



September 1, 2016
NWMI-LTR-2016-009

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

Mr. David Drucker, Senior Project Manager
Division of License Renewal
Office of Nuclear Reactor Regulation

RE: Docket No. 50-609, Northwest Medical Isotopes, LLC Responses to the U.S. Nuclear Regulatory Commission Environmental Request for Additional information (Letter dated June 16, 2016) – Additional Clarification on POSA3-1A, POSA3-1B, POSA3-2A, POSA3-3A, NOI3-1B, and PA3-1

References:

1. Northwest Medical Isotopes, LLC Letter NWMI-LTR-2016-007 to U.S. Nuclear Regulatory Commission, dated July 18, 2016, Docket No. 50-609, Responses to Request for Additional Information dated June 16, 2016 (ADAMS Accession No. ML16210A305)
2. U.S. Nuclear Regulatory Commission letter to Northwest Medical Isotopes, LLC, dated June 16, 2016, Docket No. 50-609, Request for Additional Information for the Environmental Review of the Northwest Medical Isotopes, LLC Construction Permit Application (ADAMS Accession No. ML16176A114) (TAC Nos. MF6134 and MF 6135)
3. Northwest Medical Isotopes, LLC Letter NWMI-LTR-20 15-006 to U.S. Nuclear Regulatory Commission, dated July 20, 2015, *NRC Project No. 0803 - Northwest Medical Isotopes, LLC, Submittal Part 2 Construction Permit Application for a Radioisotope Production Facility* (ADAMS Accession No. ML16056A122)
4. Northwest Medical Isotopes, LLC Letter to U.S. Nuclear Regulatory Commission, dated February 5, 2015 (ADAMS Accession No. ML14349A501) *Environmental Report and Associated Part One Submittal* (ADAMS Accession Nos. ML14349A501, ML15210A123, ML15210A128, ML15210A129, and ML15210A131)

Dear Mr. Drucker:

Northwest Medical Isotopes, LLC (NWMI) is providing additional clarification on POSA3-1A, POSA3-1B, POSA3-2A, POSA3-3A, NOI3-1B, and PA3-1 and to the response to the U.S. Nuclear Regulatory Commission request for additional information (RAI) dated June 16, 2016. These clarifications are provided in Attachment 1. NWMI submitted their original response the above referenced RAIs on July 25, 2016.

NWMI is submitting these clarifications to the NRC in accordance with 10 CFR 50.30(b), "Oath or Affirmation," and 10 CFR 50.4, "Written Communications."

I solemnly declare and affirm that the foregoing information is true and correct under the penalty of perjury.

Executed on September 1, 2016.

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

Sincerely,

A handwritten signature in black ink, reading "Carolyn C. Haass". The signature is written in a cursive, flowing style. The first name "Carolyn" is written in a larger, more prominent script, and the last name "C. Haass" follows in a similar but slightly smaller script. The signature is contained within a light gray rectangular border.

Carolyn C. Haass
Chief Operating Officer

Enclosures: Attachment 1

cc: Mr. Michael Balazik
Research and Test Reactors Branch A
Office of Nuclear Reactor Regulation

Mr. Alexander Adams
Research and Test Reactors Branch A
Office of Nuclear Reactor Regulation



ATTACHMENT 1

**Northwest Medical Isotopes, LLC
Response to the U.S. Nuclear Regulatory Commission
Request for Additional Information
Regarding Chapters 4, 13, and 19 of the
Preliminary Safety Analysis Report and Environmental Review of the
Northwest Medical Isotopes, LLC
Construction Permit Application Docket No. 50-609**

**Clarification to July 25, 2016 Submission on Request for Additional Information –
POSA3-1A, POSA3-1B, POSA3-2A, POSA3-3A, NOI3-1B, and PA3-1**

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Clarification Response to POSA3-1A: Northwest Medical Isotopes, LLC (NWMI) is continuing to evaluate chemical release accidents and will establish preventative or mitigative controls for chemical release accidents with U.S. Nuclear Regulatory Commission (NRC)-licensed material or for chemical accidents that involve processing of licensed radioactive material with high consequences for workers, members of the public, and/or the environment (as determined by the criteria in 10 CFR 70.61, “Performance Requirements”). The set of controls identified in NWMI’s Construction Permit Application, Chapter 13.0, “Accident Analysis,” along with other controls that NWMI may develop, will either reduce the accident likelihood to highly unlikely or reduce the accident consequences to be intermediate or low consequences.

