

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-0609; NRC-2018-0225]

Northwest Medical Isotopes, LLC

Medical Radioisotope Production Facility

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption to Northwest Medical Isotopes, LLC (NWMI) from the requirement that an application for an NRC license to possess and use special nuclear material for processing and fuel fabrication, scrap recovery or conversion of uranium hexafluoride, or for the conduct of any other activity which the NRC has determined will significantly affect the quality of the environment (and the associated environmental report), be submitted at least 9 months prior to commencement of construction of the plant or facility in which the activity will be conducted.

DATES: This exemption is effective November 13, 2018.

ADDRESSES: Please refer to Docket ID **NRC-2018-0225** when contacting the NRC about the availability of information regarding this document. You may access publicly-available information related to this document using any of the following methods:

- **Federal Rulemaking Web site:** Go to <http://www.regulations.gov> and search for Docket ID **NRC-2018-0225**. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301-287-9127; e-mail: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[Begin Web-based ADAMS Search](#)." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

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SUPPLEMENTARY INFORMATION:

I. Background

NWMI is the holder of Construction Permit No. CPMIF-002 (issued on May 9, 2018 (ADAMS Accession No. ML18037A308) under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR)), which authorizes NWMI to construct a medical radioisotope production facility (RPF) in Columbia, Missouri. The facility would fabricate low-enriched uranium (LEU) targets and ship them to a network of U.S. research reactors for irradiation, receive irradiated LEU targets, disassemble and dissolve irradiated LEU targets, and recover and purify Molybdenum-99 (Mo-99). These processes would take place in a single RPF building divided into two separate areas where processes subject to different regulatory regimes would take place. The processes involved in the production area, which include receipt of irradiated LEU targets, LEU target disassembly and dissolution, and Mo-99 recovery and purification, are subject to the NRC licensing requirements of 10 CFR part 50. The processes involved in target fabrication that NWMI plans to perform in a separate area of the RPF would be subject to the separate NRC licensing requirements of 10 CFR part 70.

NWMI submitted an environmental report with its construction permit application, providing environmental information about all of the processes that would occur in both portions of the RPF. In accordance with Section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 et seq.) and the NRC's regulations in 10 CFR part 51, the NRC staff prepared an environmental impact statement (EIS), NUREG-2209, "Environmental Impact Statement for the Construction Permit for the Northwest Medical Isotopes Radioisotope Production Facility," dated

May 2017 (ADAMS Accession No. ML17130A862) assessing the potential impacts of the construction, operation, and decommissioning of the proposed RPF on the quality of the human environment and reasonable alternatives. The construction and operation impacts from the portion of the RPF in which 10 CFR part 70 target fabrication activities would occur were evaluated as a connected action to the 10 CFR part 50 construction permit. A 10 CFR part 50 construction permit was issued to NWMI on May 9, 2018.

II. Request/Action

The exemption request from NWMI was submitted by letter dated December 18, 2017 (ADAMS Accession No. ML17362A040), as supplemented by a letter dated March 12, 2018 (ADAMS Accession No. ML18088A175). NWMI is requesting an exemption from the requirement that the application (and associated environmental report required by 10 CFR part 51) for 10 CFR part 70 activities be submitted at least 9 months prior to commencement of construction of the 10 CFR part 70 components of the RPF. The activities that will be subject to the 10 CFR part 70 license application are described in the construction permit application that NWMI previously submitted to the NRC under 10 CFR part 50 for an RPF to be constructed in Columbia, Missouri. (NWMI Preliminary Safety Analyses Report, Chapter 19, "Environmental Report" Corvallis, OR, Revision 0A dated June 2015 (ADAMS Accession Nos. ML15210A123, ML15210A128, ML15210A129, and ML15210A131).

