March 28, 2016

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 NOS. MF6135 AND MF6138) AND NRC STAFF REVIEW SCHEDULE

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 for a medical radioisotope production facility. If granted, the construction permit 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 construction permit and determined that this second and final portion of NWMI's two-part construction permit application contained the remainder of the preliminary safety analysis report required by 10 CFR 50.34(a) and was submitted in accordance with the requirements of 10 CFR 2.101(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 construction permit application, the NRC staff has determined that additional information is required to complete the review of NWMI's preliminary safety analysis report (PSAR) and environmental report (ER) in order for the NRC staff to prepare a safety evaluation report and environmental impact statement, respectively.

This request for additional information (RAI) supplements, in part, the NRC's RAIs related to the NWMI ER by letters dated November 2, 2015 (ADAMS Accession No. ML15288A102), and January 19, 2015 (ADAMS Accession No. ML16020A366). The specific information requested is addressed in the enclosure to this letter (Enclosure 1). It is requested that NWMI respond to this request within 30 days of 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), 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."

Additionally, this letter forwards the NRC staff's safety and environmental review schedule for the NWMI construction permit application (Enclosure 2). The NRC staff will follow the enclosed schedule to complete the 10 CFR Part 50 and Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," reviews of NWMI's PSAR and ER. Milestones dates for hearing activities are not included in the enclosed schedule because those dates would be established by the Commission or, if a contested hearing is held, the Atomic Safety and Licensing Board. The NRC staff will make every effort to meet the scheduled milestones. The NRC staff will provide updates to the enclosed schedule (1) after all RAIs have been addressed, (2) after the closing of the comment period for the draft environmental impact statement, and (3) if a significant change to the review schedule should occur.

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

Sincerely,

/RA/

Alexander Adams, Jr., Chief
Research and Test Reactors Licensing Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Docket No. 50-609

Enclosures:
As stated

cc: See next page

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ADAMS Accession No.: ML16056A122 *concurrence via e-mail

OFFICE	NRR/DPR/PRLB/PM	NRR/DPR/PRLB/LA*	NMSS/FCSE/FMB/PM	NRR/DLR
NAME	MBalazik	NParker	DTiktinsky*	NMartinez*
DATE	3/ /2016	3/1/2016	3/1/2016	2/25/2016
OFFICE	NRR/DPR/PRLB/BC	NRR/DPR/PRLB/PM		
NAME	AAdams	MBalazik		
DATE	3/ 28 /2016	3/ 28 /2016		

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REQUEST FOR ADDITIONAL INFORMATION

NORTHWEST MEDICAL ISOTOPES, LLC.

REGARDING PRELIMINARY SAFETY ANALYSIS REPORT

AND ENVIRONMENTAL 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 application, primarily consisting of NWMI's environmental report (ER). 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 construction permit. With this submittal, NWMI also provided an update to its ER.

In the course of reviewing NWMI's construction permit 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), in support of the development of its safety evaluation report. Additionally, the NRC staff has determined that additional information is required to complete the review of the NWMI ER in support of the development of the NRC environmental impact statement.

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 and Part 51
- 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),

- NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors" (ADAMS Accession No. ML062190191),
- Regulatory Guide 2.5, Revision 1, "Quality Assurance Program Requirements for Research and Test Reactors," dated June 2010 (ADAMS Accession No. ML093520099) and,
- ANSI/ANS-I5.8-1995 (R2013), "Quality Assurance Program Requirements for Research Reactors.

GENERAL INFORMATION REQUEST

RAI G-1 The NRC staff will make a finding per 10 CFR 50.35, “Issuance of Construction Permits,” regarding whether 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.

The application, as submitted, contains information on both the target fabrication and production facility activities. This information includes potential events and items relied on for safety (IROFS). NWMI has requested a review of its construction permit application for a production facility only. NWMI did not specifically identify which events, IROFS, and principal architectural and engineering criteria (PAEC) (e.g., codes and standards, etc.) apply to the production facility only.

Identify the events, PAEC, and IROFS that apply to the production facility.

CHAPTER 3 – DESIGN OF STRUCTURES, SYSTEMS, AND COMPONENTS

The following questions are based on the NRC staff's review of Chapter 3 of the NWMI PSAR (ADAMS Accession No. ML15210A117) using NUREG-1537 Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

Section 3.1 – Design Criteria

RAI 3.1-1 NUREG-1537, Part 1, Section 3.1, "Design Criteria," states, in part, that the applicant should specify the design criteria for the facility structures, systems, and components and should include applicable standards, guides, and codes.

