April 1, 2022

2022-SMT-0040
10 CFR 50.90

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

References: (1) NRC letter to SHINE Medical Technologies, Inc., "SHINE Medical Technologies, LLC – Issuance of Amendment No. 2 to Construction Permit No. CPMIF-001 for the SHINE Medical Isotope Production Facility Related to the Receipt and Possession of Certain Radioactive Materials (EPID No. L-2021-LLA-0104)," dated December 2, 2021 (ML21320A224)

SHINE Technologies, LLC Request to Amend Construction Permit No. CPMIF-001

In accordance with 10 CFR 50.90, SHINE Technologies, LLC (SHINE) hereby submits the enclosed request to amend Construction Permit No. CPMIF-001 (Reference 1) to change the licensee's name to SHINE Technologies, LLC and to extend the latest date for the completion of construction of the SHINE medical isotope production facility.

Enclosure 1 provides the amendment request. SHINE requests that the NRC approve this amendment request by December 31, 2022 to allow the continued construction of the SHINE medical isotope production facility.

If you have any questions, please contact Mr. Jeff Bartelme, Director of Licensing, at 608/210-1735.

I declare under the penalty of perjury that the foregoing is true and correct.
Executed on April 1, 2022.

Very truly yours,

DocuSigned by:
Jim Costedio
F52DB96989224FF...

James Costedio
Vice President of Regulatory Affairs and Quality
SHINE Technologies, LLC
Docket No. 50-608

Enclosure

cc: Project Manager, USNRC
SHINE General Counsel
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health

ENCLOSURE 1

SHINE TECHNOLOGIES, LLC

SHINE TECHNOLOGIES, LLC REQUEST TO AMEND CONSTRUCTION PERMIT NO. CPMIF-001

Table of Contents

1. INTRODUCTION

In accordance with 10 CFR 50.90, SHINE Technologies, LLC (SHINE) hereby requests to amend Construction Permit No. CPMIF-001 (Reference 1) to change the licensee's name to SHINE Technologies, LLC and to extend the latest date for the completion of construction of the SHINE medical isotope production facility.

SHINE requests that the NRC approve this amendment request by December 31, 2022 to allow the continued construction of the SHINE medical isotope production facility.

2. PROPOSED CHANGES

2.1 Name Change

SHINE requests to amend Construction Permit No. CPMIF-001 to change the licensee's name from SHINE Medical Technologies, LLC to SHINE Technologies, LLC in the License Title, Section 1.A, Section 2, the Appendix A Title, and Appendix A Section 2.0, of Reference 1. The changes proposed for the construction permit are provided in Attachment 1 and clean pages are provided in Attachment 2.

2.2 Construction Completion Extension

SHINE requests to amend Construction Permit No. CPMIF-001 to extend the latest date for the completion of construction of the SHINE medical isotope production facility identified in Condition 3.A of Reference 1 to December 31, 2025. The changes proposed for the construction permit are provided in Attachment 1 and clean pages are provided in Attachment 2.

3. REGULATORY EVALUATION

3.1 Name Change

SHINE Medical Technologies, LLC changed its company name to SHINE Technologies, LLC. The company name was changed for commercial reasons. There are no changes to the technical capabilities, financial qualifications, or obligations of SHINE as a result of the name change, and all of the licensee's financial responsibilities remain the same. The name change does not involve a transfer of control of the license, and the name change does not involve any change to the ownership, organization, obligations, rights, or liabilities of SHINE. The name change does not constitute a transfer either direct or indirect through a transfer of control of the license that would require NRC consent under 10 CFR 50.80. The SHINE Technologies, LLC name change and the necessary changes to SHINE construction permit are administrative only.

3.2 Construction Completion Extension

SHINE requests that NRC extend the construction permit (Reference 1) expiration date to December 31, 2025. The additional time will allow SHINE to complete the construction, pre-operational testing, and licensing of each of the four phases of the phased approach to initial SHINE medical isotope production facility operations.

Since issuance of the construction permit in 2016, SHINE has been progressing towards meeting the national need for Mo-99 production as soon as possible while ensuring all requirements related to public health and safety are met. SHINE broke ground at the

construction site of the SHINE medical isotope production facility in May 2019. SHINE submitted the operating license application in July 2019. SHINE completed construction of the main production facility structure (i.e., the production facility structure was weather tight) in March 2021.

Numerous SHINE medical isotope production facility process equipment components have been procured and are currently on site. Installation of process equipment within the SHINE medical isotope production facility has begun and continues to progress. SHINE has also begun construction of outbuildings on the SHINE site. Substantial progress has been made since issuance of the construction permit in 2016.

