NWMI
NORTHWEST MEDICAL ISOTOPES

July 18, 2016
NWMI-LTR-2016-007

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 June 16, 2016

References:

1. U.S. Nuclear Regulatory Commission letter to Northwest Medical Isotopes, LLC, dated June 16, 2016, Docket No. 50-609 (ADAMS Accession No. ML16176A114), Request for Additional Information for the Environmental Review of the Northwest Medical Isotopes, LLC Construction Permit Application (TAC Nos. MF6134 and MF 6135)
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 June 16, 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 July 18, 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

Mr. David Drucker
Division of License Renewal
Office of Nuclear Reactor Regulation

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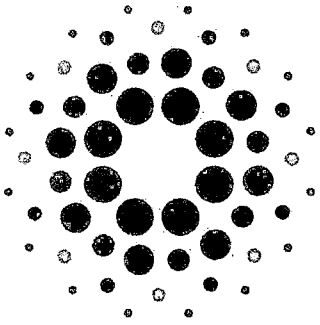
NORTHWEST MEDICAL ISOTOPES

ATTACHMENT 1

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



NWMI

NORTHWEST MEDICAL ISOTOPES

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

NWMI-2016-RAI-003, Rev. 0
July 2016

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

NWMI-2016-RAI-003, Rev. 0

Date Published:
July 15, 2016

Document Number: NWMI-2016-RAI-003	*Revision Number*: 0
Title: Response to the U.S. Nuclear Regulatory Commission Request for Additional Information Regarding Chapters 4, 13, and 19 of the Preliminary Safety Analysis Report and Environmental Review of the Northwest Medical Isotopes, LLC Construction Permit Application Docket No. 50-609	
Approved by: Carolyn Haass	*Signature*: Carolyn C. Haass

REVISION HISTORY

Rev	Date	Reason for Revision	Revised By
0	7/15/2016	Issued for Submittal to the NRC	N/A

TERMS

Acronyms and Abbreviations

^{41}Ar	argon-41
^{99}Mo	molybdenum-99
^{235}U	uranium-235
CFR	Code of Federal Regulations
CSE	criticality safety evaluation
Discovery Ridge	Discovery Ridge Research Park
DOE	U.S. Department of Energy
ER	Environmental Review
FHWA	Federal Highway Administration
HVAC	heating, ventilation, and air conditioning
IROFS	items relied on for safety
IRU	iodine retention unit
ISG	Interim Staff Guidance
LEU	low-enriched uranium
MHA	maximum hypothetical accident
MU	University of Missouri
MURR	University of Missouri Research Reactor
NRC	U.S. Nuclear Regulatory Commission
NWMI	Northwest Medical Isotopes, LLC
OSTR	Oregon State University TRIGA Reactor
OSU	Oregon State University
PSAR	preliminary safety analysis report
RAI	request for additional information
RPF	Radioisotope Production Facility
TNM	traffic noise model
TRIGA	Training, Research, Isotopes, General Atomics
U.S.	United States
UM	University of Missouri

Units

dBA	A-weighted decibel
ft	feet
ft^2	square feet
ha	hectare
hr	hour
kg	kilogram
km	kilometer
m	meter
mCi	millicurie
mi	mile
mrem	millirem
rem	roentgen equivalent in man
Sv	sievert

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No.	Request for Additional Information
	Air Quality
AIR3-1	*The ISG augmenting NUREG-1537, Part 1, Section 19.4.2, "Air Quality and Noise" states that the environmental report (ER) should provide a description of gaseous effluents (i.e., type, quantity, and origin), a description of gaseous effluent control systems, and detailed descriptions of the models and assumptions used to determine normalized concentration.*
AIR3-1A	*Design file EDF-3124-0014 was provided in the response to RAI AIR2-3 (ADAMS No. ML16053A221) to support the information provided in Table 19-59 of the NWMI ER. Table 19-59 provides the pollutant concentration for the nearest resident at 375 m (1,230 ft) from the radioisotope production facility (RPF). However, the supporting calculation, EDF-3124-0014, provides the pollutant concentration to the nearest resident at 430 m. Confirm the distance to the nearest resident distance used to calculate the pollutant concentration provided in Table 19-59 of the ER and reconcile the difference in the nearest resident distance between what is provided in Table 19-59 and EDF-3124-0014.*

The correct distance to the nearest resident is 430 m. Revision 1 of design file EDF-3124-0014, *Emission Modeling for Construction Activities Using AERSCREEN*, uses 430 m (the original EDF used a more conservative distance of 375 m). The distance and values in Table 19-59 of the ER (NWMI-2013-021, *Construction Permit Application for Radioisotope Production Facility*) will be updated to reflect the results using 430 m as the distance to the nearest resident.

