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

SHINE MEDICAL TECHNOLOGIES, INC.

DOCKET NO. 50-608

SHINE MEDICAL ISOTOPE PRODUCTION FACILITY

AMENDMENT TO CONSTRUCTION PERMIT

Amendment No. 1
Construction Permit No. CPMIF-001

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

   A. The application for a license amendment filed by SHINE Medical Technologies, Inc., dated December 11, 2018, as supplemented by letter dated March 8, 2019, complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations set forth in 10 CFR Chapter I;

   B. The facility will be constructed in conformity with the application, as supplemented, the provisions of the Act, and the rules and regulations of the Commission;

   C. There is reasonable assurance (i) that the activities authorized by this amendment can be conducted without endangering the health and safety of the public, and (ii) that such activities will be conducted in compliance with the Commission's regulations;

   D. The issuance of this amendment will not be inimical to the common defense and security or to the health and safety of the public; and

   E. The issuance of this amendment is in accordance with 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," of the Commission's regulations and all applicable requirements have been satisfied.

2. Accordingly, Construction Permit No. CPMIF-001 is amended as indicated in the attachment to this license amendment.

3. This license amendment is effective at the time the proposed indirect license transfer is completed and shall be implemented within 30 days from that date.

FOR THE NUCLEAR REGULATORY COMMISSION

Louise Lund, Director
Division of Licensing Projects
Office of Nuclear Reactor Regulation

Attachment:
Changes to Construction Permit No. CPMIF-001

Date of Issuance: [date]

ATTACHMENT TO LICENSE AMENDMENT NO. 1

SHINE MEDICAL ISOTOPE PRODUCTION FACILITY

CONSTRUCTION PERMIT NO. CPMIF-001

DOCKET NO. 50-608

Replace the following pages of Construction Permit No. CPMIF-001 and Appendix A, "Environmental Protection Plan," with the attached revised pages. The revised pages are identified by amendment number and contain marginal lines indicating the areas of change.

Construction Permit No. CPMIF-001

REMOVE	INSERT
1	1
2	2

Environmental Protection Plan

REMOVE	INSERT
A-1	A-1
A-2	A-2

SHINE MEDICAL TECHNOLOGIES, ~~INC.~~LLC

DOCKET NO. 50-608

MEDICAL ISOTOPE PRODUCTION FACILITY

CONSTRUCTION PERMIT

Amendment No. 1
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, ~~Inc.~~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;

[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.

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, ~~Inc.~~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.

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:

(1) Prior to the completion of construction, SHINE shall submit periodic reports to the NRC, at intervals not to exceed six months from the date of this permit, providing the following information related to nuclear criticality safety and radiation protection:

APPENDIX A

TO FACILITY CONSTRUCTION PERMIT NO. CPMIF-001

SHINE MEDICAL TECHNOLOGIES, ~~INC.~~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, ~~Inc.~~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.