UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 19, 2016

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

SUBJECT: REQUESTS FOR ADDITIONAL INFORMATION FOR THE ENVIRONMENTAL REVIEW OF THE NORTHWEST MEDICAL ISOTOPES, LLC CONSTRUCTION PERMIT APPLICATION

Dear Ms. Haass:

By later dated November 20, 2015 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15328A010), Northwest Medical Isotopes, LLC (NWMI) responded to the U.S. Nuclear Regulatory Commission (NRC) staff's November 2, 2015 request for additional information (RAI) (ADAMS Accession No. ML15288A102) to complete the review of NWMI's environmental report (ER).

In the course of reviewing NWMI's RAI responses submitted on November 20, 2015 (ADAMS Accession No. ML15328A010), the NRC staff has determined that additional information is required to complete the review of NWMI's ER to prepare an environmental impact statement. The specific information requested is addressed in the enclosure to this letter. Further, upon additional review of the NWMI ER and final part of NWMI's two-part application for a construction permit (Accession No. ML15210A182) for a medical radioisotope production facility, the NRC staff has determined that additional information is needed to evaluate the environmental impacts of the proposed action.

In accordance with 10 CFR Section 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." NRC staff requests that NWMI provide a response to the enclosed RAIs within 30 calendar days of this letter. Following receipt of the additional information, NRC staff will continue its evaluation of NWMI's construction permit application.

If you have any questions, please contact me by telephone at 301-415-2719 or by e-mail at Nancy.Martinez@nrc.gov.

Sincerely,

/***RA***/

Nancy Martinez, Environmental Project Manager
Environmental Review
and Guidance Update Branch
Division of License Renewal
Office of Nuclear Reactor Regulation

Docket No. 50-609

Enclosure:
Requests for Additional Information

cc: w/enclosure

If you have any questions, please contact me by telephone at 301-415-2719 or by e-mail at Nancy.Martinez@nrc.gov.

Sincerely,

/***RA***/

Nancy Martinez, Environmental Project Manager
Environmental Review
and Guidance Update Branch
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Docket No. 50-609

Enclosure:
Requests for Additional Information

cc: w/enclosure

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ADAMS Accession No: ML15364A376 *concurred via email

OFFICE	LA:DLR	PM:RERB:DLR	BC:RERB:DLR	PM:RERB:DLR
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DATE	1/6/16	1/11/16	1/12/16	1/19/16

OFFICIAL RECORD COPY

Letter to C. Haass from N. Martinez dated January 19, 2016

SUBJECT: REQUESTS FOR ADDITIONAL INFORMATION FOR THE ENVIRONMENTAL REVIEW OF THE NORTHWEST MEDICAL ISOTOPES, LLC CONSTRUCTION PERMIT APPLICATION

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NORTHWEST MEDICAL ISOTOPES, LLC RADIOISOTOPE PRODUCTION FACILITY
ENVIRONMENTAL REQUESTS FOR ADDITIONAL INFORMATION

Each request for additional information (RAI) set forth below is based on a review of Chapter 19 of Northwest Medical Isotopes, LLC's (NWMI's) environmental report (ER) (ADAMS Accession Nos. ML15210A123, ML15210A128, ML15210A129, and ML15210A131) using final Interim Staff Guidance (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 Title 10 of the *Code of Federal Regulation* (CFR) 51.41, provide the following information.

AIR QUALITY

AIR2-1
The ISG augmenting NUREG-1537, Part 1, 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, including fugitive dust. The applicant's response to AIR-1D, which requested clarification on the construction workforce travel assumed in Table 19-56 of the ER, states, in part, that Table 19-63 accounts for the commuting workforce and routine deliveries to/from the radioisotope production facility (RPF). However, Table 19-63 pertains to vehicle emissions from operations. Table 19-56 of the ER identifies 100 for workforce travel during the construction phase but Table 19-6 identifies a peak workforce of 82 during construction. Clarify why 100 workforce travel was used in Table 19-56.

AIR2-2
The ISG augmenting NUREG-1537, Part 1, Section 19.4.2, "Air Quality and Noise" states that the 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. Clarify the applicant's response to AIR-2A and AIR-2B. Specifically:

a. AIR-2A requested that the response include supporting calculations used in determining NO_x, SO_2, or CO_2 emissions resulting from the production process. Calculations for NO_X emissions were not provided. Provide the supporting calculations or a detailed description of the assumptions used to determine NO_x emissions from dissolution.
b. The applicant's response to AIR-2B, in part, references Table 4-75 of the preliminary safety analysis report (PSAR) and provides an inventory quantity. However, the RAI response and Table 4-75 do not identify the inventory turnover (e.g. monthly, year). Provide the inventory turnover.

