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) In accordance with Appendix B to this permit, SHINE shall establish a screening and evaluation process for determining whether an amendment request is necessary before changes are implemented during construction.

(3) SHINE may use a preliminary amendment request (PAR) process for amendments to this construction permit any time prior to the issuance of an operating license. To use the PAR process, SHINE shall submit a written request to the Office of Nuclear Reactor Regulation (NRR) in accordance with Appendix B of this permit. If SHINE elects to proceed and the amendment request is subsequently denied, SHINE shall return the facility to its previous condition, as described in the preliminary safety analysis report.

(4) The Environmental Protection Plan; screening and evaluation process for changes during construction; and PAR process described in Appendices A and B of this permit are 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 B – Screening and Evaluation Process for Changes During Construction and Preliminary Amendment Request Process

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]

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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. (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.

APPENDIX B

TO FACILITY CONSTRUCTION PERMIT NO. [XXX-XX]

SHINE MEDICAL TECHNOLOGIES, INC.

MEDICAL ISOTOPE PRODUCTION FACILITY

DOCKET NO. 50-608

SCREENING AND EVALUATION PROCESS FOR CHANGES DURING CONSTRUCTION

AND

PRELIMINARY AMENDMENT REQUEST PROCESS

[DATE]

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1.0 Background

Non-power production and utilization facility construction must be conducted in accordance with the construction permit, the Atomic Energy Act, and the applicable regulations. Certain changes to the facility as described in the preliminary safety analysis report (PSAR) do not require prior U.S. Nuclear Regulatory Commission (NRC) approval. Other changes require an amendment, an exemption, or both, and require NRC approval in advance of the construction[2] of the plant change or modification. For the purpose of maintaining configuration control and in order to avoid unnecessary construction delays related to changes during construction arising after the issuance of the construction permit and before the issuance of an operating license, there shall be a preliminary amendment request (PAR) process, as described below.

1.1 Discussion

A licensee that desires to depart from its construction permit must evaluate and determine if the desired facility change or modification requires NRC approval, via an amendment per 10 CFR 50.90, an exemption per 10 CFR 50.12, or both, prior to constructing the facility change or modification.

If the licensee's screening and evaluation process determines that NRC approval via an amendment, an exemption, or both, is required for the desired departure from the construction permit, the licensee may elect to use the PAR process. The PAR process preserves the design configuration control mechanisms while avoiding unnecessary construction delays by creating a process whereby a licensee can opt to submit a request to the NRC seeking a determination on whether the NRC objects to the licensee proceeding with construction changes, subject to strict conditions, before the NRC's review of the amendment request is complete. If the NRC determines it has no objection to the licensee's request, the licensee may proceed with the construction change, but the licensee is required to return the facility to its previous state, as described in the PSAR, should the related amendment request be withdrawn or denied.

The result of the PAR process is a determination of whether the NRC has any objection to a licensee proceeding with the construction and testing of a proposed facility change or proposed modification requiring an amendment or exemption while the NRC is conducting the detailed technical review of the related amendment request. A licensee may proceed with construction and testing only upon receipt of the no objection PAR determination notification. The NRC "No Objection" determination of the PAR is not a pre-approval of the amendment request on its technical merits, nor does it imply any NRC approval of the amendment request. If the amendment request is subsequently approved, the licensee shall maintain records of the changes, as described in Section 2.3 of this appendix. If the amendment request is subsequently denied, the licensee must return the facility to its previous state, as described in the PSAR. In all cases, the licensee must obtain the NRC amendment request determination for the changed or modified structure, system or component (SSC) prior to obtaining an operating license.

[2] Construction as defined in 10 CFR 50.10 is, in part, the in-place assembly, erection, fabrication or testing for specified SSCs.

2.0 Screening and Evaluation Process for Changes During Construction

The licensee shall establish a screening and evaluation process for determining whether an amendment request is necessary for a desired change during construction. Elements of this process are detailed below.

2.1 Definitions

The following definitions are applicable for this Appendix:

Change means a modification or addition to, or removal from, the facility or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.