AIR3-1B	*Design File EDF-3124-0014 was provided in the response to RAI AIR2-3 (ADAMS No. ML16053A221) to support the information provided in Table 19-59 of the NWMI ER. Page 12 of 23 of design file EDF-3124-0014 contains model inputs for process boilers, however, the design file EDF-3124-0014 is for construction activities not operation activities. Explain why the design file contains these process boiler inputs.*

NWMI acknowledges that EDF-3124-0014 contains information for the process boilers during operations. However, the process boiler information in EDF-3124-0014 was not used in the AIR2-2C response. The process boiler information was included in EDF-3124-0014 as the modeler opted to capture his process boiler AERSCREEN modeling runs in this document.

AIR3-1C	*Design file EDF-3124-0012 was provided in the response to RAI AIR2-3 (ADAMS No. ML16053A221) to support information provided in Table 19-62 of the NWMI ER. The design file EDF-3124-0012 uses a distance of 375 m to the nearest residence. Why was a distance of 375 m used rather than the 430 m distance listed in Table 19-9 of the NWMI ER?*

NWMI clarified that the correct distance to the nearest residence is 430 m, as listed in Table 19-9 of NWMI-2013-021. The design file EDF-3124-0012, *Emission Modeling for Process and HVAC Boilers Using AERSCREEN* (and Table 19-62), used 375 m, which is more conservative. However, the EDF will be updated using the 430 m distance, and Table 19-62 of NWMI-2013-021 will be updated to reflect the results.

No.	Request for additional information
	Alternatives
ALT3-1	*The ISG augmenting NUREG-1537, Part 1, Section 19.5 "Alternatives," states that ER should summarize the history and process used to formulate the reasonable alternatives.*
ALT3-1A	*The response to RAI ALT-2 (ADAMS No. ML15328A010) provided an Alternative Site Evaluation. Page 9 of the evaluation states that a direct connection to the existing reactor may require below-ground construction. However, RAI response to ALT2-3A (ML16053A221) states that there will be a need for construction of a below-grade connection to the University of Missouri Research Reactor (MURR).*

No.	Request for additional information
ALT3-1A.1	*Confirm that a below-grade connection to MURR will be needed at the MURR alternative site.*

If the Northwest Medical Isotopes, LLC (NWMI) Radioisotope Production Facility (RPF) was constructed at the University of Missouri Research Reactor (MURR) site, a below-grade corridor between the RPF and MURR would be constructed for transport of irradiated low-enriched uranium (LEU) targets.

ALT3-1A.2	*Would construction workers be exposed to radioactive material or a direct radiation dose during construction of a below grade connection to MURR? Would construction workers be considered occupational workers? Identify measures that would be used to ensure that construction workers dose would be maintained within 10 CFR Part 20 limits.*

There would be no measureable exposure to radioactive materials or direct radiation dose from the planned below-grade corridor. The corridor was envisioned to enter the MURR basement near the current MURR service corridor. MURR would move any potential sources from the construction area. Construction workers would have been occupational workers with appropriate radiation safety training. NWMI would have followed the MURR radiation safety program and controls to safely perform this work.

ALT3-1B	*The response to RAI ALT-2A provided an Alternative Site Evaluation. Page 10 of the evaluation provides a preliminary RPF layout at the MURR alternative site. The layout does not identify facility support buildings (diesel generator building, administration building, external waste management building) that were identified to be constructed at the Discovery Ridge site.*
ALT3-1B.1	*Identify where the support buildings would be constructed on the MURR alternative site.*

NWMI stated that for the MURR alternative site, the facility support buildings would be integrated within the existing infrastructure at the MURR facility. The diesel generator building and external waste management building would be located on the MURR alternative site but were not delineated on the preliminary RPF layout. In addition, the administration building for NWMI at the MURR alternative site could be located in an existing building across the street from MURR (e.g., University of Missouri [MU] Life Science Incubator Building). The Incubator Facility includes 33,000 ft^2 of conference room space, private offices, wet laboratory facilities, shared laboratory facilities, and open office and conference rooms.

ALT3-1B.2	*Provide an updated figure of the MURR alternative site that identifies the site layout of the RPF building and support buildings.*

An updated figure is not available.