SHINE completed a detailed review of the SHINE medical isotope production facility schedule and developed a revised estimate of the time and resources necessary to complete the facility. This revised estimate was formed after months of analyses, consideration of numerous lessons learned, and detailed analyses of remaining work. The estimate was then subjected to rigorous internal review which provided additional assurance and high confidence in the schedule. SHINE expects the construction of the first phase of the phased approach to initial facility operations to be substantially complete in May 2023 and expects the last phase of construction to be substantially complete by August 2025 (Reference 2). While SHINE will begin commercially producing molybdenum-99 upon completion of the first phase, SHINE has identified the need to extend the expiration date of the construction permit to support substantial completion of all four phases of the phased approach to initial facility operations. Accordingly, in an abundance of caution and conservatism that is necessary and prudent when requesting a construction permit extension, SHINE is requesting a construction permit expiration date of December 31, 2025.

The extension request is the result of developmental effort delays attributable to the first of a kind nature of the SHINE medical isotope production facility. This has included efforts contributing to engineering detailed design progression, procurement of unique and one-of-a-kind components, construction of a first of a kind facility, and progression of an operating license application that has no precedent. Additionally, since 2020, the worldwide COVID-19 pandemic has slowed efforts related to obtaining the workforce and equipment resources needed to procure and install the necessary process equipment to complete construction of the facility.

The regulations of 10 CFR 50.55(b) state, in part:

> *"... upon good cause shown, the Commission will extend the completion date for a reasonable period of time. The Commission will recognize, among other things, developmental problems attributable to the experimental nature of the facility or fire, flood, explosion, strike, sabotage, domestic violence, enemy action, an act of the elements, and other acts beyond the control of the permit holder, as a basis for extending the completion date."*

In accordance with 10 CFR 50.55(b), SHINE has shown good cause and requested a reasonable time period for the extension of the construction permit completion date.

SHINE does not request or propose any modifications to the terms of the construction permit other than to extend the completion time and to change the licensee's name. The name change and the extension of the construction permit completion time does not authorize any new activities and does not have any radiological consequences.

4. ENVIRONMENTAL CONSIDERATION

4.1 Name Change

SHINE has determined that the proposed amendment related to changing the licensee's name to SHINE Technologies, LLC is categorically excluded from requiring an environmental review in accordance with 10 CFR 51.22(c)(10)(iii).

4.2 Construction Completion Extension

The construction completion date extension does not affect the environmental impacts of operating and decommissioning the SHINE medical isotope facility. Environmental impacts of construction may be affected, but this affect is limited to the extended duration of construction activities. The environmental impact of construction, as described in Reference 3, is expected to remain small to moderate for each resource category based on the following:

- Land Use - The extended duration of construction does not alter the land usage on the SHINE site; therefore, the impacts on land use during construction remain SMALL.
- Visual Resources - The extended duration of construction does not alter the location or sizing of structures on the SHINE site; therefore, the impacts on visual resources during construction remain SMALL.
- Air Quality - The extended duration of construction does not alter the annual gaseous effluents during construction; therefore, the impacts on air quality during construction remain SMALL.
- Noise - The extended duration of construction does not alter the noise emissions during construction; therefore, the impacts on noise during construction remain SMALL.
- Geologic Environment - The extended duration of construction does not alter the geological environment for the SHINE site; therefore, the impacts on the geological environment during construction remain SMALL.
- Water Resource - The extended duration of construction does not alter the considerations related to surface-water and groundwater for the SHINE site; therefore, the impacts on water hydrology, quality, and use from construction remain SMALL.
- Ecological Resources - The extended duration of construction does not alter the considerations related to ecological resources for the SHINE site; therefore, the impacts on ecological resources from construction remain SMALL.
- History and Cultural Resources - The extended duration of construction does not alter the considerations related to historical and cultural resources for the SHINE site; therefore, the impacts on historical and cultural resources from construction remain SMALL.
- Socioeconomics - The extended duration of construction does not alter the considerations related to socioeconomics for the SHINE site (e.g., construction activities occur during a limited timeframe and do not require relocation of construction personnel to Rock County); therefore, the impacts on socioeconomics from construction remain SMALL.
- Human Health - The extended duration of construction does not alter the considerations related to human health for the SHINE site; therefore, the impacts on human health from construction remain SMALL.
- Waste Management - The extended duration of construction does not alter the considerations related to waste management for the SHINE site; therefore, the impacts on waste management from construction remain SMALL.