Departure from a method of evaluation described in the preliminary safety analysis report (PSAR) used in establishing the design bases or in the safety analyses means:

1. Changing any of the elements of the method described in the PSAR unless the results of the analysis are conservative or essentially the same; or

2. Changing from a method described in the PSAR to another method unless that method has been approved by NRC for the intended application.

Facility as described in the PSAR means:

1. The SSC that are described in the PSAR,

2. The design and performance requirements for such SSCs described in the PSAR, and

3. The evaluations or methods of evaluation included in the PSAR for such SSCs which demonstrate that their intended function(s) will be accomplished.

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2.2 Screening and Evaluation Criteria

Proposed activities should be screened to determine whether the activity represents a change in the facility as described in PSAR, as defined in Section 2.1 of this Appendix.

If the proposed activity represents a change, a licensee may make such a change in the facility as described in the PSAR without obtaining an amendment pursuant to 10 CFR 50.90 only if the change does not meet any of the following criteria:

1. The change would result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the PSAR;

2. The change would result in more than a minimal increase in the likelihood of occurrence of a malfunction of a SSC important to safety previously evaluated in the PSAR;

3. The change would result in more than a minimal increase in the consequences of an accident previously evaluated in the PSAR;

4. The change would result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the PSAR;

5. The change would create a possibility for an accident of a different type than any previously evaluated in the PSAR;

6. The change would create a possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the PSAR;

7. The change would result in a design basis limit for the primary system boundary as described in the PSAR being exceeded or altered; or

8. The change would result in a departure from a method of evaluation described in the PSAR used in establishing a design bases or in the safety analyses.

2.3 Documentation Requirements

The licensee shall maintain records of changes in the facility. These records must include a written evaluation which provides the bases for the determination that the change does not require an amendment.

The licensee shall submit, a report containing a brief description of any changes, including a summary of the evaluation of each. A report must be submitted at intervals not to exceed six months during the period from the date of issuance of a construction permit to the date of the issuance of the operating license.

The records of changes in the facility must be maintained until the issuance of an operating license.

3.0 Preliminary Amendment Request Process

3.1 Contents

If the licensee determines that an amendment is necessary after applying its screening and evaluation, it may elect to submit a PAR. The minimal requirements for PARs include the following:

- Oath or affirmation[3]
- Date by which a PAR determination is requested
- Description of the proposed change
- Description of the impact on associated structures, systems, or components (if any)

3.2 Review and Applicability

The review of PAR submissions and their related amendment or exemption requests is one of the primary mechanisms for regulating changes to the facility under construction. Frequent and early communications between the staff and the licensee can help avoid unnecessary delays in the processing of licensing actions. Discussions between the licensee and staff

[3] RIS 2001-018, "NRC Regulatory Issue Summary 2001-018: Requirements for Oath or Affirmation," August 22, 2001, ADAMS Accession No. ML010990211.

members regarding future licensing action requests prior to submission are encouraged to allow sufficient exchange of information concerning technical information, schedules and resource planning.

The licensee may use the PAR process for amendments at any time before the issuance of an operating license. To use the PAR process, the licensee should submit a written request to the NRC in accordance with this Appendix.

3.3 Determination

The NRC will not issue a determination on the PAR until: (1) the licensee submits the related amendment request; and (2) the NRC has accepted the related amendment request for detailed technical review.

The NRC's PAR determination letter will state whether the licensee may proceed in accordance with the PAR, amendment request and this Appendix. The objection or no objection determination of the PAR is part of the continuous process of managing issues related to non-power production and utilization facility construction. The PAR determination is not a pre-approval of the amendment request, nor does it imply any NRC approval of the amendment request. If the licensee elects to proceed with construction after receiving the NRC's PAR determination of "No Objection," and the amendment request is subsequently withdrawn or denied, the licensee must return the facility to its previous state, as described in the PSAR.

The timeframe for issuance of the PAR determination notification will be established with consideration of the licensee's construction schedules and NRC resources.