ALT3-1B.3	*Clarify whether the distances from radiological/chemical release points to the nearest site boundary (nearest location where a member of the public could potentially be exposed to the radiological or chemical release) for the MURR alternative site would be the same as those for the Discovery Ridge site (approximately 10 m for radiological releases from the facility stack, and approximately 24 m for nonradiological releases during a chemical accident, as stated in the ER), or whether these distances would be different. If the distance differs, identify this distance and state whether that difference in distance would be significant enough to change the radiological doses and/or chemical effects to a member of the public.*

The identification of the release points for an RPF at the MURR reactor site was not part of the alternative process. However, considering the MURR boundary and the planned location of the RPF on the MURR site, the distance to site boundary would be similar to the distance for the Discovery Ridge Research Park (Discovery Ridge) site boundary.

No.	Request for additional information
ALT3-1C	*The response to RAI ALT-2 states that the MURR alternative site has the minimum amount of space required to construct and operate the proposed NWMI facility. The ER states the "site is located directly to the south of the existing reactor building on a partially paved parking lot…the MURR site situated on a 3.0 ha (7.4-acre) lot in the central portion of the University Research Park…" Clarify if the 3.0 ha (7.4-acre) lot relates to the size of the entire MURR facility complex or if this is the available space to construct the proposed facility. If the 3.0 ha (7.4-acre) lot is the size of the entire MURR facility complex, what space is available to construct the proposed facility?*

The 3.0 ha (7.5-acre) lot refers to the entire MURR facility complex, and the RPF would be built within the complex. The RPF was originally planned to be constructed in the area south of the reactor on the partially paved parking lot, which is less than 1 ha (2.5 acre). An error was found in Section 19.5.2.3.1 for the size of the MURR alternative site; the size of the site is 7.5 acres, not 7.4 acres, which is still approximately 3.0 ha.

ALT3-1D	*The response to RAI ALT-2 states that the Oregon State University (OSU) TRIGA Reactor (OSTR) site has the minimum amount of space required to construct and operate the proposed NWMI facility. The ER states, for OSTR, that the "site is immediately east of the university reactor on an area covering approximately 1.21 ha (3 acres)." Clarify if the 1.21 ha (3 acres) includes the Radiation Center and university reactor or if the 1.21 ha (3 acres) is the space available to construct the proposed facility.*

The potential proposed site at the Oregon State University (OSU) TRIGA Reactor (OSTR) is northeast of the Radiation Center Building and immediately east of the Nuclear Reactor Building. The potential site available for the RPF is approximately 3 acres and does not include the Radiation Center Building or Nuclear Reactor Building.

No.	Request for additional information
	Connected Actions
CONN3-1	*In support of analyzing the environmental impacts associated with the connected actions, provide the following information:*
CONN3-1A	*The response to RAI CONN-5 (ADAMS No. ML15328A010) identifies that solid waste will increase as a result of target handling and the response points to the discussions in Section 19.4.13.3.1, 19.4.13.3.2, and 19.4.13.3.3 of NWMI ER. The NWMI ER provides waste volume but activity is not provided. Provide the activity of the waste.*

The waste generated at MURR, OSTR, and the third reactor would be of small volume and would be Class A waste. The radioactivity of the waste generated is expected to be minimal, if any at all.

CONN3-1B	*Response to RAI CONN-1 and CONN-6 (ADAMS No. ML15328A010) identified facility modifications at the three research reactors. For MURR, OSTR, and the hypothetical third reactor, would facility modification and refurbishment activities change the types or quantities of effluents that may be released? Will these activities result in an increase in individual or cumulative public or occupational radiation exposure?*

None of the modifications and refurbishment activities at MURR, OSTR, or the hypothetical third reactor will change the types or quantities of effluents that may be released nor will these activities result in an increase in individual or cumulative public or occupational radiation exposure. The reason for this is because none of the facility modifications or refurbishment activities will change the quantities or radioisotopes produced nor will they affect their effluent discharge rate. When completed, the modifications and refurbishments are projected to assist in the handling of the targets at each facility but are not related to the generation or release of radioactive material.