Clarification Response to POSA3-1B: NWMI is continuing to evaluate chemical release accidents and will establish preventative or mitigative controls for chemical release accidents with NRC-licensed material or for chemical accidents that involve processing of licensed radioactive material with intermediate consequences for workers, members of the public, and/or the environment (as determined by the criteria in 10 CFR 70.61). The set of controls set of controls identified in NWMI’s Construction Permit Application, Chapter 13.0, along with other controls that NWMI may develop, will either reduce the accident likelihood to unlikely or reduce the accident consequences to be low consequences.

Clarification Response to POSA3-2A: NWMI is continuing to evaluate radiological accidents and will establish preventative or mitigative controls for radiological accidents with high consequences for workers, members of the public, and/or the environment (as determined by the criteria in 10 CFR 70.61). The set of controls identified in NWMI’s Construction Permit Application, Chapter 13.0, will either reduce the accident likelihood to highly unlikely or reduce the accident consequences to be intermediate or low consequences.

Clarification Response to POSA3-3A: Clarification to this response was discussed at the non-public portion of a meeting held between NWMI and the NRC on August 11, 2016. In summary, the Radioisotope Production Facility (RPF) bounding radiological source term is based on the number of low-enriched uranium (LEU) targets irradiated at the nearby research reactor (MURR). Each irradiated MURR LEU target has nominally four times the radioactivity of an irradiated OSTR (or the hypothetical third reactor) LEU target. Even if the LEU targets from both MURR and OSTR (or the hypothetical third reactor) were both processed in a single week, the OSTR (or hypothetical third reactor) LEU target would dilute the radiological source term in the RPF.

Clarification Response to NOI3-1B: The nearest resident used in noise modeling is nearest to both U.S. Highway 63 and to the proposed RPF. The approximate distance to the residence from U.S. Highway 63 is 85.3 meters (m) [280 feet (ft)], and the distance to the proposed RPF site is 792.5 m (2,600 ft). The noise receptor used in the noise model is 85.3 m (280 ft).

Clarification Response to PA3-1: Off-specification uranium can be generated during target fabrication in the target fabrication system. The off-specification uranium is anticipated to be generated intermittently. The general approach to deal with off specification uranium is for it to be recycled and processed into fresh LEU target material. The exception is if the uranium is not suitable for LEU target material production (e.g., the enrichment is too low). Any LEU material with low enrichment will be stabilized, packaged for secured storage, and then returned to DOE per the Uranium Lease and Take-Back contract.

For the RPF preliminary design, the off-specification uranium operations will be sized to accommodate 25 percent of the total throughput. An allowance has been made in the mass balance for the generation of off-specification uranium. There are three potential areas in the target fabrication system that off-specification uranium may be recovered including:

- Uranium that has been irradiated, recovered during irradiated target processing, and recycled into new LEU target material may eventually be unacceptable for continued ⁹⁹Mo production due to the burnup of ²³⁵U and buildup of unwanted uranium isotopes. This material, which is recovered as uranyl nitrate, will be converted into a stable form for disposition, packaged for secured storage, and returned to DOE.

- If uranium is identified as being off-specification due to the presence of chemical impurities, the material will be recycled to the uranium recycle system within the hot cells. The purified uranyl nitrate will then be recycled to the target fabrication process.
- If LEU target material is identified as being off-specification after being produced (e.g., does not meet process requirements), the material will be recycled to the uranium dissolution step in the target fabrication system.