March 29, 2017

Ms. Carolyn C. Haass, Vice President
Northwest Medical Isotopes, LLC
815 Northwest 9th Street, Suite 256
Corvallis, OR 97330

SUBJECT: NORTHWEST MEDICAL ISOTOPES, LLC – REQUEST FOR ADDITIONAL INFORMATION REGARDING APPLICATION FOR CONSTRUCTION PERMIT (TAC NO. MF6138)

Dear Ms. Haass:

By letter dated July 20, 2015 (NWMI-LTR-2015-006, Agencywide Documents Access and Management System (ADAMS) Accession No. ML15210A114), Northwest Medical Isotopes, LLC. (NWMI) filed with the U.S. Nuclear Regulatory Commission (NRC), pursuant to Section 103 of the Atomic Energy Act of 1954, as amended (the Act), and Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," the second part of its two-part application for a construction permit (CP) for a medical radioisotope production facility. If granted, the CP would allow NWMI to construct a production facility in Columbia, Missouri.

By letter dated December 24, 2015 (ADAMS Accession No. ML15341A112), the NRC staff completed its acceptance review of part two of NWMI's application for a CP. The NRC staff determined that this second and final portion of NWMI's two-part CP application contained the remainder of the preliminary safety analysis report (PSAR) required by 10 CFR 50.34(a), "Preliminary safety analysis report," and was submitted in accordance with the requirements of 10 CFR 2.101, "Filing of application," paragraph (a)(5). Therefore, the application was determined to be complete for docketing and was assigned Docket No. 50-609.

In the course of reviewing NWMI's CP application and request for additional information (RAI) responses, the NRC staff has determined that additional information is required to complete the review of NWMI's PSAR. This RAI supports the NRC staff effort to prepare a safety evaluation report that evaluates the requisite findings for the issuance of a CP.

This RAI supplements the NRC's previous RAI related to the NWMI's CP application sent by letters dated March 28, 2016, September 29, 2016, and January 25, 2017 (ADAMS Accession Nos. ML16056A122, ML16236A013, and ML17013A584, respectively). The specific information requested is addressed in the enclosure to this letter. NWMI's response is due within 30 days from the date of this letter. Timely responses to RAIs contribute toward an efficient and effective review of the application.

In accordance with 10 CFR 50.30(b), “Oath or affirmation,” NWMI must execute its response in a signed original document under oath or affirmation. NWMI’s response must be submitted in accordance with 10 CFR 50.4, “Written communications.” Information included in this response that NWMI considers sensitive or proprietary must be marked in accordance with 10 CFR 2.390, “Public inspections, exemptions, requests for withholding.” Any information related to security should be submitted in accordance with 10 CFR 73.21, “Protection of Safeguards Information: Performance Requirements.”

If you have any questions, please contact me at 301-415-2856 or by electronic mail at Michael.Balazik@nrc.gov.

Sincerely,

/RA/

Michael F. Balazik, Project Manager
Research and Test Reactors Licensing Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Docket No. 50-609

Enclosure:
As stated

SUBJECT: NORTHWEST MEDICAL ISOTOPES, LLC – REQUEST FOR ADDITIONAL INFORMATION REGARDING APPLICATION FOR CONSTRUCTION PERMIT (TAC NO. MF6138) DATED: MARCH 29, 2017

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DATE	3/20/2017	3/20/2017	3/22/2017	3/29/2017

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REQUEST FOR ADDITIONAL INFORMATION

NORTHWEST MEDICAL ISOTOPES, LLC.

REGARDING PRELIMINARY SAFETY ANALYSIS REPORT

CONSTRUCTION PERMIT APPLICATION

DOCKET NO. 50-609

By letter dated February 5, 2015 (NWMI-LTR-2015-003, Agencywide Documents Access and Management System (ADAMS) Accession No. ML15086A262), Northwest Medical Isotopes, LLC. (NWMI) submitted part one of its two-part construction permit (CP) application, primarily consisting of NWMI's environmental report. By letter dated July 20, 2015 (NWMI LTR-2015-006, ADAMS Accession No. ML15210A114), NWMI submitted the second and final part of its application for a CP.