No.	Request for additional information
CONN3-1C	*The response to RAI CONN-1 (ADAMS No. ML15328A010) identifies that ^{41}Ar would normally be measured and emitted from the research reactor and that gaseous releases from the operation of the hypothetical third reactor may change depending on how the facility is operated. Explain whether any increase in dose to public (from direct radiation, or any other sources other than increased ^{41}Ar effluents) would be expected from irradiation services at the hypothetical third reactor and provide a basis for this determination.*

NWMI expects no increases in dose to the public (from direct radiation, or any other sources other than increased ^{41}Ar effluents) at the hypothetical third reactor. The basis is that before irradiation, the dose rates are too low and are measurable except (maybe) at contact. After irradiation, the loading of the targets is performed with shielded transfer casks. The anticipated dose rate on the surface of the transfer cask is estimated to be <100 mrem/hr on contact. Given the distance, short time duration, and intervening shielding presented by equipment and walls, the dose to the general public is unlikely to increase as a result of this activity.

CONN3-1D	*The response to RAI CONN-1 and CONN-5, which requested expected radiological impacts from transportation due to the shipments to and from the research reactors, refers to Section 19.4.10 of the ER. State whether the 3.93E-06 Sv dose to a maximally exposed individual from highway transportation of radioactive materials (in Section 19.4.10.2.2 of the ER) is per year.*

The maximally exposed individual dose from highway transportation of radioactive materials was provided on an annual basis in Section 19.4.10.2.2 of NWMI-2013-021.

No.	Request for additional information
	Ecology
ECO3-1	*The ISG augmenting NUREG-1537, Part 1, Section 19.3.5, "Ecological Resources" states that the applicant should provide a description of the types of vegetative communities found within the potentially affected area.*
ECO3-1A	*The vegetation assessment submitted with the response to RAI ECO-1 (ADAMS No. ML15328A010) identifies the most common vegetative species as Indian grass (Sorghastrum nutans). The vegetation assessment also states that "plant species encountered during the quantitative assessment consisted mostly of non-native plants typically found in disturbed areas such as pastures and right-of-ways." Indian grass, however, is a native grass species in Missouri that grows 3 to 5 ft tall, and is representative of the tallgrass prairie community. Confirm that Indian grass is the correct species identified in the surveys.*

Indian Grass (*Sorghatrum nutans*) is a native grass of Missouri tallgrass prairie communities. The NWMI site (Lot 15) at Discovery Ridge is considered as part of a historical tallgrass prairie. Indian grass is considered to be weedy or invasive is some regions or habitats and may displace desirable vegetation (Owsley, 2011). Based on the current use of the property (pastureland), Indian grass can be considered a weedy species because it is not the most desirable for that location. RAI ECO-1 should classify Indian grass as weedy instead of non-native. Based on the photos taken while on site and plant identification reference books, the majority of the grass observed at the site is identified as Indian grass. Note that at the time of NWMI's vegetation assessment, all grasses had been heavily grazed, and therefore, appeared to be short. In addition, horsenettle and horseweed are listed on the UM Weed ID guide (UM, 2016). These species are considered native; however, based on the listing, these species are undesirable. RAI ECO-1 should classify Indian grass as weedy instead of non-native.

No.	Request for additional information
ECO3-1B	*Table 2 within the vegetation assessment identifies Indian grass, horseweed (Conyza Canadensis), and horsenettle (Solanum carolinense) as non-native. However, these species are native to Missouri. Provide the source NWMI used to determine whether each species was native or non-native to Missouri.*

See response to ECO3-1A.

No.	Request for additional information
	Geologic Environment
GEO3-1	*The ISG augmenting NUREG-1537, Part 1, Section 19.3.3, "Geologic Environment," states that the applicant should identify the geological, seismological, and geotechnical characteristics of the site and surrounding area. ISG to NUREG-1537, Part 1, Section 19.3.4, "Water Resources," further states that the applicant should describe site-specific and regional data on the physical and hydrological characteristics of surface water and groundwater, etc.* *The response to RAI GEO-1 (ADAMS No. ML15328A010) states that NWMI anticipates conducting a site-specific geotechnical and hydrologic study starting January 2016. Has a site-specific geotechnical and hydrologic study been conducted? If so, please provide this study.*

The study has not be conducted to date.

No.	Request for additional information
	Human Health – Radiological
HH3-R-1	*The ISG augmenting NUREG-1537, Part 1, Section 19.4.10, "Human Health," states that the ER should discuss the public health impacts from radioactive material and include dose rates.* *The response to RAI HH2-R-1 (ADAMS No. ML16053A221) provided the dose to a member of the public on the ground when a plane used to transport ^{99}Mo is at a cruising altitude of 20,000 ft. Clarify whether ^{99}Mo will be transported on aircraft carrying members of the public, and if so, provide the public doses (total person-rem per year, and annual dose to maximally exposed individual) from this transport, or justify why the dose to members of the public on the plane is negligible.*

NWMI planning basis is that no commercial passenger airliners would be used to transport molybdenum-99 (^{99}Mo) product.