NUREG-1537, Part 2, Section 3.1, "Design Criteria," states, in part, that the reviewer find that the design criteria are based on applicable standards, guides, codes, and criteria and provide reasonable assurance that the facility structures, systems, and components can be built and will function as designed and required by the analyses in the safety analysis report. The design criteria provide reasonable assurance that the public will be protected from radiological risks resulting from operation of the production facility.

While the NWMI PSAR, Section 3.1, "Design Criteria," describes the design criteria applied to the radioisotope production facility (RPF) to include NRC guidance, *Code of Federal Regulations*, local government documents, Discovery Ridge/University of Missouri Requirements, and design codes and standards Table 3.7, "Design Codes and Standards," lists additional design inputs for the RPF. NWMI has not specifically identified to which standards, guides, codes, and criteria it is committing to construct its production facility.

a. Identify which design codes, standards and other referenced documents are commitments that are intended to demonstrate that the regulatory requirements have been met for the 10 CFR Part 50 production facility.

b. Identify what specific parts of the design codes, standards and other referenced documents NWMI is committing to if it is not committing to them in their entirety.

Section 3.5 – Systems and Components

RAI 3.5-1 The ISG Augmenting NUREG-1537, Part 2, Section 12.1, "Organization," states, in part, that the use of Integrated Safety Analysis (ISA) methodologies as described in 10 CFR Part 70 "Domestic Licensing of Special Nuclear Material" and NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," are an acceptable way of demonstrating adequate safety for construction and operation of a medical isotope production facility. As stated in the ISG, NUREG-1520, Section 3.4, provides additional criteria for adherence to the safety program and ISA performance.

NUREG-1520, Section 3.4.3.2(9), states that the determination that an event is "not credible" must not depend on any facility features that may credibly fail or be rendered ineffective as the result of a change to a system.

NWMI PSAR, Radioisotope Production Facility Integrated Safety Analysis Summary, Section 3.3, "Definitions of Likelihood and Likelihood Categorization," includes three definitions used to define an event as "not credible" from NUREG-1520, but without the prohibition against the use of facility features in making this determination. NWMI PSAR, Section 3.5.1.3.1, "Safety-Related Structures, Systems, and Components," and Section 3.5.2.2, "Classification of Systems and Components Important to Safety," refer to structures, systems, and components being designed to remain functional following a design basis event to ensure the potential for criticality is "not credible."

Clarify that the determination that an event is "not credible" does not depend on facility features that may credibly fail or be rendered ineffective as the result of a change or demonstrate that an alternative approach is acceptable.

CHAPTER 6 – ENGINEERED SAFETY FEATURES

The following questions of this chapter are based on a review of Chapter 6 of the NWMI PSAR (ADAMS Accession No. ML15210A120) 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 Control in the Radioisotope Production Facility

(Applies to RAIs 6.3-1 through 6.3-7)

As required by 10 CFR 50.34(a)(4), the minimum information in the PSAR shall include "[a] preliminary analysis and evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility…, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents."

The ISG Augmenting NUREG-1537, Part 1, Chapter 13b, "Radioisotope Production Facility Accident Analyses," states, in part, that the use of ISA methodologies as described in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," and NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," Revision 1, May 2010, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR Section 70.61, designation of IROFS, and establishment of management measures are acceptable ways of demonstrating adequate safety for the medical isotopes production facility. Applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features, and alternate methods of assuring the availability and reliability of the safety features. As used in this ISG, the term "performance requirements," when referencing 10 CFR Part 70, Subpart H, is not intended to mean that the performance requirements of Subpart H are required for a radioisotope production facility license, only that their use as accident consequence and likelihood criteria may be found acceptable by NRC staff.

RAI 6.3-1 The ISG augmenting NUREG-1537, Part 2, Section 6.b.3, "Nuclear Criticality Safety (NCS) for the Processing Facility," states, in part, that the reviewer should review all aspects of the applicant's NCS program including management, organization, and technical practices.

NWMI PSAR, Section 6.3, "Nuclear Criticality Safety in the Radioisotope Production Facility," describes numerous elements of the NCS Program as being "developed for the Construction Permit Application." However, several of these program elements only appear applicable to operating facilities (e.g., operator training, operating procedures, maintenance, and postings).

Identify those specific parts of the NCS Program that will be implemented during design and construction.

RAI 6.3-2 The ISG augmenting NUREG-1537, Part 2, Section 6.b.3, "Nuclear Criticality Safety for the Processing Facility," states in the acceptance criteria that "NCS limits on controlled parameters will be established to ensure that all nuclear processes are subcritical, including an adequate margin of sub-criticality for safety."