AIR2-3
The ISG augmenting NUREG-1537, Part 1, Section 19.4.2, "Air Quality and Noise" states that the 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. Provide the following ER references:

a. EDF-3124-0001, 2015, *Estimate of Excavation for the NWMI Radioisotope Production Facility*, Rev. 3, Portage, Inc., Idaho Falls, Idaho, February 2, 2015.

b. EDF-3124-0004, 2015, *Calculation for the Determination of Fugitive Dust during Construction Activities from Construction Equipment*, Rev. 1, Portage, Inc., Idaho Falls, Idaho, February 3, 2015.
c. EDF-3124-0005, 2014, *On-Road Emissions for Vehicles During Construction*, Rev. 0, Portage, Inc., Idaho Falls, Idaho, June 26, 2014.
d. EDF-3124-0006, 2014, *Determination of Wind-Blown Dust during Construction Activities*, Rev. 0, Portage, Inc., Idaho Falls, Idaho, June 26, 2014.EDF-3124-0005, 2014, *On-Road Emissions for Vehicles During Construction*, Rev. 0, Portage, Inc., Idaho Falls, Idaho, June 26, 2014.
e. EDF-3124-0009, 2014, *Off-Road Emissions during Construction*, Rev. 0, Portage, Inc., Idaho Falls, Idaho, June 26, 2014.
f. EDF-3124-0014, 2014, *Emission Modeling for Construction Activities using AERSCREEN*, Rev. 0, Portage, Inc., Idaho Falls, Idaho, June 26, 2014.

ALTERNATIVES

ALT2-1
10 CFR 51.45(b)(3) and the ISG augmenting NUREG-1537, Part 1, Section 19.5 "Alternatives" state that ER should summarize the history and process used to formulate the reasonable alternatives. Section 19.5.2 of the ER describes four sites that NWMI considered in its site selection process.

a. Describe the process NWMI used to initially narrow down the large number of potential sites to the four sites described in the ER.
b. Clarify whether NWMI considered potential sites at or near all existing research and test reactors.
c. Clarify whether the process considered any regional/State-wide factors or any other regional-scale factors or constraints.

ALT2-2
10 CFR 51.45(b)(3) and the ISG augmenting NUREG-1537, Part 1, Section 19.5 "Alternatives" state that ER should summarize the history and process used to formulate the reasonable alternatives. Section 19.5.2 of the ER states that NWMI considered the University of Missouri Research Reactor (MURR) to be a viable site. Clarify whether NWMI considered Oregon State University TRIGA Reactor (OSTR) and McClellan to be viable sites, and what factors NWMI considered to make this determination.

ALT2-3
10 CFR 51.45(b)(3) and the ISG augmenting NUREG-1537, Part 1, Section 19.5 "Alternatives" state that ER should summarize the history and process used to formulate the reasonable alternatives. The NWMI Site Alternative Study provided in the applicant's response to RAI ALT-2A describes some site-specific factors that NWMI considered to develop the scoring for each site under each category listed in Table 19-88 of the ER. The following RAIs pertain to the NWMI Site Alternative Study:

a. For "Production Logistics," clarify the differentiating factor(s) for why NWMI assigned Discovery Ridge a score of 4 and MURR a score of 2 given that the study states that both facilities are the same distance to the primary and secondary reactors. In addition, clarify why NWMI gave OSTR and McClellan a score of 3 and MURR a score of 2 given that MURR is the location of the primary irradiation reactor.
b. For "Transportation," clarify why NMWI gave Discovery Ridge and MURR a score of 4 given that the study states that if the RPF is located at Discovery Ridge or MURR, more Rocky Mountain crossings would occur, which may increase the probability of delays. In

addition, clarify the differentiating factor(s) for why NWMI gave OSTR a score of 2 and McClellan a score of 3.

c. For "Waste Generation," clarify the differentiating factor(s) for why NWMI gave McClellan a score of 3 and the other three sites a score of 4.
d. For Federal, State, and Local Requirements, clarify what State and local requirements are expected to be most significant at McClellan and less significant at the other three sites.
e. For "Federal and State Taxes and Incentives," clarify the differential factor(s) for why NWMI gave OSTR a score of 3 and Discovery Ridge and MURR a score of 5 given that Oregon does not have sales tax and Missouri has a sales tax of 4.225 percent, the corporate tax is slightly higher for Oregon compared to Missouri, and the alternative study characterized property tax and incentives to be similar for OSTR, Discovery Ridge, and MURR.
f. For "Available Space," clarify the differentiating factor(s) for why NWMI gave MURR a score of 3, OSTR a score of 1, and McClellan a score of 2 given that the study states that MURR only has availability for limited future expansion, whereas OSTR and McClellan both have sufficient space for future expansion.
g. For "Construction Costs," clarify why NWMI gave Discovery Ridge and MURR a score of 4 and OSTR a score of 3 given that the study states that the construction cost for Discovery Ridge and MURR are expected to be similar to OSTR. In addition, clarify why the alternatives study states that the construction cost would be similar for Discovery Ridge, MURR, and OSTR whereas the applicant's response to RAI ALT-2B states that the construction costs would be higher at MURR and OSTR than at Discovery Ridge.