HH3-R-2	*The ISG augmenting NUREG-1537, Part 1, Section 19.3.8, "Human Health," states that the ER should provide effluent release points and expected radioactive effluent releases and exposures from construction, operational, and decommissioning activities.* *The response to RAI HH2-R-2 (ADAMS No. ML16053A221) does not include tritium in the stack release source term input to the COMPLY computer modeling code. The NWMI ER (p.19-213) states that radioactive tritium could be present in the airborne effluent exhaust. Discuss why tritium was not included in the COMPLY calculation and if tritium is released, provide the amount.*

The tritium release value is proprietary. Tritium release rate would be a small fraction of the noble gas rates provided in Table 11-2 of NWMI-2013-021 (several orders of magnitude less). The dose contribution from tritium would be a small fraction of the dose contributions, and the total public dose from all routine gaseous releases including tritium would remain well below 10 CFR 20 limits. Tritium was not included in the original COMPLY calculation, which were based on the top 100 radionuclides generated during target irradiation and used in the mass balance calculations.

No.	Request for additional information
	Noise
NOI3-1	*The ISG augmenting NUREG-1537, Part 1, Section, 19.3.2, "Air Quality and Noise," states that the ER should provide a description of any current or past noise studies and analyses conducted at the proposed site or within an audible range of the site and predicted noise levels using the dBA-weighted scale and major sources of noise, including all models, assumptions, and input data.*
NOI3-1A	*The response to RAI NOI2-1 (ADAMS No. ML16053A221) states that peak traffic counts to assess facility impacts included an increase of 100 vehicles traveling on U.S. Highway 63 and were 918 in the southbound lane and 1,102 in the northbound lane. Clarify if the model run was conducted with the peak traffic count both in the southbound and northbound lane simultaneously?*

The predicted change in noise levels resulting from increased workforce traffic have been modeled using the Federal Highway Administration's Traffic Noise Model (TNM) 2.5. Peak traffic counts were used to assess baseline noise conditions at the nearest residence. Noise levels resulting from the addition of 100 vehicles traveling 70 mi/hr on Highway 63 during peak traffic times (both ways simultaneously) were modeled to determine the potential increase over baseline conditions. Based on modeled results, an increase of less than 1 dBA (A-weighted decibel) is anticipated due to the increase in traffic from the workforce. This information will be added to Section 19.3.2.3.1 of NWMI-2013-021.

NOI3-1B	*The response to RAI NOI2-1 (ADAMS No. ML16053A221) states that the nearest resident distance to the proposed RPF is 792.5 m (2,600 ft). However, the ER identifies the nearest resident of 0.43 km (0.27 mi; 430 m). Reconcile the difference in the nearest resident distance between that used in the noise model and the distance in the ER.*

The noise levels provided in NWMI-2013-021 were calculated using noise level estimates from Table 1 of the Federal Highway Administration's (FHWA) traffic noise model (TNM) 2.5 lookup tables. The noise values assume hard ground and no noise barrier, and were used to assess existing noise levels at the proposed RPF site. Current guidance (November 2015) from the FHWA states the TNM 2.5 lookup tables should not be used to estimate noise levels. To incorporate the FHWA's current guidance, noise modeling for the nearest resident has been performed using the TNM 2.5 model. This information indicates the change in existing noise levels will be less than 1 dBA. This information will be added to Section 19.3.2.3.1 of NWMI-2013-021.

No.	Request for additional information
	Proposed Action
PA3-1	*The ISG augmenting NUREG-1537, Part 1, Section 19.2, "Proposed Action," states that the ER should describe the radioisotope production system. Provide a non-proprietary discussion of Section 4.4.2.7.1 of the PSAR.*

Off-specification uranium can be generated in the target fabrication system. The general approach to deal with off-specification uranium is for the material to be recycled and processed into fresh LEU target material. The off-specification uranium is anticipated to be generated intermittently. Since target fabrication will be completed in discrete batches, if any off-specification uranium is encountered in a batch, the entire batch will require recycle and processing into fresh LEU target material. The exception is if the uranium is not suitable for LEU target material production (e.g., the enrichment is too low). Any LEU material with low enrichment will be stabilized, packaged for secured storage, and then returned to the U.S. Department of Energy (DOE) per the Uranium Lease/Take-Back contract. For the preliminary design, the uranium recycle system was sized to accommodate off-specification uranium equivalent to 25 percent of the total throughput. An allowance has been made in the mass balance for the generation of off-specification uranium.