In the course of reviewing NWMI's CP application, the U.S. Nuclear Regulatory Commission (NRC) staff has determined that additional information is required to complete the review of the NWMI preliminary safety analysis report (PSAR) submitted on July 20, 2015 (ADAMS Package No. ML15210A182), and NWMI's request for additional information (RAI) responses (ADAMS Accession No. ML16344A053) in support of the development of its safety evaluation report.

These RAIs have been developed based on the following requirements and guidance applicable to the NWMI production facility, as described in the NWMI PSAR:

- Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50
- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (ADAMS Accession No. ML042430055)
- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (ADAMS Accession No. ML042430048)
- "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ADAMS Accession No. ML12156A069)
- "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ADAMS Accession No. ML12156A075)

Enclosure

- Regulatory Guide 2.5, Revision 1, “Quality Assurance Program Requirements for Research and Test Reactors,” dated June 2010 (ADAMS Accession No. ML093520099)

- American National Standards Institute/ American Nuclear Society (ANSI/ANS)-I5.8-1995 (R2013), “Quality Assurance Program Requirements for Research Reactors

CHAPTER 3.0 – DESIGN OF STRUCTURES, SYSTEMS, AND COMPONENTS

The following RAI is based on the NRC staff review of Section 3.5, Revision A, of the NWMI PSAR and response to RAI 3.5-2 (ADAMS Accession No. ML16344A053) using NUREG-1537, Parts 1 and 2, in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

Section 3.5 – Systems and Components

RAI 3.5-10 Section 50.9, "Completeness and accuracy of information," of 10 CFR Part 50 requires that information maintained by the applicant be complete and accurate in all material respects.

The definition for items relied on for safety (IROFS) is provided in 10 CFR 70.4, "Definitions." The definition states:

> *Items relied on for safety* mean structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at a facility that could exceed the performance requirements in § 70.61 or to mitigate their potential consequences. This does not limit the licensee from identifying additional structures, systems, equipment, components, or activities of personnel (i.e., beyond those in the minimum set necessary for compliance with the performance requirements) as items relied on for safety.

In response to RAI 3.5-2, NWMI revised its PSAR. The NWMI PSAR, Revision A, Section 3.5.1.3, "Nuclear Safety Classifications for Structures, Systems, and Components," states the following classification for structures, systems, and components (SSCs):

> **Safety-related IROFS** - SSCs identified through accident analyses as required to meet the performance requirements of 10 CFR 70.61 (see Table 3-2)
>
> **Safety-related** - SSCs that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of workers, the public, and environment, includes SSCs to meet 10 CFR 20 normal release or exposure limits
>
> **Non-safety-related** - SSCs related to the production and delivery of products or services that are not in the above safety classifications

NWMI PSAR, Revision A, Section 3.5.1.2, "Classifications Definitions," defines Safety-related (SR) as follows:

The definitions used in classifications of SSCs include the following:

> **Safety-related** is a classification applied to items relied on to remain functional during or following a design basis event (DBE) to ensure the:
>
> - Integrity of the facility infrastructure

- Capability to shut down the facility and maintain it in a safe shutdown condition

- Capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to the applicable guideline exposures set forth in 10 CFR 70.61, "Performance Requirements," as applicable

Additional information is needed to understand the application of these definitions to SSCs at the proposed NWMI facility. However, it is not clear if whether all IROFS are classified as SR. Additionally, there appears to be an inconsistency between the definition of SR in revised PSAR Section 3.5.1.2 and SR SSCs in revised PSAR Section 3.5.1.3. SR in Section 3.5.1.2 uses guidelines exposures set forth in 10 CFR 70.61 and SR in Section 3.5.1.3 includes SSCs to meet 10 CFR Part 20 normal release or exposure limits. In response to RAI 3.5-3 and RAI G-4 (ADAMS Accession No. ML16344A053), it is the NRC staff's understanding that NWMI will follow the performance requirements in 10 CFR 70.61(b), 10 CFR 70.61(c), and 10 CFR 70.61(d).

a) Clarify if all engineering safety features and administrative controls IROFS are classified as SR.

b) With respect to the PSAR, Revision A, Sections 3.5.1.2 and 3.5.1.3, clarify if all SSCs that are used to comply with 10 CFR Part 20 dose criteria are classified as SR.