CONNECTED ACTIONS

CONN2-1
In RAI CONN-1A2, the NRC staff asked for information to evaluate the site-specific environmental impacts associated with the connected actions.

The applicant's response to CONN-1A2 states that refurbishment will require subcontracted personnel and will be temporary. Provide the total approximate number of workers needed to support modifications.

GEOLOGIC ENVIRONMENT

GEO2-1
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.

The applicant's response to GEO-1A and GEO-2 in part, indicates that the maximum depth for below-grade portions of the RPF could range from 17 to 23 ft. Section 19.3.4.3.2 of the ER states that groundwater was observed in Boring B-5 (located midway between Lots 14 and 15) and in Boring B-6 (located on Lot 10) at depths ranging from approximately 12–18.5 ft. Section 19.4.4.2.1 of the ER acknowledges that some dewatering may be required during construction. Given the identified potential for high water table elevations (or perched groundwater conditions) beneath the site, please describe and elaborate on how high water table elevations will be managed during construction, the projected rate and duration of dewatering, and the potential impacts on local groundwater sources and direction of flow. Also, please discuss the facility

design considerations for permanently or seasonally high water tables as well as the implications for facility operations.

Human Health

HH2-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. Section 19.4.10.1.3 of the ER states that "[e]xposure from ^{99}Mo to the general public during the flight is assumed to be negligible and was not calculated." Provide a technical basis for why NWMI assumes that exposure from ^{99}Mo to the general public resulting from flight mode transportation is negligible.

HH2-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. Table 11-2 in PSAR Chapter 11 titled "Radionuclide Stack Release Source Term Input to COMPLY" contains the types and quantities of estimated radionuclide gaseous releases under normal operating conditions. Please provide a non-proprietary version of this table and the corresponding calculated maximum dose to the public from the normal operational stack releases used in determining 10 CFR 20.1101(d) compliance with the as low as reasonably achievable (ALARA) dose constraint.

HH2-R-3
The ISG augmenting NUREG-1537, Part 1, Section 19.3.8, "Human Health," states that the ER should provide a description of the facility's radiological programs and radiological monitoring systems. In response to RAI GEO-1B and in the ER, NWMI has stated that there will be no liquid radioactive effluent releases to the environment or the sanitary sewer from the RPF, and therefore there will be no environmental liquid monitoring conducted. Given that there is no liquid environmental monitoring proposed for the site around the RPF:

a. Please describe how the applicant plans to quantify an inadvertent liquid radiological release and determine the environmental impact of such release and associated radioactive dose to the public.
b. Please describe how the applicant will determine and quantify the environmental impacts and associated radioactive doses to the public from deposition of normal gaseous effluent release radionuclides from vent stack emissions to any nearby surface water and the underlying groundwater aquifer.

HH2-R-4
The ISG augmenting NUREG-1537, Part 1, 13b.2, "Analyses of Accident with Radiological Consequences," states the applicant's maximum hypothetical accident analyses should provide radiation dose estimates for the operating staff throughout the event and during recovery operations and also for the maximally exposed individual in the uncontrolled areas and at the nearest permanent residence . Section 19.4.11.1.1 of Chapter 19 of the ER does not provide calculated doses for the licensee staff, calculated doses at the fence boundary or the nearest residence. Please provide the calculated doses for the licensee staff as well as the calculated doses at the fence boundary and the nearest residence (as provided in the chemical Maximum Hypothetical Accident analysis). Also, please state whether these doses are within 10 CFR Part 20 limits.

HH2-R-5
Section 19.4.11.1.1 of Chapter 19 of the ER contains Table 19-83, "MHA Dose Analysis Results." The applicant states that the dose estimates are derived from EDF-3124-0003, 2015, *Preliminary Maximum Hypothetical Accident to Support the Northwest Medical Isotope Facility Environmental Report*, Rev. 1, Portage, Inc., Idaho Falls, Idaho, February 5, 2015. Please provide a copy of this document.

