NWMI
NORTHWEST MEDICAL ISOTOPES

April 25, 2016
NWMI-LTR-2016-006

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: Docket No. 50-609. Northwest Medical Isotopes, LLC Responses to the U.S. Nuclear Regulatory Commission Environmental Request for Additional information – Letter Dated March 28, 2016

References:

1. U.S. Nuclear Regulatory Commission letter to Northwest Medical Isotopes, LLC, dated March 28, 2016, Docket No. 50-609 (ADAMS Accession No. ML16056A122), Request For Additional Information Regarding Application For Construction Permit (TAC Nos. Mf6135 And Mf6138) and NRC Staff Review Schedule
2. Northwest Medical Isotopes, LLC Letter NWMI-LTR-20 15-006 to U.S. Nuclear Regulatory Commission, dated July 20, 2015 (ADAMS Accession No. ML16056A122), *NRC Project No. 0803- Northwest Medical Isotopes, LLC, Submittal Part 2 Construction Permit Application for a Radioisotope Production Facility*
3. Northwest Medical Isotopes, LLC Letter to U.S. Nuclear Regulatory Commission, dated February 5, 2015 (ADAMS Accession No. ML14349A501) and Associated Part One Submittal, Environmental Report ADAMS Accession Nos. ML15210A123, ML15210A128, ML15210A129, and ML15210A131)

Dear Mr. Balazik:

Northwest Medical Isotopes, LLC (NWMI) is providing the attached response (Attachment 1) to the U.S. Nuclear Regulatory Commission request for additional information dated March 28, 2016.

NWMI is submitting this response 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 April 25, 2016.

A001
NRR

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

Sincerely,

Carolyn C. Haass

Carolyn C. Haass
Chief Operating Officer

Enclosures: Attachment 1

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

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NORTHWEST MEDICAL ISOTOPES

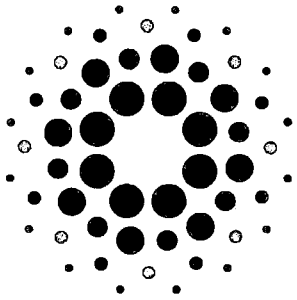
ATTACHMENT 1

Northwest Medical Isotopes, LLC

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

(Document No. NWMI-2016-RAI-002, April 2016)

Information is being provided via hard copy



NWMI

NORTHWEST MEDICAL ISOTOPES

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

NWMI-2016-RAI-002, Rev. 0
April 2016

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

NWMI-2016-RAI-002, Rev. 0

Date Published:
April 25, 2016

***Document Number*: NWMI-2016-RAI-002**	***Revision Number*: 0**
***Title*: Response to the U.S. Nuclear Regulatory Commission Request for Additional Information Regarding Preliminary Safety Analysis Report and Environmental Review of the Northwest Medical Isotopes, LLC Construction Permit Application Docket No. 50-609**	
***Approved by*: Carolyn Haass**	***Signature*:** Carolyn C Haass

REVISION HISTORY

Rev	Date	Reason for Revision	Revised By
0	4/25/2016	Issued for Submittal to the NRC	N/A

TERMS

Acronyms and Abbreviations

^{99}Mo	molybdenum-99
AEC	active engineered control
CAAS	criticality accident alarm system
CFR	Code of Federal Regulations
CPA	Construction Permit Application
CSE	criticality safety evaluation
ER	Environmental Review
HVAC	heating, ventilation, and air conditioning
IROFS	items relied on for safety
ISA	integrated safety analysis
ISG	Interim Staff Guidance
LEU	low-enriched uranium
MCNP	Monte-Carlo N-Particle
MURR	University of Missouri Research Reactor
NCS	nuclear criticality safety
NCSE	nuclear criticality safety evaluation
NRC	U.S. Nuclear Regulatory Commission
NWMI	Northwest Medical Isotopes, LLC
OSTR	Oregon State University TRIGA Reactor
PAEC	principle architectural and engineering criteria
PEC	passive engineered control
PHA	process hazards analysis
PSAR	preliminary safety analysis report
RAI	request for additional information
RPF	Radioisotope Production Facility
SNM	special nuclear material
SSC	structures, systems, and components
TRIGA	Training, Research, Isotopes, General Atomics
U.S.	United States
USL	upper subcritical limit

Units

ft	feet
ft^2	square feet
m	meter
min	minute

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No.	Request for Additional Information
	General Information
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.*

RAI G-1 requests identification of events, principal architectural and engineering criteria (PAEC), and items relied on for safety (IROFS) that apply to the 10 CFR 50 production facility. The Northwest Medical Isotopes, LLC (NWMI) Radioisotope Production Facility (RPF) is an integrated facility and there are very few sections of the Construction Permit Application (CPA) that exclusively apply to the 10 CFR 70 area. Therefore, our response identifies the limited amount of information/sections that are only applicable to 10 CFR 70.