c) Provide additional information to resolve the apparent inconsistency between the definitions of SR in PSAR, Revision A, Section 3.5.1.2 and Section 3.5.1.3, as both of these definitions applies to SSCs but uses different exposure criteria.

d) PSAR, Revision A, Table 3-25, "Systems Safety and Seismic Classifications and Associated Quality Level Group," classifies the Process Steam System as an IROFS with a quality assurance (QA) level 2. Explain the application of QA Level 2 to a system that is classified as an IROFS.

e) Confirm if NWMI plans to comply with the performance requirements in 10 CFR 70.61(b), 10 CFR 70.61(c), and 10 CFR 70.61(d).

CHAPTER 6.0 – ENGINEERED SAFETY FEATURES

The following RAI is based on the NRC staff review of Chapter 6 of the NWMI PSAR (ADAMS Accession No. ML15210A120) and response to RAI 6.3-12 (ADAMS Accession No. ML16344A053) using NUREG-1537, Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

Section 6.3 – Nuclear Criticality Safety in the Radioisotope Production Facility

RAI 6.3-17 Section 6b.3 of the ISG Augmenting NUREG-1537, Part 2, states that the applicant should include a summary description of a documented, reviewed, and approved validation report (by NCS function and management) for each methodology that will be used to perform an NCS analysis. The summary description of a reference manual or validation report should include the following: a summary of the theory of the methodology that is sufficiently detailed and clear to be understood, including the method used to select the benchmark experiments, determine the bias and uncertainty in the bias, and determine the upper subcritical limit.

The Validation Report (NWMI-2014-RPT-006, "MCNP 6.1 Validations with Continuous Energy ENDF/B-VII.1 Cross-Sections," Rev. 0) includes a discussion of physical parameters in the area of applicability (AOA). Additional information is needed to determine if the range of parameters to be modeled to support the facility design are within the AOA and the justification of your margin of subcriticality of 0.05. Specifically, address the following requests in regard to NWMI's response to RAI 6.3-12, dated November 28, 2016 (ADAMS Accession No. ML16344A053).

NWMI's response to RAI 6.3-12b states that "Moving from higher to lower ^{235}U enrichment, the $^{238}U/^{235}U$ ratio decreases and the incident neutron energy spectrum softens due to decreased parasitic absorption of thermal neutrons from ^{238}U." The NRC staff notes that many factors can affect the neutron spectrum. For example, as enrichment increases, the dimensions of fissile material containers and equipment will tend to reduce so as to ensure subcriticality. This can result in more neutron leakage and a corresponding hardening of the neutron energy spectrum. Additionally, NWMI's response states that "Fissions from fast neutrons increases, which results in a softening of the neutron spectrum," appears to be inconsistent.

a) Provide additional information to address the various effects that can affect the neutron spectrum or, if a general case that increasing enrichment always results in spectral softening cannot be made, provide alternate justification for the margin of subcriticality.

b) Justify the choice of benchmarks in the similar enrichment range to your proposed operations. In particular, justify not including benchmarks such as IEU-SOL-THERM-001 that are known to have a large negative bias. Exclusion of these benchmarks could be non-conservative if design calculations are susceptible to similar biases.

CHAPTER 9.0 – AUXILIARY SYSTEMS

The following RAIs on this chapter are based on the NRC staff review of Chapter 9.0 of the NWMI PSAR (ADAMS Accession No. ML15210A118) using NUREG-1537, Parts 1 and 2, in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

Section 9.7 – Other Auxiliary Systems

(Applies to RAIs 9.7-3 through 9.7-5)

Section 50.9, “Completeness and accuracy of information,” of 10 CFR Part 50 requires that information maintained by the applicant be complete and accurate in all material respects.

NUREG-1537, Part 1, Chapter 9, “Auxiliary Systems,” states, in part, that the applicant should provide sufficient information for all auxiliary systems to support an understanding of the design and functions of the systems, with emphasis on those aspects that could affect the production facility and its safety features, radiation exposures, and the control or release of radioactive material. The applicant should include the-following information for each auxiliary system:

(1) design bases

(2) system description, including drawings and specifications of principal components and any special materials

(3) operational analysis and safety function

(4) instrumentation and control requirements not described in Chapter 7, “Instrumentation and Controls Systems," of the safety analysis report (SAR)

(5) required technical specifications and their bases, including testing and surveillance.

