NORTHWEST MEDICAL ISOTOPES, LLC

DOCKET NO. 50-609

MEDICAL ISOTOPE PRODUCTION FACILITY

CONSTRUCTION PERMIT

Construction Permit No. CPMIF-00X

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 Northwest Medical Isotopes, LLC (NWMI, 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 (FSAR);

   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 and testing reactors, and not the NWMI facility, the staff considered in Chapter 2.0 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 NWMI'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. NWMI is technically qualified to design and construct the facility in accordance with the Commission's regulations set forth in 10 CFR Chapter I;

H. NWMI 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-00X is hereby issued to NWMI pursuant to Sections 103 and 185a of the Act and 10 CFR Part 50 for a production facility, as defined in 10 CFR 50.2, "Definitions," 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 production facility, owned by Northwest Medical Isotopes, LLC, will be located on previously undeveloped property in Boone County, Missouri, within the boundaries of the City of Columbia, 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, 2019, 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 Columbia, Boone County, Missouri.

C. The construction permit authorizes the applicant to construct a production 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. Prior to the completion of construction, NWMI shall ensure that all nuclear processes are evaluated to be subcritical under all normal and credible abnormal conditions. This determination shall be done for each area as described in Section 6.3.1.1 of the NWMI preliminary safety analysis report (PSAR) prior to each area being completed, and shall be done consistent with the Upper Subcritical Limit (USL) established in Revision 2 of NWMI's Validation Report. NWMI shall submit periodic reports to the NRC, at intervals

not to exceed 6 months from the date of the construction permit, summarizing any changes or indicate no change to the criticality safety evaluations as a result of the revised USL. This condition terminates once NWMI submits its FSAR.

E. Prior to the completion of construction, NWMI shall submit periodic reports to the NRC, at intervals not to exceed 6 months from the date of the construction permit. These reports shall provide the technical basis for the design of the Criticality Accident Alarm System or notify the NRC of no change. Prior to the completion of construction, the reports shall demonstrate detector coverage as defined in the requirements of 10 CFR 70.24(a). This condition terminates once NWMI submits its FSAR.

F. NWMI shall implement the quality assurance program described, pursuant to 10 CFR 50.34(a)(7), in Revision 3 of the NWMI PSAR, including revisions to the quality assurance program in accordance with the provisions below.

NWMI may make a change to its previously accepted quality assurance program description included in Revision 3 of the NWMI PSAR, provided the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the PSAR quality assurance program description that do not reduce the commitments must be submitted to the NRC within 90 days. Changes to the PSAR quality assurance program description that do reduce the commitments must be submitted to the NRC and receive NRC approval before implementation, as follows:

(1) Changes made to the previously accepted quality assurance program description must be submitted as specified in 10 CFR 50.4.

(2) The submittal of a change to the PSAR quality assurance program description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the PSAR quality assurance program description commitments previously accepted by the NRC. The letter need not provide the basis for changes that correct spelling, punctuation, or editorial items.

(3) A copy of the forwarding letter identifying the changes must be maintained as a facility record for three years.

(4) Changes to the quality assurance program description included in the NWMI PSAR shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.

G. Prior to the beginning of construction, NWMI shall (a) complete a geotechnical investigation to identify sinkhole potential, soil characteristics, and liquefaction potential at the site and (b) submit the results of this investigation, including any design changes made to the facility based on the findings of the investigation, in a report to the NRC. This condition terminates once NWMI submits the results of the geotechnical investigation in either this report or as part of its FSAR, whichever occurs first.

H. 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 FSAR, 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

Brian Holian, Director (Acting)
Office of Nuclear Reactor Regulation

Appendix:

Appendix A – Environmental Protection Plan

Date of Issuance:

APPENDIX A

TO FACILITY CONSTRUCTION PERMIT NO. CPMIF-00x

NORTHWEST MEDICAL ISOTOPES, LLC

RADIOISOTOPE PRODUCTION FACILITY

DOCKET NO. 50-609

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 May 2017, the NRC staff considered the environmental impacts associated with the construction, operation, and decommissioning of the proposed Northwest Medical Isotopes, LLC (NWMI or the licensee) radioisotope production facility (RPF). This EPP applies to NWMI's actions affecting the protected environmental resources evaluated in the final EIS and NWMI'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 NWMI'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.

NWMI 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. 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.

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.

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. 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 2.2 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 2.2 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.