The process hazards analysis (PHA) does identify events that mainly apply to the 10 CFR 70 target fabrication area. These events are reflected in the PHA node 1.0.0 sequences for target fabrication (see Table 13-9 of NWMI-2013-021, *Construction Permit Application for Radioisotope Production Facility*). However, there are events in the target fabrication node 1.0.0 that evaluate the interface events (e.g., transfers between the 10 CFR 70 and 10 CFR 50 areas). 10 CFR 70 services are also provided from 10 CFR 50 systems (e.g., steam and cooling water, and the heating, ventilation, and air conditioning [HVAC] systems).

There are no IROFS that currently only apply to 10 CFR 70 target fabrication (there are numerous criticality-based IROFS that apply to both 10 CFR 70 and 10 CFR 50 areas of the facility). There are four criticality safety evaluations (CSE) and associated controls that only apply to 10 CFR 70 target fabrication. The preliminary CSEs define a series of passive engineered controls (PEC), active engineered controls (AEC), and administrative controls that are credited to satisfy the double-contingency control principle for prevention of nuclear criticality events such that at least two changes in process conditions must occur before criticality is possible. These PECs, AECs, and administrative controls are described in Chapter 6.0, "Engineered Safety Features," and summarized in Table 6-9 of the CPA (NWMI-2013-021). The following is a list of 10 CFR 70 CSEs:

- NWMI-2015-CSE-04, *Low-Enriched Uranium Target Material Production*
- NWMI-2015-CSE-05, *Target Fabrication Uranium Solution Processes*
- NWMI-2015-CSE-06, *Target Finishing*
- NWMI-2015-CSE-07, *Target and Can Storage and Carts*

There are no PAECs in Chapter 3.0, "Design of Structures, Systems, and Components," of NWMI-2013-021 identified at this time that only apply to 10 CFR 70 structures, systems, and components (SSC).

There are three section is Chapter 4.0, "Facility Description," that focus on 10 CFR 70 target fabrication: Sections 4.1.3.1, "Target Fabrication," 4.1.4.4, "Target Fabrication Area," and 4.4.2, "Processing of Unirradiated Special Nuclear Material."

No.	Request for additional information
	Section 3.1 – Design Criteria
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.*
3.1-1A	*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.*

The CPA and associated preliminary design identifies codes, standards, and other referenced documents that may be applicable to the RPF. The specific RPF design codes, standards, and other referenced documents, including exceptions or exemptions to the identified requirements, will be finalized in the RPF final design and provided to the U.S. Nuclear Regulatory Commission (NRC) in late 2016. In addition, the codes, standards, and referenced documents for the RPF safety SSCs that are needed to demonstrate compliance with regulatory requirements will be identified and committed to in the Operating License Application.

3.1-1B	*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.*

The codes, standards, and referenced documents for the RPF SSCs that are needed to demonstrate compliance with regulatory requirements will be identified and committed to in the Operating License Application. If there are specific exceptions to code requirements, NWMI will identify the exceptions as part of the Operating License Application submittal.

No.	Request for additional information
	Section 3.5 – Systems and Components
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.*

NWMI understands that for an event to be "not credible," the event must not depend on facility features that may fail or be rendered ineffective. This definition was implemented and used in the integrated safety analysis (ISA) process and in Chapter 13.0, "Accident Analysis," of the CPA (NWMI-2013-021).

The Chapter 3.0 bullet in question, located in both referenced sections, Sections 3.5.1.3.1 and 3.5.2.2:

- Ensure the potential for an inadvertent criticality accident is not credible

will be changed to:

- Prevent an inadvertent criticality accident

No.	Request for additional information
	Section 6.3 – Nuclear Criticality Control in the Radioisotope Production Facility
6.3	*(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.*
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.*

The intent of Section 6.3 of the CPA (NWMI-2013-021) is to demonstrate an understanding of a nuclear criticality safety (NCS) program by describing aspects of the program. The discussion was not meant to imply that the program would be implemented in its entirety for the CPA. The program will be fully developed as part of the Operating License Application activities. Components of an NCS program specifically being implemented during the design and construction phases of the RPF include:

- NCS program policy
- NCS program procedure
- Nuclear criticality safety evaluation (NCSE) procedure
- NCS technical/peer review procedure
- NCS engineer training and qualification procedure
- NCS validation procedure

