



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

February 13, 2019

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. – REQUEST FOR ADDITIONAL INFORMATION REGARDING THE APPLICATION FOR INDIRECT LICENSE TRANSFER AND CONFORMING AMENDMENT (EPID NO. L-2018-LLM-0154)

Dear Dr. Piefer:

By letter dated December 11, 2018 (Agencywide Documents Access and Management System Accession No. ML18347A215), SHINE Medical Technologies, Inc. (SHINE) submitted an application, which, pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.80, "Transfer of licenses," seeks U.S. Nuclear Regulatory Commission (NRC) approval of the proposed indirect transfer of Construction Permit No. CPMIF-001 for the SHINE Medical Isotope Production Facility, currently held by SHINE. The indirect transfer would result from the establishment of a holding company, Illuminated Holdings, Inc. (Illuminated).

The application also seeks, pursuant to 10 CFR 50.90, "Application for amendment of license, construction permit, or early site permit," the issuance of a conforming amendment to the license to reflect the transfer. The conforming administrative amendment would revise SHINE's construction permit to reflect SHINE's new name, SHINE Medical Technologies, LLC (SHINE LLC), resulting from its conversion from a corporation into a single-member limited liability company, owned and controlled by Illuminated.

During the NRC staff's review of SHINE's application, questions have arisen for which additional information is needed. The enclosed request for additional information (RAI) identifies the additional information needed for the NRC staff to continue its review. It is requested that SHINE provide responses to the enclosed RAIs within 30 days from the date of this letter.

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 SHINE's application for indirect license transfer and conforming amendment.

G. Piefer

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

Sincerely,

/RA/

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

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

Enclosure:
As stated

cc: See next page

SHINE Medical Technologies, Inc.

Docket No. 50-608

cc:

Jeff Bartelme
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

Test, Research and Training
Reactor Newsletter
Attention: Amber Johnson
Dept of Materials Science and Engineering
University of Maryland
4418 Stadium Dr.
College Park, MD 20742-2115

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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 DATE FEBRUARY 13, 2019

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ADAMS Accession No. ML19024A530***concurrence via e-mail**

OFFICE	NRR/DLP/PRLB/PM	NRR/DLP/PRLB/LA*	OGC
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DATE	1/29/2019	1/29/2019	2/6/2019
OFFICE	NRR/DLP/PFPB/BC	NRR/DLP/PRLB/ABC	NRR/DLP/PRLB/PM
NAME	ABowers	WKennedy	SLynch
DATE	2/12/2019	2/13/2019	2/13/2019

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REQUEST FOR ADDITIONAL INFORMATION

REGARDING THE INDIRECT LICENSE TRANSFER AND CONFORMING AMENDMENT FOR

THE SHINE MEDICAL ISOTOPE PRODUCTION FACILITY

CONSTRUCTION PERMIT NO. CPMIF-001; DOCKET NO. 50-608

By letter dated December 11, 2018 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML18347A215), SHINE Medical Technologies, Inc. (SHINE) submitted an application, which, pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) 50.80, "Transfer of licenses," seeks U.S. Nuclear Regulatory Commission (NRC) approval of the proposed indirect transfer of Construction Permit No. CPMIF-001 for the SHINE Medical Isotope Production Facility, currently held by SHINE. The indirect transfer would result from the establishment of a holding company, Illuminated Holdings, Inc. (Illuminated).

The application also seeks, pursuant to 10 CFR 50.90, "Application for amendment of license, construction permit, or early site permit," the issuance of a conforming amendment to the license to reflect the transfer. The conforming administrative amendment would revise SHINE's construction permit to reflect SHINE's new name, SHINE Medical Technologies, LLC (SHINE LLC), resulting from its conversion from a corporation into a single-member limited liability company, owned and controlled by Illuminated.

During the NRC staff's review of SHINE's application, questions have arisen for which additional information is needed. The enclosed request for additional information (RAI) identifies the additional information needed for the NRC staff to continue its review. It is requested that SHINE provide responses to the enclosed RAIs within 30 days from the date of this letter.