NWMI PSAR, Section 6.3, "Nuclear Criticality Safety in the Radioisotope Production Facility," does not contain commitments to the technical practices identified in Section 6b.3, of the ISG. Specifically, the application does not contain commitments related to the use of each controlled parameter.

Identify commitments to the technical practices to ensure that all nuclear processes are subcritical, including an adequate margin of subcriticality for safety as stated in Section 6b.3 of the ISG.

RAI 6.3-3 The ISG augmenting NUREG-1537, Part 2, Section 6.b.3, "Nuclear Criticality Safety for the Processing Facility," states, in part, 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.

NWMI PSAR, Section 6.3, "Nuclear Criticality Safety in the Radioisotope Production Facility," does not contain a description of the validation methodology or justification of the minimum margin of subcriticality.

Provide a description of the validation methodology and the validation report that was used in the criticality evaluation.

RAI 6.3-4 The ISG augmenting NUREG-1537, Part 2, Section 6.b.3, "Nuclear Criticality Safety for the Processing Facility," states that the applicant should include the configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other quality assurance elements used by the applicant.

NWMI PSAR, Section 6.3, "Nuclear Criticality Safety in the Radioisotope Production Facility," does not contain a description of the qualifications for staff responsible for NCS during construction.

Provide a description of the qualifications for NWMI staff responsible for NCS during construction.

RAI 6.3-5 The ISG augmenting NUREG-1537, Part 2, Section 6.b.3, "Nuclear Criticality Safety for the Processing Facility," states that the applicant should provide a description of a criticality accident alarm system (CAAS) that is appropriate for the facility for the type of radiation detected, the intervening shielding, and the

magnitude of the minimum accident of concern. The technical basis shall demonstrate that the CAAS will meet the requirements of 10 CFR 70.24(a).

NWMI PSAR, Section 6.3, "Nuclear Criticality Safety in the Radioisotope Production Facility," states that evaluation of CAAS coverage will be performed after the final design is complete but prior to startup.

Provide a description of the methods that will be used to evaluate coverage and include appropriate construction related commitments to ensure CAAS coverage in the facility where shielding is present.

RAI 6.3-6 The ISG augmenting NUREG-1537, Part 2, Section 6.b.3, "Nuclear Criticality Safety for the Processing Facility," states that the applicant should describe the criticality accident alarm system that is capable of detecting a criticality.

NWMI PSAR, Section 2.5, "Criticality Accident Monitoring and Alarms," states the facility CAAS will comply with ANSI/ANS-8.3, "Criticality Accident Alarm System," as modified by Regulatory Guide 3.71, "Nuclear Criticality Safety Standards for Fuels and Materials Facilities." The guidance on criticality accident alarm systems, as specified in ANSI/ANS-8.3-1997 is generally acceptable to the NRC staff with the exception that 10 CFR 70.24, "Criticality Accident Requirements," requires criticality alarm systems in each area in which special nuclear material is handled, used, or stored.

Various sections in the NWMI PSAR seem to be inconsistent on where a CAAS is needed. Section 4.3.2.2.5, "Special Nuclear Material Description," states there will be CAAS coverage in all areas where special nuclear material (SNM) is handled, processed, or stored. Section 3.5.2.7.7, "Criticality Accident Alarm System," states the design bases for the CAAS is to "provide for continuous monitoring, indication, and recording of neutron or gamma radiation levels in areas where personnel may be present and wherever an accidental criticality event could result from operational processes," however, the design basis values includes "except for events occurring in areas not normally accessed by personnel and where shielding provides protection against a criticality."

a. Provide information to resolve the apparent inconsistency between NWMI PSAR Sections 2.5, 4.3.2.2.5 and 3.5.2.7.7.

b. Identify areas in which sufficient quantities of SNM, as specified in 10 CFR 70.24(a), are handled, processed, or stored but are not under CAAS coverage does not comply with Regulatory Guide 3.71 or the ISG augmenting NUREG-1537, Part 2, Section 6.b.3.

   If the applicant is intending to propose a different approach from the guidance in the ISG, provide a justification for the proposed approach.

RAI 6.3-7 The ISG augmenting NUREG-1537, Part 2, Section 6.b.3, "Nuclear Criticality Safety for the Processing Facility," states, in part, that the applicant should commit to ANSI/ANS-8.19-1996, "Administrative Practices for Nuclear Criticality Safety," as it relates to audits and assessments. Audits should be independent of the programs being audited to the extent practical.

NWMI PSAR, Section 6.3, "Nuclear Criticality Safety in the Radioisotope Production Facility," states that management assessments of the NCS Program (program audits) will be led by the NCS Manager, but does not indicate how independency will be maintained when performing management assessments.