No.	Request for additional information
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.*

NCS limits established for controlled parameters in the NWMI facility processes will ensure that all nuclear processes are subcritical, including an adequate margin of subcriticality for safety in accordance with the Interim Staff Guidance (ISG) augmenting NUREG-1537, *Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria*, Part 2, Section 6.b.3. Monte-Carlo N Particle (MCNP) calculation results used to set limits on parameters are compared to the upper subcritical limit (USL) established in the NWMI MCNP code validation report (NWMI-2014-RPT-006, *MCNP 6.1 Validations with Continuous Energy ENDF/B-VII.1 Cross-Sections*), after applying a 2σ calculation uncertainty. The USL includes the method bias and uncertainty established in NWMI-2014-RPT-006 and a 0.05 Δk margin of subcriticality. In addition, the area of applicability, also established in NWMI-2014-RPT-006, is checked to ensure that the NWMI RPF process model physics and materials are within the bands of applicability. If either the physics or materials are outside the bands of applicability, an additional margin of subcriticality will be applied.

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.*

A summary description of the validation methodology and the determination of the minimum margin of subcriticality can be found in Section 6.3.1.1 of the CPA (NWMI-2013-021).

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.*

NCS staff members and NCS contract support will meet the qualification and training requirements contained in the NWMI NCS qualification and training program. The NWMI NCS qualification and training program is compliant with ANS 2.26, *Criticality Safety Engineering Training and Qualification Program*.

No.	Request for additional information
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.*

NWMI will maintain a rigorous NCS program at the RPF, using the double-contingency principle as a basis for criticality safety analysis.

In the highly unlikely event that an inadvertent nuclear criticality accident were to occur in the facility, members of the workforce could receive a radiation dose from neutrons and photons emitted from the critical excursion. Therefore, NWMI is installing a criticality accident alarm system (CAAS) that will alert the workforce and allow for evacuation of the facility.

To ensure the CAAS coverage is adequate for the facility, NWMI will conduct a coverage analysis using the minimum accident of concern that produces a detector response when the dose rate at the detector is equivalent to 20 rad/minute (min) at 2 meters (m) from the reacting material. Using the source from the minimum accident of concern, NWMI will conduct one-dimensional deterministic computations, when practical, to evaluate CAAS coverage. For areas of the facility where the use of one-dimensional deterministic computations is not practical, NWMI will use 3D Monte Carlo analysis to determine adequate CAAS coverage.

NWMI is designing the CAAS in accordance with ANSI/ANS-8.3, *Criticality Accident Alarm System.*

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."*

No.	Request for additional information
6.3-6A	*Provide information to resolve the apparent inconsistency between NWMI PSAR Sections 2.5, 4.3.2.2.5, and 3.5.2.7.7.*

NWMI will provide analysis for CAAS coverage in all areas where special nuclear material (SNM) is handled, processed, or stored. Section 3.5.2.7.7 will be revised to be consistent with this approach.

6.3-6B	*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.*

NWMI will not seek an exemption to the CAAS coverage requirement.

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.*

An audit to assess the overall effectiveness of the NCS program will be performed at least once every three years. The audit will be led by a qualified senior criticality safety engineer from outside the NWMI organization. The senior NCS engineer conducting the audit will be independent of the NWMI program and will not have participated in any NCS evaluation that will be a subject of the audit. In addition to the triennial audit from an outside organization, NWMI senior management will perform periodic audits of the NWMI NCS program. The senior manager will be chosen from an NWMI organization other than the NCS group. The NWMI QA Manager will select and assign auditors who are independent of the NWMI NCS program.

No.	Request for additional information
	Section 6.4 – References
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.*

NWMI commits to the following standards and guides:

- ANSI/ANS-8.1, *Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors* – NCS practices, including administrative practices, technical practices, and validation of a calculational method
- ANSI/ANS-8.3, *Criticality Accident Alarm System* – CAAS placement analysis and procedure development; the standard is used as modified by NRC Regulatory Guide 3.71, *Nuclear Criticality Safety Standards for Fuels and Material Facilities*
- ANSI/ANS-8.19, *Administrative Practices for Nuclear Criticality Safety* – NWMI NCS program development as it applies to organization, administration, roles, and responsibilities
- ANSI/ANS-8.20, *Nuclear Criticality Safety Training* – NCS staff and contractor qualification and training procedure development
- ANSI/ANS-8.24, *Validation of Neutron Transport Methods for Nuclear Criticality Safety Calculations* – Validation of a calculational method
- NUREG-1520, *Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility* – Guidance for meeting 10 CFR 70.61, Performance Requirements"
- NUREG/CR-4604, *Statistical Methods for Nuclear Material Management* – Guidance for normality testing of the data from critical experiment calculations
- NUREG/CR-6698, *Guide for Validation of Nuclear Criticality Safety Calculational Methodology* – Guidance for validation of a calculational method

Chapters 3.0 and 6.0 of the CPA (NWMI-2013-021) will be verified and/or modified to reflect these commitments.

