



May 9, 2019
NWMI-LTR-2019-006

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
11555 Rockville Pike
Washington, DC 20555

Mr. Michael Balazik
Research and Test Reactors Branch A
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

RE: Northwest Medical Isotopes, LLC (NWMI) Periodic Report Required by the License Conditions in Construction Permit No. CPMIF-002 (Docket No. 50-609), May 9, 2019

References:

1. Lund, A.L., 2018, "Northwest Medical Isotopes, LLC – Issuance of Construction Permit for Medical Radioisotope Production Facility," Docket No. 50-609, (Letter to C. Haass, Northwest Medical Isotopes, LLC, May 9), U.S. Nuclear Regulatory Commission, Washington, D.C. (ML18037A308)
2. Construction Permit No. CPMIF-002, *Northwest Medical Isotopes, LLC, Docket No. 50-609 Medical Radioisotope Production Facility Construction Permit*, Docket No. 50-609, dated May 9, 2018.

Dear Mr. Balazik:

Pursuant to the construction permit conditions described in Items 3.D and 3.E of the Northwest Medical Isotopes, LLC (NWMI) Construction Permit (References 1 and 2), NWMI is submitting this periodic report, updating the NRC staff on progress addressing the specified conditions related to Radioisotope Production Facility nuclear criticality activities.

In addition, pursuant to the construction permit condition described in Item 3.G of the NWMI Construction Permit (References 1 and 2), NWMI submitted a completed geotechnical investigation report via NWMI-LTR-2019-007 dated April 17, 2019.

If you have questions, I can be reached at (509) 430-6921 or carolyn.haass@nwmedicalisotopes.com.

I solemnly declare and affirm that the foregoing information is true and correct under the penalty of perjury. Executed on May 9, 2019.

Sincerely,

Carolyn C. Haass
Chief Operating Officer

Enclosure

cc: Mr. David Tiktinsky, Office of Nuclear Material Safety and Safeguards

ADZD

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ATTACHMENT A

**Northwest Medical Isotopes, LLC (Docket No. 50-609)
Medical Radioisotope Production Facility Construction Permit
(Construction Permit No. CPMIF-002)
Periodic Report Required in Items 3.D and 3.E**

Northwest Medical Isotopes, LLC (Docket No. 50-609)
Medical Radioisotope Production Facility Construction Permit
(Construction Permit No. CPMIF-002)
Periodic Report Required in Items 3.D and 3.E

Pursuant to the license conditions described in Items 3.D and 3.E of the Northwest Medical Isotopes, LLC (NWMI) Construction Permit (Reference 2), NWMI is submitting the enclosed periodic report, updating the NRC staff on progress addressing the specified conditions related to Radioisotope Production Facility (RPF) nuclear criticality activities.

License Condition 3.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.*

NWMI Update: Since the U.S. Nuclear Regulatory Commission (NRC) issued the NWMI Construction Permit in May 2018 and NWMI's last periodic report dated November 9, 2018, NWMI has continued updating the RPF criticality safety evaluations (CSE) based on the revised USL. The revised CSEs are being used in the development of the RPF final safety analysis report (FSAR) and will be available for review by the NRC staff.

License Condition 3.E(1): *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, and these reports shall:*

(1) Provide the technical basis for the design of the Criticality Accident Alarm System or notify the NRC of no change.

NWMI Update: Since the NRC issued the NWMI Construction Permit, NWMI has completed a preliminary evaluation for placement of the criticality accident alarm system (CAAS), a radiation zone (immediate evacuation zone) analysis, and dose to the public from an accidental criticality. NWMI will be completing a detailed analysis to determine the final placement of detectors as part of the technical basis for the design of the CAAS. In addition, we have initiated the development of a CAAS analysis procedure, including planning, documentation development, and independent review/comment resolution.

License Condition 3.E(2): *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, and these reports shall:*

(2) Demonstrate detector coverage as defined in the requirements of 10 CFR 70.24(a).

NWMI Update: See response to License Condition 3.E(1).