No.	Request for additional information
	Postulated Accidents
POSA3-1	*The regulations at 10 CFR 70.61, "Performance Requirements," require that the risk of high- and intermediate consequence accident events be limited, either by reducing the consequences or the likelihood of those events. The ISG augmenting NUREG-1537, Part 1, Section 13b.3, "Analyses of Accidents with Hazardous Chemicals," states that the application should "identify controls for those accidents containing a chemical system or process failure that could ultimately lead to radiological consequences that exceed the performance requirements. The applicant should demonstrate that the consequences of each credible event will be reduced after the implementation of controls, so that the consequences of the event will be low." Additionally, the ISG augmenting NUREG-1537, Part 2, Section 19.4.11, "Postulated Accidents," states that the environmental impact statement should "describe measures to mitigate adverse impacts." Section 19.4.11.1.8 of the ER states that for the hazardous chemical release, "releases above the PAC-2/EPRG-2 limit will be evaluated, and additional controls will be developed." The PSAR, Chapter 13, "Accident Analysis," discusses potential chemical accidents, and identifies measures that would prevent, mitigate the consequences of, and/or reduce the likelihood of chemical accidents.*
POSA3-1A	*Clarify whether the mitigation measures discussed in the PSAR would, for any chemical release accident with high consequences for workers, members of the public, and/or the environment (as determined by the criteria in 10 CFR 70.61), either reduce the likelihood of the chemical release accident such that it would be highly unlikely; or, reduce the accident consequences such that it would be intermediate- or low-consequence.*

NWMI is continuing to evaluate chemical release accidents and will establish preventative or mitigative controls for chemical release accidents with U.S. Nuclear Regulatory Commission (NRC)-licensed material or for accidents that affect licensed radioactive material with high consequences for the worker, members of the public, and/or the environment (as determined by the criteria in 10 CFR 70.61, "Performance Requirements"). These controls will either reduce the accident likelihood to highly unlikely or reduce the accident consequences to be intermediate or low consequences.

POSA3-1B	*Clarify whether the mitigation measures provided in the PSAR would, for any chemical release accident with intermediate consequences for workers, members of the public, and/or the environment (as determined by the criteria in 10 CFR 70.61), either reduce the likelihood of the chemical release accident such that it would be unlikely; or, reduce the consequences such that it would be low-consequence.*

NWMI is continuing to evaluate chemical release accidents and will establish preventative or mitigative controls for chemical release accidents with NRC-licensed material, or for accidents that affect licensed radioactive material with intermediate consequences for the worker, members of the public, and/or the environment (as determined by the criteria in 10 CFR 70.61). These controls will either reduce the likelihood to unlikely or reduce the accident consequences such to be low consequences.

POSA3-2	*The regulations at 10 CFR 70.61, "Performance Requirements," require that the risk of high- and intermediate consequence accident events be limited, either by reducing the consequences or the likelihood of those events. The ISG augmenting NUREG-1537, Part 1, Section 13b.3, "Analyses of Accidents with Radiological Consequences," states that the applications should "[i]dentify IROFS and their function as preventive, mitigative, or both." Section 19.4.11.1.1 of the ER identifies controls that would mitigate the consequences of the maximum hypothetical accident and includes use of hot cells and shielding in process areas; radiation monitoring; design of the facility ventilation system and dissolution offgas treatment system; and, sizing of the target dissolution system. The PSAR, Chapter 13, "Accident Analysis," discusses potential radiological accidents, and also identifies additional controls that would prevent, mitigate the consequences of, or reduce the likelihood of radiological accidents.*

No.	Request for additional information
POSA3-2A	*Clarify whether the mitigation measures discussed in Chapter 13 and 19 of the PSAR would, for any accident with high radiological consequences for workers, members of the public, and/or the environment (as determined by the criteria in 10 CFR 70.61), either reduce the accident likelihood such that it would be highly unlikely; or, reduce the accident consequences such that it would be intermediate- or low-consequence.*

NWMI is continuing to evaluate radiological release accidents and will establish preventative or mitigative controls for radiological release accidents with high consequences for the worker, members of the public, and/or the environment (as determined by the criteria in 10 CFR 70.61). The set of controls identified in Chapter 13 of NWMI-2013-021will either reduce the accident likelihood to highly unlikely or reduce the accident consequences to be intermediate or low consequences.