The NRC evaluated the environmental impacts from the 10 CFR part 70 target fabrication activities in the RPF as part of its EIS supporting NWMI's 10 CFR part 50 construction permit application. The exemption would allow NWMI to initiate construction of the 10 CFR part 70 components of the RPF upon the issuance of the

10 CFR part 50 construction permit for the RPF even if the 10 CFR 70.21(f) timing requirement is not met.

III. Discussion

Pursuant to 10 CFR 70.17(a), the Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of 10 CFR part 70 as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Authorized by Law

The applicant has stated that the requested exemption from the requirement to submit an application and associated environmental report at least 9 months prior to the commencement of construction of the RPF, including 10 CFR part 70 components (i.e., the target fabrication facility), will enable it to initiate construction of the entire RPF based upon the environmental review for the 10 CFR Part 50 construction permit. The applicant has also stated there have been no significant changes to the environmental information that was previously submitted to the NRC as part of the 10 CFR part 50 construction permit application. NWMI also stated that it will submit the application and environmental report required by 10 CFR 70.21(f) as part of a consolidated operating license application for both the 10 CFR part 50 Production Facility and to possess and use special nuclear material for the 10 CFR part 70 target fabrication facility activities.

The staff evaluated the environmental impacts of the RPF, including the 10 CFR part 70 target fabrication activities as a connected action, in the EIS dated May 31, 2017

(NUREG-2209, "Environmental Impact Statement for the Construction Permit for the Northwest Medical Isotopes Radioisotope Production Facility", ADAMS Accession No. ML17130A862). The staff concludes, as documented in the EIS, that after weighing the environmental, economic, technical, and other benefits against environmental and other costs, and considering reasonable alternatives, the NRC staff's recommendation, unless safety issues mandate otherwise, is the issuance of a construction permit to NWMI.

The NRC regulation, 10 CFR 70.17, allows the NRC to grant exemptions from the requirements of 10 CFR part 70 provided certain findings are made. Granting the applicant's proposed exemption is not otherwise inconsistent with NRC regulations or other applicable laws. As explained below, the proposed exemption will not endanger life or property, or the common defense and security, and is otherwise in the public interest.

NWMI indicates that it will submit an environmental report with its application for an operating license for the entire RPF which the NRC will be able to review for any significant new information. The NRC will not make a decision on an application to operate the production portion of the facility under 10 CFR part 50 or a license to possess and use special nuclear material for target fabrication under 10 CFR part 70 until after the NRC has completed a NEPA review based on NWMI's proposed application and environmental report, and made the appropriate regulatory findings. Therefore, the exemption is authorized by law.

Will Not Endanger Life or Property or the Common Defense and Security

Construction of the facility has not yet begun. Since the exemption request relates to the timing of when construction may begin, the proposed exemption would not:

a) impact the probabilities of evaluated accidents; b) affect margins of safety; c) affect

effectiveness of programs contained in licensing documents; d) increase effluents; e) increase occupational radiological exposures; or f) impact operations or decommissioning activities. The proposed exemption also will not have an impact on common defense and security since the exemption only relates to the timing of construction. NWMI's construction permit does not authorize possession of any nuclear material at the RPF.

Based on its evaluation, the NRC staff has determined that this exemption will not endanger life or property or the common defense and security.

Otherwise in the Public Interest

The NRC staff has determined that granting the proposed exemption would allow for efficient construction of the NWMI RPF at an earlier date. The purpose of the NWMI RPF is to produce medical isotopes and help meet the U.S. goal of establishing a domestic supply of Mo-99 as stated in the American Medical Isotopes Production Act, 42 U.S.C 2065 et seq. Accordingly, the NRC staff has determined that granting the requested exemption is otherwise in the public interest.

IV. Environmental Consideration

As required by 10 CFR 51.21, the NRC performed an environmental assessment (EA) that analyzes the environmental impacts of the proposed exemption in accordance with NEPA. Based on that EA, the NRC staff has determined not to prepare an EIS for the proposed exemption, and has issued a finding of no significant impact (FONSI). The EA and FONSI were published in the *Federal Register* on August 29, 2018 (83 FR 44068-44070).

V. Conclusion

Accordingly, the NRC has determined that, pursuant to 10 CFR 70.17, the exemption is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest. Therefore, the NRC hereby grants NWMI an exemption from the 10 CFR 70.21(f) requirement to submit a 10 CFR part 70 application, and the associated environmental report, 9 months prior to the commencement of construction, to allow NWMI to begin construction of the 10 CFR part 70 portions of the facility along with the rest of the RPF.

This exemption is effective upon issuance.

Dated at Rockville, Maryland this 1st day of November, 2018.

For the Nuclear Regulatory Commission.

/RA/

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