No.	Request for additional information
	Section 13.1 – Analysis of Accidents Methodology and Preliminary Hazards Analysis
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.*

NWMI intends to prevent the occurrence of a criticality accident regardless of whether it results in a high radiation dose. In the Operating License Application, NWMI will clearly state our intent to prevent the occurrence of a criticality accident regardless of whether the event results in a high radiation dose.

No.	Request for additional information
	Section 13.2 – Analysis of Accidents with Radiological and Criticality Safety Consequences
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.*

NWMI considers a shielded criticality accident to be a high-consequence event.

No.	Request for additional information
	Proposed Action
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.*

No.	Request for additional information
PA2-4A	*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).*

Section 19.2.1 discusses bounding the number of batches (68) that could be processed in a year. Both of the annual processing numbers (900 or 1,104 targets) are based on 68 batches a year. The response to PA-1B uses the normal University of Missouri Research Reactor (MURR) target loading a week, plus the planned operation of the second and third reactors as discussed above, for a total of 900 targets irradiated and processed. Due to the potential fragility of the domestic molybdenum-99 (^{99}Mo) supply chain, NWMI assumed MURR would irradiate additional targets each week to generate a bounding target processing capacity for the Environmental Review (ER). These additional targets, plus the planned operation of the second and third reactors as discussed above, equate to a total of 1,104 targets irradiated and processed. The actual number of targets processed each year will be driven by the US demand for ^{99}Mo.

PA2-4B	*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.*

The response to PA2-4A explains the basis for the annual RPF target processing capacity if the domestic ^{99}Mo supply chain requires NWMI to process at the bounding number (1,104 targets). Additional weekend and shifts would be required in target fabrication to create the additional 64 targets. This additional processing is within the overall analysis of the ER.

PA2-4C	*Clarify the RPF LEU target fabrication capacity and the nominal operational processing capacity of the RPF.*

Target fabrication will produce targets sufficient to meet NWMI nominal irradiation requirements. The nominal number of targets irradiated (900 targets) does not exceed the fabrication capacity (1,040 targets).

PA2-4D	*Clarify whether the impacts analyzed in the PSAR are based on fabricating 900 LEU targets, 1,040 LEU targets, or 1,104 LEU targets.*

The NWMI preliminary safety analysis report (PSAR) is based on bounding conditions of the SNM and radioactive inventory. Target fabrication is a series of the same batch processes. From a safety perspective, 900, 1,040, and 1,104 targets all provide a similar hazard profile for target fabrication. The tanks are of a fixed size, and the batch flowsheet is set. The material/inventory moving through target fabrication is about the same for each case. For the 900 target case, there are several weeks where the process does not need to run or runs at a lower capacity. For the 1,104 target case, there are a number of weeks where additional shift/weekend operation will be required to produce the additional targets.

PA2-4E	*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.*

The PSAR is based on the bounding condition of the SNM and radioactive inventories. Bounding conditions (including a margin of safety) are used for the radioactive source terms. Similarly, the CSEs use bounding SNM concentrations/masses. The impacts analyzed are valid for each of the potential RPF annual production rates.

No.	Request for additional information
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*

The NWMI preliminary design process has not yet sized these ancillary facilities. Therefore, for this RAI response, the following estimates are provided:

- Waste Staging and Shipping Building: Approximately 30 × 40 feet (ft), or nominally a 1,200 square foot (ft^2) footprint
- Diesel Generator Building (or skid): Approximately 10 × 20 ft, or nominally a 200 ft^2 footprint
- Administrative Building (two floors): Approximately 50 × 100 ft, or nominally a 5,000 ft^2 footprint

Security stations: <10 × 10 ft, or nominally less than a 100 ft^2 footprint

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.*

The Administrative Building (outside the fence), Diesel Generator Building, and security stations will have electric heat and air conditioning. The Waste Staging and Shipping Building will have electric heat, with no air conditioning planned. There will be no air emissions from these energy sources.

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10 CFR 50.35, "Issuance of Construction Permits," *Code of Federal Regulations*, Office of the Federal Register, as amended.

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