In the course of reviewing the SHINE application for indirect license transfer and conforming amendment, the NRC staff has determined that additional information or clarification is needed to continue its review in support of the development of its safety evaluation. The application is being evaluated using the following regulations in 10 CFR and guidance:

- 10 CFR 50.33, "Contents of applications; general information."
- 10 CFR 50.34, "Contents of applications; technical information."
- 10 CFR 50.40, "Common standards."
- 10 CFR 50.80
- 10 CFR 50.90
- 10 CFR Part 50, Appendix C, "A Guide for the Financial Data and Related Information Required to Establish Financial Qualifications for Construction Permits and Combined Licenses."

Enclosure

- 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)
- 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)
- “Final Interim Staff Guidance 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)
- “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 Accession No. ML12156A075)

The NRC issued Construction Permit No. CPMIF-001 to SHINE on February 29, 2016, finding, in part, that the SHINE was financially qualified to design and construct its proposed medical radioisotope facility in accordance with the Commission’s regulations set forth in 10 CFR Chapter I, “Nuclear Regulatory Commission,” based on the information provided in the SHINE preliminary safety analysis report supporting its construction permit application. However, the NRC staff’s financial qualifications review for a construction permit is limited to estimates of construction costs, estimates of fuel cycle costs, and sources to cover costs. At the time of issuance of the construction permit, SHINE had not requested to possess special nuclear material. Therefore, the NRC staff deferred evaluation of information related to nuclear insurance and indemnity to such a time when SHINE applies for either an operating license application or a license under 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material,” to possess special nuclear material. Similarly, the scope of the NRC staff’s financial qualifications review of SHINE’s application for indirect license transfer and conforming amendment is limited to estimates of construction costs, estimates of fuel cycle costs, and sources to cover costs.

The following requests for information are based on the NRC staff’s review of SHINE’s application for indirect license transfer and conforming amendment. The regulations in 10 CFR 50.80(b)(1)(i) state, in part, that an applicant for the transfer of a construction permit shall provide as much technical and financial qualification information in its application as would be required for an initial license application submission, as described in 10 CFR 50.33 and 10 CFR 50.34. Additionally, pursuant to 10 CFR 50.33(f)(5), the Commission may request that SHINE “submit additional or more detailed information respecting its financial arrangements and status of funds if the Commission considers this information appropriate. This may include information regarding [SHINE’s] ability to continue the conduct of the activities authorized by” Construction Permit No. CPMIF-001 under Docket No. 50-608. As such, the NRC staff finds that it is appropriate to request that SHINE provide the applicable information required for initial construction permit applicants in 10 CFR Part 50, Appendix C. Consistent with the regulations in 10 CFR 50.40(b), the requests for information below are intended to solicit information necessary for the NRC staff to evaluate SHINE LLC’s technical and financial qualifications to

construct the SHINE Medical Isotope Production Facility in accordance with Construction Permit CPMIF-001 and the Commission's regulations in 10 CFR, Chapter I.

Financial and Technical Qualifications

RAI 1

The regulation, 10 CFR 50.33(f)(1), states, in part, that a construction permit applicant shall submit estimates of the total construction and related fuel cycle costs.

The total estimated costs of construction provided in Section VI, "Financial Qualifications," of SHINE's application for indirect license transfer and conforming amendment differ from the initial total estimated costs of construction provided initially in Section 15.1, "Financial Ability to Construct the SHINE Facility," in SHINE's preliminary safety analysis report (ADAMS Accession No. ML15258A385). Based on the information provided in SHINE's application for indirect license transfer and conforming amendment, the basis for SHINE's current estimated construction and related fuel cycle costs is not clear to the NRC staff. This information is necessary for the NRC staff to determine whether SHINE LLC would be financially qualified and would possess or have reasonable assurance of obtaining the funding necessary to cover estimated construction and related fuel cycle costs following the establishment of Illuminated.

Provide the basis for the current estimated construction and related fuel cycle costs provided in SHINE's application for indirect license transfer and conforming amendment. Include the basis for the estimates of total production plant costs, plant equipment, uranium inventory cost for the first year of operation, and the total estimated cost. The basis could include information related to construction and related fuel cycle costs for similar facilities; input and experience from SHINE's prime construction contractor; design changes; or other new information made available to or developed by SHINE since its initial construction cost estimates.