- Transportation - The extended duration of construction does not alter the considerations related to transportation during construction for the SHINE site (e.g., average daily traffic flow); therefore, the impacts on transportation from construction remain MODERATE.

Overall, the environmental impacts of construction, operations, and decommissioning for the SHINE medical isotope facility are expected to remain small to moderate as described in References 3 and 4.

5. REFERENCES

1. NRC letter to SHINE Medical Technologies, Inc., "SHINE Medical Technologies, LLC – Issuance of Amendment No. 2 to Construction Permit No. CPMIF-001 for the SHINE Medical Isotope Production Facility Related to the Receipt and Possession of Certain Radioactive Materials (EPID No. L-2021-LLA-0104)," dated December 2, 2021 (ML21320A224)

2. SHINE Technologies, LLC letter to the NRC, “SHINE Technologies, LLC Schedule Update – Expected Dates for Completion of Construction and Request for Receipt of Additional Radioactive Material,” dated October 15, 2021 (ML21288A543)

3. U.S. Nuclear Regulatory Commission, “Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility Final Report,” NUREG-2183, dated October 2015 (ML15288A046)

4. SHINE Technologies, LLC letter to the NRC, “SHINE Technologies, LLC Operating License Application Supplement No. 19 Submittal of a Revision to the SHINE Supplement to the Environmental Report,” dated March 16, 2022 (ML22075A144)

ENCLOSURE 1
ATTACHMENT 1

SHINE TECHNOLOGIES, LLC

SHINE TECHNOLOGIES, LLC REQUEST TO AMEND
CONSTRUCTION PERMIT NO. CPMIF-001

CONSTRUCTION PERMIT (CHANGES)
MEDICAL ISOTOPE PRODUCTION FACILITY
CONSTRUCTION PERMIT NO. CPMIF-001

4 pages follow

SHINE ~~MEDICAL~~ TECHNOLOGIES, LLC

DOCKET NO. 50-608

MEDICAL ISOTOPE PRODUCTION FACILITY

CONSTRUCTION PERMIT

Amendment No. ~~2~~
Construction Permit No. CPMIF-001

1. The Nuclear Regulatory Commission (NRC or the Commission) has found that:

   A. The application for a construction permit, as supplemented and revised (the application), filed by SHINE ~~Medical~~ Technologies, LLC (SHINE, the applicant), complies with the requirements of the Atomic Energy Act of 1954, as amended (the Act), and the rules and regulations of the Commission set forth in Title 10 of the *Code of Federal Regulations* (10 CFR) Chapter I – Nuclear Regulatory Commission. There is reasonable assurance that the activities authorized by the permit will be conducted in compliance with the rules and regulations of the Commission, and all required notifications to other agencies or bodies have been duly made;

   B. The applicant has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public;

   C. Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report;

   D. Safety features or components, if any, which require research and development have been described by the applicant. The applicant has identified, and will conduct, a research and development program reasonably designed to resolve any safety questions associated with such features or components;

   E. On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for the completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100,[1] the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public;

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1 While the site criteria contained in 10 CFR Part 100 are applicable to nuclear power reactors, and not the SHINE facility, the staff considered in Chapter 2 of its safety evaluation report, site-specific conditions similar to those listed in 10 CFR Part 100. Using the guidance in NUREG-1537, the staff evaluated SHINE's analysis of site geography and demography; nearby industrial, transportation, and military facilities; site meteorology; site hydrology; and site geology, seismology, and geotechnical engineering to ensure that issuance of the permit will not be inimical to the common defense and security or to the health and safety of the public.

F. The processes to be performed provide reasonable assurance the applicant will comply with the regulations in 10 CFR Chapter I, including the regulations in 10 CFR Part 20, and that the health and safety of the public will not be endangered.;

G. SHINE is technically qualified to design and construct the facility in accordance with the Commission's regulations set forth in 10 CFR Chapter I;

H. SHINE is financially qualified to design and construct the facility in accordance with the Commission's regulations set forth in 10 CFR Chapter I;

I. The issuance of a permit for the construction of the facility will not be inimical to the common defense and security or to the health and safety of the public; and

J. After weighing the environmental, economic, technical and other benefits of the facility against environmental and other costs and considering reasonable available alternatives, the issuance of this construction permit, subject to the conditions for protection of the environment set forth herein, is in accordance with Subpart A of 10 CFR Part 51 of the Commission's regulations and all applicable requirements have been satisfied.

K. The receipt and possession of byproduct and source material as authorized by this license will be in accordance with the Commission's regulations in 10 CFR Parts 30 and 40.