NUREG-1537, Part 1, Chapter 9, “Auxiliary Systems,” also states, in part that typical systems discussed in this chapter include the control and storage of radioactive waste and reusable radioactive components and that the applicant should describe the systems and show how they are designed to perform the design-basis functions derived in Chapter 11, “Radiation Protection Program and Waste Management,” of the SAR.

NUREG-1537, Part 1, Chapter 9, Section 9.5, “Possession and Use of Byproduct, Source, and Special Nuclear Material,” states, in part, that the radiological design bases for handling radioactive materials and radioactive waste should be derived from Chapter 11 of the SAR.

NUREG-1537, Part 1, Chapter 9, Section 9.7, “Other Auxiliary Systems,” states, in part, that the applicant should demonstrate that the auxiliary system and any malfunction could not create conditions or events that could cause an

unanalyzed production facility accident or the uncontrolled release of radioactive material beyond those analyzed in Chapter 13 of the SAR.

NUREG-1537, Part 2, Chapter 9, Section 9.5, "Possession and Use of Byproduct, Source, and Special Nuclear Material," states, in part, that the areas of review should include the provisions for controlling and disposing of radioactive wastes, including special drains for liquids and chemicals, and air exhaust hoods for airborne materials, with design bases derived in Chapter 11 of the SAR.

NUREG-1537, Part 2, Chapter 9, Section 9.7, "Other Auxiliary Systems," Acceptance Criteria, states, in part that the design and functional description of the auxiliary system should ensure that it [the system] conforms to the design bases. Section 9.7 further states, in part, under "Evaluation Findings," that this section of the SAR should contain sufficient information to support the following types of conclusions:

- The system has been designed to perform the functions required by the design bases.

- No analyzed functions or malfunctions could initiate the uncontrolled release of radioactive material.

RAI 9.7-3 NWMI PSAR Section 9.7.2, "Control and Storage of Radioactive Waste," does not include sufficient information to determine whether the design as described in the PSAR will meet the design bases. Preliminary input flows, tank volumes, high-dose waste concentrator flow, and a discussion of system operation and control were not provided in the PSAR.

For example, the PSAR describes weekly target processing resulting in frequent additions of different acids and radionuclides to the single high-dose waste collection tank. PSAR Section 9.7.2.2.1 provides no preliminary discussion of the processes used to add and mix sufficient NaOH to maintain the solution pH within the range required for high-dose waste concentrator operation. PSAR Section 9.7.2.2.2 provides no preliminary information on water quality requirements for recycle or quantitative estimates of how much will be recycled and how much will flow to the low-dose waste collection tank. More information is needed to understand system function and operation for both the high-dose and low-dose waste systems.

a) Provide process flow diagrams of the radioactive waste systems, including inputs, storage, preparation for processing, sampling and analysis, and expected throughputs/frequency of processing to support target processing. Show anticipated values of relevant parameters (e.g., nuclides, concentrations, chemical constituents, activity, volumes, flowrates, batch sizes, etc.) to enable evaluation of the design. Anticipated values presented should reflect the maximum waste generation rates resulting from nominal operational processing capability as presented in PSAR Section 4.1.2.1, "Process Design Basis."

b) Provide a discussion of the operation of the high-dose liquid waste handling system. This discussion should include sufficient information to understand how the contents of the high-dose waste collection tank are sampled and controlled coincident with inputs from the offgas system, the molybdenum waste tanks, and the uranium recovery system.

RAI 9.7-4 NWMI PSAR Chapter 3, Table 3-3 "Relevant U.S. Nuclear Regulatory Commission Guidance," does not list Regulatory Guide (RG) 1.143, "Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants". PSAR Section 3.1.7 "Codes and Standards," states the codes and standards listed in Table 3-7 "Design Codes and Standards," are design inputs but further states, in part that the specific requirements for that system produced by each applicable reference are identified in system design descriptions. Although Table 3-7, lists ANSI/ANS-55.1, "Solid Radioactive Waste Processing System for Light Water Cooled Reactor Plants," 1992 (R2009), ANSI/ANS-55.4, "Gaseous Radioactive Waste Processing Systems for Light Water Reactor Plants," 1993 (R2007) and ANSI/ANS-55.6, "Liquid Radioactive Waste Processing System for Light Water Cooled Reactor Plants," 1993 (R2007), these standards are not included in PSAR Section 9.7.2. In response to RAI 3.5-1 (ADAMS Accession No. ML16123A119), NWMI stated that specific design codes and standards will be finalized in the final design.

