SHINE MEDICAL TECHNOLOGIES, INC.

DOCKET NO. 50-608

MEDICAL ISOTOPE PRODUCTION FACILITY

CONSTRUCTION PERMIT

Construction Permit No. CP-[XXX]

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. (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. CP- [XXX] 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., 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:

(a) The technical basis for the design of the criticality accident alarm system (CAAS), including a description of the methodology for determining detector placement. The technical basis shall demonstrate that the CAAS will meet the requirements of 10 CFR 70.24(a) and the commitments listed on page 6b-19 of the Preliminary Safety Analysis Report, Revision 0.

(b) The basis for determining that criticality events are "not credible" for radioisotope production facility (RPF) processes even though fissile materials may be present. The basis shall demonstrate that the each such event satisfies the definition of "not credible," as described in the SHINE integrated safety analysis Summary.

(c) Summaries of the criticality safety analysis for the affected processes that include the following: (1) a list of identified criticality hazards, (2) a list of controlled parameters, (3) a description of evaluated normal and abnormal conditions, (4) a description of the licensee's approach to meeting the double contingency principle, and (5) a list of anticipated passive and active engineered controls, including any assumptions, to ensure the process(es) will remain subcritical under normal and credible abnormal conditions. The criticality safety analysis summaries shall demonstrate that all RPF processes will remain subcritical under all normal and credible abnormal conditions and will satisfy the double contingency principle.

(d) The relevant nuclear criticality safety evaluations (NCSEs) shall address the reactivity contributions from all fissile isotopes or SHINE shall apply an additional subcritical margin to account for neglecting these nuclides. The treatment of fissile nuclides other than U-235, whether through the NCSEs or the addition of subcritical margin, shall demonstrate that all RPF processes will remain subcritical under all normal and credible abnormal conditions.

(e) The design information on the RPF supercells, tank vaults containing the liquid waste storage tanks, evaporation hot cells, and liquid waste solidification hot cells demonstrating shielding, and occupancy times within the RPF are consistent with as low as is reasonably achievable practices and dose requirements of 10 CFR Part 20.

(2) The Environmental Protection Plan described in Appendix A of this permit is hereby incorporated into this permit.

4. This permit is subject to the limitation that a license authorizing operation of the facility will not be issued by the Commission unless: (a) the applicant submits to the Commission the complete final safety analysis report, portions of which may be submitted and evaluated from time to time; (b) the Commission finds that the final design provides reasonable assurance that the health and safety of the public will not be endangered by the operation of the facility in accordance with procedures approved by it in connection with the issuance of said license; (c) the Commission finds that operation of the facility will be in accordance with 10 CFR Part 51 of the Commission's regulations and all applicable requirements were satisfied; and (d) the applicant submits proof of financial protection and executes an indemnity agreement as required by Section 170 of the Act.

5. This permit is effective as of its date of issuance and shall expire on the latest completion date indicated in paragraph 3.A. above.

FOR THE NUCLEAR REGULATORY COMMISSION

William M. Dean, Director
Office of Nuclear Reactor Regulation

Appendix:

Appendix A – Environmental Protection Plan

APPENDIX A

TO FACILITY CONSTRUCTION PERMIT NO. [XXX-XX]

SHINE MEDICAL TECHNOLOGIES, INC.

MEDICAL ISOTOPE PRODUCTION FACILITY

DOCKET NO. 50-608

ENVIRONMENTAL PROTECTION PLAN

(NONRADIOLOGICAL)

[DATE]

TABLE OF CONTENTS

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. (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.

2.3 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.

Unusual Event - The licensee shall inform the NRC of any onsite mortality, injury, or unusual occurrence of any species protected by the ESA within four hours of discovery, followed by a written report in accordance with Section 4.1. The time of discovery is identified as the specific time when a decision is made to notify another agency or to issue a press release. Such incidents shall be reported regardless of the licensee's assessment of causal relation to facility construction.

3.0 Consistency Requirements

The licensee shall notify the NRC of proposed changes to permits or certifications concerning aquatic or terrestrial resources by providing the NRC with a copy of the proposed change at the same time it is submitted to the permitting agency. The licensee shall provide the NRC with a copy of the application for renewal of permits or certifications at the same time the application is submitted to the permitting agency.

Changes to or renewals of permits or certifications shall be reported to the NRC within 30 days following the later of the date the change or renewal is approved or the date the change becomes effective. If a permit or certification, in part or in its entirety, is appealed and stayed, the NRC shall be notified within 30 days following the date the stay is granted.

4.0 Administrative Procedures

4.1 Facility Reporting Requirements: Non-routine Reports

A written report shall be submitted to the NRC within 30 days of occurrence of any unusual event described in Section 2.3 of this EPP. The report shall (a) describe, analyze, and evaluate the event, including extent and magnitude of the impact and facility construction characteristics at the time of the event, (b) describe the probable cause of the event, (c) indicate the action taken to correct the reported event, (d) indicate the corrective action taken to preclude repetition of the event and to prevent similar occurrences involving similar components or systems, and (e) indicate the agencies notified and their preliminary responses.

Events reportable under this subsection, which also require reports to other Federal, State, or local agencies, shall be reported in accordance with those reporting requirements in lieu of the requirements of this subsection. The NRC shall be provided a copy of such report at the same time it is submitted to the other agency.

4.2 Review and Audit

The licensee shall provide for review and audit of compliance with Section 2.3 of this EPP. The audits shall be conducted independently of the individual or groups responsible for performing the specific activity. A description of the organizational structure utilized to achieve the independent review and audit function and results of the audit activities shall be maintained and made available for inspection.

4.3 Records Retention

Records required by this EPP shall be made and retained in a manner convenient for review and inspection. These records shall be made available to the NRC on request. The records, data, and logs relating to this EPP shall be retained for five years or, where applicable, in accordance with the requirements of other agencies.

4.4 Changes in Environmental Protection Plan

A request for a change in the EPP shall include an assessment of the environmental impact of the proposed change and a supporting justification. Implementation of such changes in this EPP shall not commence prior to NRC approval of the proposed changes in the form of a license amendment incorporating the appropriate revision to this EPP.