2. On the basis of the foregoing findings regarding this facility, construction permit No. CPMIF-001 is hereby issued to SHINE pursuant to Sections 103 and 185a of the Act and 10 CFR Part 50 for eight utilization facilities and one production facility designed for the production of medical radioisotopes, as described in the application, filed in this matter by the applicant and as more fully described in the evidence received at the public hearing upon that application. The facility, known as the SHINE Medical Isotope Production Facility, owned by SHINE ~~Medical~~ Technologies, LLC, will be located on previously undeveloped agricultural property in Rock County, Wisconsin, within the southern corporate boundaries of the City of Janesville, and is described in the application.

3. This permit shall be deemed to contain and be subject to the conditions specified in 10 CFR 50.54(b)-(f), (h), (v), (aa), and (cc) and 10 CFR 50.55; is subject to all applicable provisions of the Act, and rules, regulations, and orders of the Commission now or hereafter in effect; and is subject to the conditions specified or incorporated below:

A. The earliest date for the completion of the construction of the facility is December 31, 2017, and the latest date for completion is December 31, ~~2022~~2025.

B. The facility shall be constructed and located at the site as described in the application, in the City of Janesville, Rock County, Wisconsin.

C. The construction permit authorizes the applicant to construct the facility described in the application and the hearing record, in accordance with the principal architectural and engineering criteria and environmental protection commitments set forth therein.

D. The permit is subject to, and SHINE shall comply with, the conditions specified and incorporated below:

APPENDIX A

TO FACILITY CONSTRUCTION PERMIT NO. CPMIF-001

SHINE ~~MEDICAL~~ TECHNOLOGIES, LLC

MEDICAL ISOTOPE PRODUCTION FACILITY

DOCKET NO. 50-608

ENVIRONMENTAL PROTECTION PLAN

(NONRADIOLOGICAL)

February 29, 2016

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1.0 Objective of the Environmental Protection Plan

The Environmental Protection Plan's (EPP) objective is to ensure compliance with the Endangered Species Act of 1973, as amended (ESA), and to ensure that the Commission is kept informed of other environmental matters. The EPP is intended to be consistent with Federal, State, and local requirements for environmental protection.

2.0 Environmental Protection Issues

In the Final Environmental Impact Statement (final EIS) dated October 2015, the NRC staff considered the environmental impacts associated with the construction, operation, and decommissioning of the proposed SHINE ~~Medical~~ Technologies, LLC (SHINE or the licensee) radioisotope production facility (SHINE facility). This EPP applies to SHINE's actions affecting the protected environmental resources evaluated in the final EIS and SHINE's actions that may affect any newly discovered protected environmental resources.

2.1 Ecological Resources Issues

Federal agencies other than the U.S. Nuclear Regulatory Commission (NRC), such as the U.S. Environmental Protection Agency and the U.S. Army Corps of Engineers, have jurisdiction to regulate aquatic resources under the Federal Water Pollution Control Act (Clean Water Act or CWA) and the Rivers and Harbors Appropriation Act of 1899 (RHA). Water quality environmental concerns identified in the final EIS including mitigation measures would be regulated under SHINE's CWA permits, such as the National Pollutant Discharge Elimination System. Nothing within this EPP shall be construed to place additional requirements on the regulation of aquatic resources.

The U.S. Fish and Wildlife Service (FWS) regulates matters involving migratory birds and their nests in accordance with the Migratory Bird Treaty Act. The FWS also regulates matters involving the protection and taking of bald and golden eagles in accordance with the Bald and Golden Eagle Protection Acts.

SHINE shall inform the NRC of events or situations concerning aquatic or terrestrial resources for which a news release is planned or notification to other government agencies has been or will be made. These notifications shall be made to the NRC Operations Center within four hours of discovery.

2.2 Endangered Species Act of 1973

The NRC may be required to protect some aquatic resources and terrestrial resources in accordance with the Endangered Species Act of 1973 (ESA). If any Federally listed species or critical habitat occurs in an area affected by construction of the facility that was not previously identified as occurring in such areas, including species and critical habitat that were not previously Federally listed, the licensee shall inform the NRC within four hours of discovery. Similarly, the licensee shall inform the NRC within four hours of discovery of any take, as defined in the ESA, of a Federally listed species or destruction or adverse modification of critical habitat. These notifications shall be made to the NRC Operations Center. The licensee shall provide any necessary information to the NRC if the NRC initiates or reinitiates consultation under the ESA.