Thus, NWMI has made no design commitments for waste systems and there is insufficient information on the design of the radioactive waste systems and the waste staging and shipping building to conclude definitively that the design of radioactive waste systems will comply with NRC regulatory requirements.

a) Verify if NWMI intends to use RG 1.143 and the associated ANSI/ANS standards as a design input for the radioactive waste system. If so, these guidance and standards should be listed in PSAR Sections 3.1.7 and 9.7.2.

With a single input tank (i.e., high dose waste collection tank) and output tank (i.e., waste concentrate collection tank) for the high-dose waste system and with frequent inputs to the collection tank from various waste sources, it is unclear how the output tank can be isolated and recirculated to assure a representative sample can be obtained and analyzed.

b) Provide additional information to explain how the radioactive waste system design will provide for sampling and analysis of the high dose waste collection tanks and/or waste concentrate collection tank.

RAI 9.7-5 PSAR Section 9.7.2 provides a description of the radioactive waste control and storage systems. As stated in PSAR Section 9.7.2.1, the waste handling system design basis provides:

- Lag storage capability for liquid waste, divided into high-dose and low-dose source terms
- Safely transit solid waste from hot cells to a waste encapsulation area
- Capability to solidify low-dose liquid waste and load drums

- Capability to solidify high-dose liquid waste and load high-integrity containers (HICs)
- Capability to encapsulate solid waste in drums
- Capability to handle and load a waste shipping cask with radiological waste drums or containers
- Storage space for Class A radioactive waste
- Storage space for decay of high-dose waste in HICs to meet DOT shipping requirements.

The radioisotope production facility (RPF) is designed for continuous sequential batch operation. After startup and operations longer than the longest lag storage, systems will contain an equilibrium in-process radioactive material inventory. PSAR Table 1-3 presents that inventory as 187,000 curies for the high-dose waste tanks. The concentration of radioactive material in the high-dose waste concentrate tank will be elevated by the volume reduction provided by the high-dose waste concentrator. Thus radioactive material concentrations in HICs will be significant and decay prior to shipment may be necessary to meet shipping requirements. The RPF design includes a high-dose waste decay cell with 15 locations for HICs or drum pallets. This is the only location identified for storage of high-dose waste. The HICs, containing the same solidified high-dose liquid waste stream, should have similar radiation levels and require similar decay durations to be acceptable for shipment. The reserve storage locations for high-dose waste HICs to account for any delay in shipment of waste is reduced by the number of weeks required for decay in storage.

NUREG-1537, Part 2, Acceptance Criteria for Section 11.2.1, "Radioactive Waste Management Program," states: "The program should be sufficiently flexible to accommodate changing radioactive waste loads, changing regulatory requirements, and changing environmental factors, and should remain effective in protecting the health and safety of the facility staff and the public." NUREG-1537 does not contain guidance regarding what constitutes adequate storage to be "sufficiently flexible."

Waste production volumes presented in PSAR Table 11-6 indicate waste generation rates of between one and two HICs per week. At one HIC per week the maximum available decay in storage in the high-dose waste decay cell would be 15 weeks. Any delay in transport and/or disposal strategies assumed could reduce reserve storage capacity. Failure to maintain reserve on-site storage capacity could significantly disrupt the as-designed, continuous operations.

a) Provide additional information that quantifies the duration of required decay in storage in the high-dose waste decay cell for waste representative of the "total equilibrium in-process inventory" before the dose rate on the HIC is sufficiently low to meet the shipping requirements in the proposed cask.

b) Justify that the high-dose waste decay cell has adequate capacity to accommodate both waste being decayed in storage and waste shipments that are delayed due to weather or other conditions that delay transport.