Clarify how management will independently assess criticality evaluations performed by the NWMI staff.

Section 6.4 – References

RAI 6.4-1 10 CFR Section 50.9, "Completeness and accuracy of information," requires that information maintained by the applicant be complete and accurate in all material respects.

NWMI PSAR, Section 6.4, "References," contains a list of ANSI/ANS-8 NCS standards to which NWMI is committing. There is a different (shorter) list of these standards contained in Section 3.1.7, Table 3.7, "Design Codes and Standards," of the application.

Clarify which standards NWMI is committing to during design and construction.

CHAPTER 13 – ACCIDENT ANALYSIS

The following questions are based on the NRC staff's review of Chapter 13 of the NWMI PSAR (ADAMS Accession No. ML15210A122 and ML15210A124) using the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

Section 13.1 – Analysis of Accidents Methodology and Preliminary Hazards Analysis

RAI 13.1-1 The ISG augmenting NUREG-1537, Part 2, Section 6.b.3, "Nuclear Criticality Safety for the Processing Facility," states, in part, that the applicant needs to meet the acceptance criteria in Section 13b, of the standard review plan, as they are related to the identification, consequences, and likelihood of NCS accident sequences, as well as descriptions of IROFS for NCS accident sequences.

While the NWMI PSAR, Section 1.2.3.2.2, "Identification of Hazards," and Section 13.1.1.2, "Accident Consequence Analysis," states that among the hazards identified are "high radiation dose due to accidental nuclear criticality," it is not clear that among the prevented hazards is the occurrence of accidental criticality regardless of whether it results in a high radiation dose.

Provide clarification that among the prevented hazards is the occurrence of accidental criticality regardless of whether it results in a high radiation dose or demonstrate that an alternative approach to the ISG is acceptable.

Section 13.2 – Analysis of Accidents with Radiological and Criticality Safety Consequences

RAI 13.2-1 The ISG augmenting NUREG-1537, Part 2, Section 6.b.3, "Nuclear Criticality Safety for the Processing Facility," states that criticality accident analyses should be identified, including the assumption that all criticality accidents are high-consequence events and that the applicant's bases and methods are based on using preventive controls.

NWMI PSAR, Section 13.2, "Analysis of Accidents with Radiological and Criticality Safety Consequences," of the application states that a criticality accident is assumed to have high consequences to the worker if not prevented. Table 13-3, "Radioisotope Production Facility Consequence Severity Categories Derived from 10 CFR 70.61," which defines consequence categories, includes as a high-consequence event "unshielded nuclear criticality." ISA Section 3.4.1, also defined criticality as a high-consequence event. It is not clear whether a shielded criticality would be considered a high-consequence event.

Clarify whether a shielded criticality accident is considered a high-consequence event.

CHAPTER 19 – ENVIRONMENTAL REVIEW

The request for additional information (RAI) set forth below is based on a review of Chapter 19 of NWMI's PSAR (ADAMS Accession Nos. ML15210A182) using the final ISG augmenting NUREG-1537, Parts 1 and 2 and NWMI's RAI responses submitted on November 20, 2015 (ADAMS Accession No. ML15328A010). The requested information is needed to evaluate the environmental impacts of the proposed action. In accordance with 10 CFR 51.41, "Requirement to Submit Environmental Information," provide the following information.

Section 19.2 – Proposed Action

RAI PA2-4 The ISG augmenting NUREG-1537, Part 1, Section 19.2, "Proposed Action," states that the application should describe the proposed action and provide a detailed description of the proposed action and the general progression of the project including, in part, pre-operational and operational activities.

NWMI's response to RAI PA-1B, states that the estimated number of low enriched uranium (LEU) targets that can be irradiated (e.g., per batch) at the Oregon State University TRIGA Reactor (OSTR) or hypothetical third reactor is one batch per week with a maximum of 30 LEU targets/batch. Each reactor can irradiate up to eight batches per year for a total of 16 batches annually. Further, the response states that the NWMI RPF will be designed to fabricate a maximum of 1,040 targets annually and will have the capacity to process up to 900 irradiated LEU targets for ^{99}Mo production. Section 19.2.1, of the ER states the nominal operational processing capacity of the RPF would be one batch per week (up to 12 targets per batch) for up to 52 weeks, and approximately 30 targets from the OSTR or a third university reactor for eight weeks per year per reactor. Therefore, the maximum irradiated target capacity at each research reactor would be 624 LEU targets at the University of Missouri Research Reactor (1 batch/week, 12 LEU targets/batch, 52 batches/year), 240 targets at the OSTR (1 batch/week, 30 LEU targets/batch, 8 batches/year), and 240 targets at a third reactor (1 batch/week, 30 LEU targets/batch, 8 batches/year), for a total of 1,104 irradiated targets, which would also equal the nominal operation processing capacity of the RPF.