ENCLOSURE 1
ATTACHMENT 2

SHINE TECHNOLOGIES, LLC

SHINE TECHNOLOGIES, LLC REQUEST TO AMEND
CONSTRUCTION PERMIT NO. CPMIF-001

CONSTRUCTION PERMIT (CLEAN)
MEDICAL ISOTOPE PRODUCTION FACILITY
CONSTRUCTION PERMIT NO. CPMIF-001

4 pages follow

SHINE TECHNOLOGIES, LLC

DOCKET NO. 50-608

MEDICAL ISOTOPE PRODUCTION FACILITY

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   B. The applicant has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public;

   C. Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report;

   D. Safety features or components, if any, which require research and development have been described by the applicant. The applicant has identified, and will conduct, a research and development program reasonably designed to resolve any safety questions associated with such features or components;

   E. On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for the completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100,[1] the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public;

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1 While the site criteria contained in 10 CFR Part 100 are applicable to nuclear power reactors, and not the SHINE facility, the staff considered in Chapter 2 of its safety evaluation report, site-specific conditions similar to those listed in 10 CFR Part 100. Using the guidance in NUREG-1537, the staff evaluated SHINE's analysis of site geography and demography; nearby industrial, transportation, and military facilities; site meteorology; site hydrology; and site geology, seismology, and geotechnical engineering to ensure that issuance of the permit will not be inimical to the common defense and security or to the health and safety of the public.

F. The processes to be performed provide reasonable assurance the applicant will comply with the regulations in 10 CFR Chapter I, including the regulations in 10 CFR Part 20, and that the health and safety of the public will not be endangered.;

G. SHINE is technically qualified to design and construct the facility in accordance with the Commission's regulations set forth in 10 CFR Chapter I;

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I. The issuance of a permit for the construction of the facility will not be inimical to the common defense and security or to the health and safety of the public; and

J. After weighing the environmental, economic, technical and other benefits of the facility against environmental and other costs and considering reasonable available alternatives, the issuance of this construction permit, subject to the conditions for protection of the environment set forth herein, is in accordance with Subpart A of 10 CFR Part 51 of the Commission's regulations and all applicable requirements have been satisfied.

K. The receipt and possession of byproduct and source material as authorized by this license will be in accordance with the Commission's regulations in 10 CFR Parts 30 and 40.

2. On the basis of the foregoing findings regarding this facility, construction permit No. CPMIF-001 is hereby issued to SHINE pursuant to Sections 103 and 185a of the Act and 10 CFR Part 50 for eight utilization facilities and one production facility designed for the production of medical radioisotopes, as described in the application, filed in this matter by the applicant and as more fully described in the evidence received at the public hearing upon that application. The facility, known as the SHINE Medical Isotope Production Facility, owned by SHINE Technologies, LLC, will be located on previously undeveloped agricultural property in Rock County, Wisconsin, within the southern corporate boundaries of the City of Janesville, and is described in the application.

3. This permit shall be deemed to contain and be subject to the conditions specified in 10 CFR 50.54(b)-(f), (h), (v), (aa), and (cc) and 10 CFR 50.55; is subject to all applicable provisions of the Act, and rules, regulations, and orders of the Commission now or hereafter in effect; and is subject to the conditions specified or incorporated below:

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SHINE TECHNOLOGIES, LLC

MEDICAL ISOTOPE PRODUCTION FACILITY

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(NONRADIOLOGICAL)

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The U.S. Fish and Wildlife Service (FWS) regulates matters involving migratory birds and their nests in accordance with the Migratory Bird Treaty Act. The FWS also regulates matters involving the protection and taking of bald and golden eagles in accordance with the Bald and Golden Eagle Protection Acts.

SHINE shall inform the NRC of events or situations concerning aquatic or terrestrial resources for which a news release is planned or notification to other government agencies has been or will be made. These notifications shall be made to the NRC Operations Center within four hours of discovery.

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The NRC may be required to protect some aquatic resources and terrestrial resources in accordance with the Endangered Species Act of 1973 (ESA). If any Federally listed species or critical habitat occurs in an area affected by construction of the facility that was not previously identified as occurring in such areas, including species and critical habitat that were not previously Federally listed, the licensee shall inform the NRC within four hours of discovery. Similarly, the licensee shall inform the NRC within four hours of discovery of any take, as defined in the ESA, of a Federally listed species or destruction or adverse modification of critical habitat. These notifications shall be made to the NRC Operations Center. The licensee shall provide any necessary information to the NRC if the NRC initiates or reinitiates consultation under the ESA.