NOISE

NOI2-1
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. The applicant's responses to RAI NOI-2 and NOI-3 states that noise modeling was performed using Federal Highway Administration's Traffic Noise Model 2.5 and that changes from existing noise levels due to the increased workforce during construction, operation, and decommissioning would be less than 1 dBA. Provide the following information pertaining to the noise modelling conducted:

a. What baseline noise levels were assumed or calculated from the model and what is the basis for the baseline levels?
b. The peak traffic count input value used in the model
c. Clarify if the nearest resident mentioned in the response is the nearest resident from the proposed radioisotope productions facility or nearest resident along Highway 63 and provide that distance.

PRECONSTRUCTION

PREC2-1
10 CFR 51.45(c) states that the applicant must include a description of impacts of the preconstruction activities performed by the applicant at the proposed site (i.e., those activities listed in paragraph (1)(ii) in the definition of "construction" contained in 10 CFR 51.4). The ER does not separate preconstruction from construction activities and resources. Provide the following:

a. A description of the preconstruction activities
b. Duration of pre-construction activities
c. Average and peak-workforce required during pre-construction activities
d. Number of delivery trucks and offsite shipments during pre-construction activities
e. Fuel consumed during pre-construction
f. Volume of water required for onsite activities and the expected source
g. Estimated land disturbed and cleared during pre-construction activities
h. Estimated material consumed for the pre-construction portion of activities that is presented in Table 19-7 of the ER
i. Number of hours and material moved for the pre-construction portion of the activity and equipment identified in Table 19-51

PROPOSED ACTION

PA2-1
The ISG augmenting NUREG-1537, Part 1, Section 19.2, "Proposed Action" states that the application should provide a schedule showing the major phases of the proposed action. Section 19.2.1.1 of the ER identifies the start date of decommissioning, however, information on the duration of decommissioning activities (similar to what was provided for construction) is not included. Please provide information on the duration (e.g. months, years) of the decommissioning phase.

PA2-2
The ISG augmenting NUREG-1537, Part 1, Section 19.2, "Proposed Action" states that the application should estimate the average number of truck deliveries and shipments of waste material offsite per day, week, or month during each of the major phases of the proposed action.

The applicant's response to RAI PA-4 states that Table 19-6 of the ER, row "Offsite radioactive materials and waste shipment," includes irradiated and unirradiated LEU targets, ^{99}Mo shipments, radioactive waste, and low enriched uranium (LEU) shipments. Table 19-6 identifies 10 offsite radioactive materials and waste shipments per week during operation, therefore approximately 520 shipments/year. Table 19-14 identifies 2 shipments/year of fresh LEU, 42 shipments/year of unirradiated LEU targets, 136 shipments/year of irradiated LEU targets, 104 shipments/year of ^{99}Mo product, 2 shipments/year of spent LEU, and 200 shipments/year of radioactive waste which results in a total of 486 shipments/year. Please explain the differences in the number of offsite shipments (520 shipment/year versus 486 shipments/year) identified in Table 19-6 and Table 19-14.

PA2-3
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.

The applicant's response to RAI PA-1 states that the impacts associated with the preoperational phase were considered within the operating phase of the RPF. Table 19-6 of the ER identifies 2 delivery trucks per week and 0.5 offsite radioactive materials and waste shipments per week during the pre-operation phase. Please identify and summarize the types of materials (for instance, LEU) that will be delivered and off-site shipments during the pre-operation phase, as was provided for operations in ER Table 19-14.

WATER RESOURCES

WAT2-1
ISG to NUREG-1537, Part 1, Section 19.3.4, "Water Resources," states that the applicant should describe site-specific and regional data on the physical and hydrological characteristics of surface water and groundwater, etc. Section 19.3.4 further states that the following groundwater characteristics should be provided for features that could be affected by the construction, operation, and decommissioning of proposed facilities as follows:

a. Historical and seasonal trends in groundwater elevation or piezometric levels.

b. Piezometric contour maps, water table contour maps, and hydraulic gradients (historical, if available, and current).
c. Depth to water table for unconfined aquifer systems.
d. Historical and current data from site wells (e.g., monitoring, background, corrective action, or other uses).
e. Hydrostratigraphy of the site, including cross sections and hydrostratigraphic unit descriptions.
f. Qualitative description of groundwater aquifers, including identification of U.S. Environmental Protection Agency (EPA)-designated sole-source aquifers.

The information the applicant provided in the ER and response to RAI GEO-1 do not provide sufficient information with respect to the above referenced items, and site-specific information on groundwater conditions relative to the proposed RPF site and vicinity, including static water levels and groundwater flow direction. Please provide the information in items (a) through (f) above and in sufficient detail to specifically address the issue of whether groundwater encountered in previously completed soil borings across the Discovery Ridge Site reflects a surficial water-table aquifer or perched groundwater and/or whether this groundwater is a local water supply source.