POSA3-2B	*Clarify whether the mitigation measures provided in Chapter 13 and 19 of the PSAR would, for any accident with intermediate radiological consequences for workers, members of the public, and/or the environment (as determined by the criteria in 10 CFR 70.61), either reduce the accident likelihood such that it would be unlikely; or, reduce the accident consequences such that it would be low-consequence.*

NWMI is continuing to evaluate radiological accidents and will establish preventative or mitigative controls for radiological accidents with intermediate consequences for the worker, members of the public, and/or the environment (as determined by the criteria in 10 CFR 70.61). The set of controls identified in Chapter 13 of NWMI-2013-021 will either reduce the accident likelihood to unlikely or reduce the accident consequences to be low consequences.

POSA3-3	*The ISG augmenting NUREG-1537, Part 1, Section 13a2.2, "Accident Analyses and Determination Consequences," states that the applicant should discuss the degree of conservatism in the evaluation.* *ER Section 19.2.1, of the ER states the "RPF is being designed to have a nominal operational processing capability of one batch per week of up to 12 targets from MURR for up to 52 weeks per year and approximately 30 targets from the Oregon State University (OSU) TRIGA Reactor (OSTR) or a third university reactor for eight weeks per year per." Response to RAI PA-1B, states that the estimated number of low-enriched uranium (LEU) targets that can be irradiated at the OSTR or hypothetical third reactor is one batch per week with a maximum of 30 LEU targets/batch and each reactor can irradiate up to eight batches per year for a total of 16 batches annually. ER Section 19.4.11.1.1 states that the maximum hypothetical accident (MHA) assumptions include "estimating 12 MURR targets for the process batch upstream of the IRU system, which is beyond the process design capacity of eight MURR targets." Response to RAI PA2-4 states that: "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 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."*
POSA3-3A	*Explain why the MHA is conservative if targets irradiated only from MURR (12 targets per week) were accounted for in the MHA and irradiated targets that would be processed from OSTR and the third reactor were not considered in the MHA.*

The RPF bounding radiological source term is based on targets irradiated at the nearby research reactor (MURR). Each irradiated MURR target has nominally four times the radioactivity of an irradiated OSTR (or the third reactor) target. Therefore, Section 19.4.11 of NWMI-2013-021 evaluates MURR target processing only to predict the maximum hypothetical accident (MHA) consequences.

No.	Request for additional information
POSA3-3B	*Reconcile the differences in target capacity discussed in Section 19.4.11.1.1 of the ER (i.e., process design capacity of eight MURR targets) and Section 19.2.1 of the ER stating a processing capability of 12 targets from MURR a week and clarify the target processing capability of the RPF.*

See response to RAI PA2-4A-E for additional information on overall RPF target processing capacity. The RPF is primarily a batch operation, the equipment is being sized to process/dissolve 30 OSTR targets in four batches and the MURR target in two or three batches (8 or 12 target respectively). The nominal MURR number of targets expected to be processed per week is eight. However, shortfall in ^{99}Mo production/availability could be addressed by processing 12 MURR targets per week. NWMI has used the 12 irradiated MURR targets to bound postulated radioactive release accidents.

No.	Request for additional information
	Waste Management – Nonradiological
WM3-NR-1	*The ISG augmenting NUREG-1537, Part 1, Section 19.2, "Proposed Action" states that the ER should provide a description of all (i.e., nonradioactive, radioactive, mixed, and hazardous waste materials) proposed or current waste systems, including quantities, composition, and frequency of waste generation.*
WM3-NR-1A	*Table 19-13 provided in RAI response to WM-NR-1 identifies solid waste that will be encapsulated in cement. Section 19.2.7.3.2 of the NWMI ER states that solid radioactive waste would be encapsulated in cement when practicable. Clarify if all solid radioactive waste would be encapsulated in cement or only when practicable as stated in Section 19.2.7.3.2 of the ER. If not all waste will be encapsulated, what mass and class of waste will not be encapsulated and will it also be shipped to Waste Control Specialists in Andrews, Texas?*

NWMI clarified that there would be Class A waste that would not be encapsulated onsite at the proposed NWMI facility and could include of large pieces of equipment (e.g., equipment that may fail) and for which encapsulating in cement onsite may be difficult. Class A waste that would not be encapsulated could also include other items (e.g., laboratory waste, used personal protective equipment) included in Table 19-13 of the RAI response under Laboratory facilities, or under facility support, potentially contaminated waste. The volume and mass of any Class A waste that would not be encapsulated are included in the quantities listed in Table 19-13 of the RAI response under Laboratory facilities, or under Facility support, potentially contaminated waste. The non-encapsulated waste would be collected and size-reduced at the proposed NWMI facility and then shipped to Waste Control Specialist in Andrews, Texas, where it could be encapsulated. The volume of waste not encapsulated in cement onsite is not expected to be substantial.