a. Explain the differences in the total annual RPF target processing capacity number stated in the RAI response PA-1B (900 irradiated LEU target for ^{99}Mo production) versus the total annual RPF designed operational processing capability discussed in Section 19.2.1, of the ER (1,104 irradiated LEU targets for ^{99}Mo production).

b. Explain the differences in the total annual RPF designed operational processing capability discussed in Section 19.2.1, of the ER (1,104 irradiated LEU targets for ^{99}Mo production) versus the total annual RPF LEU target fabrication capacity (1,040 LEU targets) stated in RAI response PA-1B.

c. Clarify the RPF LEU target fabrication capacity and the nominal operational processing capacity of the RPF.

d. Clarify whether the impacts analyzed in the PSAR are based on fabricating 900 LEU targets, 1,040 LEU targets, or 1,104 LEU targets.

e. Clarify whether the impacts analyzed in the PSAR are based on an RPF target processing for ^{99}Mo production of 900 LEU targets, 1,040 LEU targets, or 1,104 LEU targets.

RAI PA2-5 The ISG Augmenting NUREG-1537, Part 1, Section 19.2, "Proposed Action," and Section 19.4.1, "Land Use and Visual Resources," state that the applicant should estimate the footprint of major buildings and the number of acres that would be changed on a temporary and permanent basis during construction, operation, and decommissioning.

NWMI PSAR, Section 19.2.2.2, "Radioisotope Production Facility Site Location and Layout," states, in part, that the major structures include the RPF, Waste Staging and Shipping Building, and Diesel Generator Building. Additionally, the site has an Administration Building and Security Stations. The RPF main building is approximately 106.7 m (350 ft) long and 56.4 m (185 ft) wide.

The dimensions for the Waste Staging and Shipping Building, and Diesel Generator Building and the Administration Building and Security Stations, however, are not provided in the PSAR.

Provide the building dimensions and approximate footprint for: the Waste Staging and Shipping Building, Diesel Generator Building and the Administration Building, and Security Stations.

RAI PA2-6 The ISG augmenting NUREG-1537, Part 1, Section 19.2, "Proposed Action," states that the application should describe heating and cooling dissipation systems and Section 19.4.2, "Air Quality and Noise," states that the ER should provide estimates of on-site and off-site vehicle and other emissions resulting from construction, operations, and decommissioning.

NWMI's response to RAI PA-6, in part, states that one set of boilers will be used for heating, ventilation and air conditioning of the RPF.

Clarify and identify the heating energy source for the administration building, waste staging and shipping building, and diesel generator building. Additionally, quantify and provide air emissions from the energy source.

Preliminary Construction Permit Application Review Schedule for

Northwest Medical Isotopes, LLC

Milestone	Completion Date Actual (A) Target (T)
Application Receipt	
Receipt of Environmental Report (Part One of Two-Part Construction Permit Application)	02/2015 (A)
Receipt of Preliminary Safety Analysis Report (Part Two of Two-Part Construction Permit Application)	07/2015 (A)
Acceptance Review	
Acceptance of Environmental Report for Docketing	06/2015 (A)
Acceptance of Preliminary Safety Analysis Report for Docketing	12/2015 (A)
Environmental Review Schedule	
Environmental Site Audit	09/2015 (A)
Issuance of Request for Additional Information on Environmental Report	11/2015 (A)
Environmental Scoping Meeting in Columbia, MO	12/2015 (A)
Issuance of Supplemental Request for Additional Information on Environmental Report	01/2016 (A)
Draft Environmental Impact Statement	12/2016 (T)
Final Environmental Impact Statement	05/2017 (T)
Safety Review Schedule	
Issuance of Request for Additional Information on Preliminary Safety Analysis Report	03/2016 (A)
Issuance of Supplemental Request for Additional Information on Preliminary Safety Analysis Report	08/2016 (T)
Completion of Draft Safety Evaluation Report	06/2017 (T)
Advisory Committee on Reactor Safeguards Subcommittee Meeting	07/2017 (T)
Advisory Committee on Reactor Safeguards Subcommittee Meeting	08/2017 (T)
Advisory Committee on Reactor Safeguards Full Committee Meeting	09/2017 (T)
Completion of Safety Evaluation Report	09/2017 (T)
Hearing	
Mandatory Hearing on Construction Permit Application	TBD
License	
Commission Decision on Construction Permit	TBD