Program that “[l]icensed operators and senior licensed operators who have not met the periodicity requirements for proficiency in Table 4-1 will perform a minimum of six hours of licensed duty under the direction of a qualified individual holding the same or higher-level license prior to being reinstated.” This is consistent with the requirements for research and test reactors in 10 CFR 55.53(f)(2). However, SHINE is not a research reactor or a test reactor. As such, the research and test reactor provisions of 10 CFR 55.53(e) and (f)(2) are not applicable to SHINE.

- (a) Describe, in detail, how SHINE intends to implement this requirement to ensure operators can remain proficient and regain proficiency, including: an illustrative list of activities or duties, in addition to various examples of control manipulations, that are considered “actively performing the functions of an operator or senior operator.”
- (b) Justify how the number of hours proposed for licensed operators to actively perform functions to maintain an active status or restore an active status, as described in the SHINE Licensed Operator Continuing Training Program, is in accordance with 10 CFR 55.53(e) and (f)(2), respectively. Alternatively, SHINE may consider requesting an exemption from the NRC’s regulations to require a different number of hours for licensed operators to maintain an active status or restore an active status.

This information is necessary for the NRC staff to determine that SHINE has established appropriate provisions to ensure the adequacy of training for licensed operators and senior operators consistent with 10 CFR 55.53.

RAI OTR-4 The regulation, 10 CFR 50.74, “Notification of change in operator or senior operator status,” requires that each licensee notify the NRC within 30 days of a change in the status of a licensed operator or senior operator. The specific

circumstances when a notification is required are (a) permanent reassignment from the position for which the licensee has certified the need for a licensed operator or senior operator under paragraph (a)(3) of 10 CFR 55.31, "How to Apply;" (b) termination of any operator or senior operator; (c) permanent disability or illness as described in 10 CFR 55.25, "Incapacitation because of disability or illness."

While SHINE states that "[a]ny change in licensed personnel status must be communicated to the NRC within 30 days of the change in status" in Section 4.1, "Medical Certification," of the Licensed Operator Continuing Training Program, it is unclear if this is only limited changes to medical status or covers the full scope of status changes requiring notification as identified in 10 CFR 50.74.

Revise the SHINE Licensed Operator Continuing Training Program to clarify that SHINE will provide notifications related to the change in status of a licensed operator or senior operator, as required by 10 CFR 50.74.

This information is necessary for the NRC staff to determine that SHINE has established appropriate provisions to provide notifications to the NRC as required by 10 CFR 50.74.

RAI OTR-5 Paragraph (a)(2) of 10 CFR 55.59 requires that each licensee shall "[p]ass a comprehensive requalification written examination and an annual operating test." Section 5.4, "Examinations," of ANSI/ANS 15.4-2016 describes how exams are to be administered.

The NRC staff could not identify who will be developing, administering, and grading exams in Section 5, "Examinations," of the SHINE Licensed Operator Continuing Training Program.

Update the SHINE Licensed Operator Continuing Training Program and Licensed Operator Initial Training Program, as appropriate, to describe how SHINE will ensure that the individual who develops, administers, and grades these exams is not indefinitely exempt from the requirements of taking a written examination and operating test themselves.

This information is necessary for the NRC staff to determine that SHINE has established appropriate examination requirements consistent with 10 CFR 55.59.