RAI 2

The regulation, 10 CFR 50.33(f)(1), states, in part, that a construction permit applicant shall submit information to demonstrate that it possesses or will possess the funds necessary to cover estimated construction and related fuel cycle costs. Applicants are also to provide the source(s) of the funds to cover these costs. Additionally, 10 CFR Part 50, Appendix C, Section II, "Applicants which are newly formed entities," states, in part, that for each source of funding, the applicant should describe in detail the legal and financial relationships upon which it is relying for financial assistance. This may include copies of agreements or contracts, as necessary.

While SHINE has provided the amounts of financing commitments remaining for use in its development and construction project, its application for indirect license transfer and conforming amendment does not 1) indicate the amount of this funding dedicated to covering construction and related fuel cycle costs or 2) provide the basis for determining that there is reasonable assurance that amount of currently committed and future funding will be sufficient to cover estimated total construction and related fuel cycle costs. It is also unclear whether previously committed funding will be used for construction and related fuel cycle costs. This information is necessary for NRC staff to determine that SHINE LLC would possess or have reasonable assurance of obtaining the funding necessary to cover estimated construction and related fuel cycle costs following the establishment of Illuminated.

- a. Clarify the amounts of committed financing for each source described in Section VI of SHINE's application for indirect license transfer and conforming amendment dedicated to construction and related fuel cycle costs, including the dedicated amounts of existing cash-on-hand; the Deerfield Management Company, L.P. financing; the City of

Janesville loan packages and guarantees; and 90 acres of land for the building site provided by the City of Janesville. For each source of funding, describe in detail the legal and financial relationships upon which SHINE is relying for financial assistance, including copies of agreements or contracts, as necessary.

- b. Provide the amounts and sources of previously committed financing, if any, to be applied to construction and related fuel cycle costs.
- c. Provide the basis for determining that there is reasonable assurance the amount of currently committed and future financing will be sufficient to cover the estimated total construction and related fuel cycle costs.

RAI 3

Appendix C, Section II of 10 CFR Part 50, requires that a newly formed entity include in its application a statement of its assets, liabilities, and capital structure as of the date of the application.

By letter dated June 13, 2018 (ADAMS Accession No. ML18166A178), SHINE submitted to the NRC its annual financial report, including certified financial statements, in accordance with the requirements of 10 CFR 50.71, "Maintenance of records, making of reports," paragraph (b). However, SHINE's application for indirect license transfer and conforming amendment does not indicate whether its most recent financial report reflects its current financial statements as of the date of its application. This information is necessary for the NRC staff to determine whether SHINE LLC would be financially qualified and would possess or have reasonable assurance of obtaining the funding necessary to cover estimated construction and related fuel cycle costs following the establishment of Illuminated.

Provide current financial statements, reflecting, as applicable, either balance sheets and operating statements covering the latest complete accounting year together with all pertinent notes thereto and certification by a public accountant or a statement of assets, liabilities, and capital structure as of the date of the application.

RAI 4

The regulation, 10 CFR 50.34(a)(9), requires that an applicant provide its technical qualifications to engage in the activities proposed in its application in accordance with the regulations in 10 CFR, Chapter I.

While SHINE indicated in its application for indirect license transfer and conforming amendment that the formation of a holding company would not change the technical qualifications of SHINE LLC, it has not provided a basis for the technical qualifications of SHINE LLC as required in 10 CFR 50.34(a)(9) and 10 CFR 50.80(b)(1)(i). This information is necessary for the NRC staff to determine whether any changes in staffing and/or facility design may impact the technical qualifications of SHINE LLC to construct the proposed SHINE Medical Isotope Production Facility since the issuance of Construction Permit CPMIF-001 and following the establishment of Illuminated.

Provide the basis for SHINE's determination that SHINE LLC would be technically qualified to construct the proposed SHINE Medical Isotope Production Facility following the establishment of Illuminated, including the technical qualifications of key personnel and information indicating whether any staffing or design changes would impact the technical qualifications of SHINE LLC since the issuance of Construction Permit CPMIF-001.