WM3-NR-1B	*Clarify if the mass provided in Table 19-13 of the RAI response to WM-NR-1 (ADAMS No. ML15328A010) accounts for mixed waste and clarify if the Laboratory Facilities waste and Facility Support waste provided in the Table 19-13 will be non-radiological, radiological waste, or mixed waste.*

NWMI clarified that mixed waste is accounted for in Table 19-13 of NWMI-2013-021. The laboratory facility waste provided in Table 19-13 is radiological waste, a portion of which could be mixed waste and the remainder radiological non-hazardous waste. The Facility support, potentially contaminated waste provided in Table 19-13 is low-level, radiological non-hazardous waste. The Facility support, municipal waste provided in the Table 19-13 is nonradiological, non-hazardous waste.

No.	Request for additional information
WM3-NR-1	*The ISG augmenting NUREG-1537, Part 1, Section 19.2, "Proposed Action," states that the ER should identify the type of hazardous materials associated with the facility.* *The response to RAI WM-NR-4 (ADAMS No. ML15328A010) identifies that less than 1,000 kg of hazardous waste will be generated per month. Clarify whether the 1,000 kg hazardous waste estimate is nonradiological waste or whether it includes radiological and nonradiological hazardous waste. Provide the amount of hazardous, nonradiological waste that will be generated during operation of the proposed RPF.*

NWMI clarified that the 1,000 kg of hazardous waste a month includes both radiological and nonradiological waste. NWMI does not have an estimate for the hazardous nonradiological portion of waste generated.

No.	Request for additional information
	Waste Management – Radiological
WM3-R-1	*The ISG augmenting NUREG-1537, Part 1, Section 19.4.9, "Waste Management," states that the ER should provide information with respect to waste management as a result of construction, operation, and decommissioning activities.* *The response to RAI WM-R-1 (ADAMS No. ML15328A010) discussed waste generated by the proposed NWMI facility as identified in Table 19-14 (Summary of Radioactive Materials and Wastes Required or Generated at the Radioisotope Production Facility for Ongoing Operations) of the ER, and states that radioactive wastes are anticipated to be shipped to Waste Control Specialists and that no Greater than Class C waste will be generated by the proposed RPF. Table 19-14 of the ER identifies spent LEU generated from operation of the proposed facility that will be shipped to the Savannah River Site. State what NWMI considers spent LEU and discuss how spent LEU will be handled*

NWMI clarified that spent LEU is uranium in which the uranium-235 (^{235}U) isotopic ratio has decreased, and it is no longer economically feasible to use for ^{99}Mo production. This uranium will be returned to DOE. Conditions for which NWMI will return LEU to DOE will be stipulated in the Uranium Lease contract between DOE and NWMI.

REFERENCES

10 CFR 20, "Standards for Protection Against Radiation," *Code of Federal Regulations*, Office of the Federal Register, as amended.

10 CFR 70.61, "Performance Requirements," *Code of Federal Regulations*, Office of the Federal Register, as amended.

EDF-3124-0012, *Emission Modeling for Process and HVAC Boilers Using AERSCREEN*, Rev. 1, Portage, Inc., Idaho Falls, Idaho, February 4, 2015.

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NUREG-1537, *Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors – Format and Content*, Part 1, U.S. Nuclear Regulatory Commission, Office of Nuclear Reactor Regulation, Washington, D.C., February 1996.

NUREG-1537, *Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria*, Part 2, U.S. Nuclear Regulatory Commission, Office of Nuclear Reactor Regulation, Washington, D.C., February 1996.

NWMI-2013-021, *Construction Permit Application for Radioisotope Production Facility*, Rev. 0, Northwest Medical Isotopes, LLC, Corvallis, Oregon, June 29, 2015.

Owsley, M., 2011. Plant fact sheet for Indiangrass (*Sorghastrum nutans[L.] Nash*), USDA-Natural Resources Conservation Service, Jimmy Carter PMC Americus, Georgia, February 2011.

UM, 2016, *Weed ID Guide*, http://weedid.missouri.edu/, University of Missouri, Division of Plant Science, Columbia, Missouri, 2016.

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