



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

June 16, 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 (TAC NOS. MF6134 AND MF6135)

Dear Ms. Haass:

On November 7, 2014, Northwest Medical Isotopes, LLC (NWMI) filed with the U.S. Nuclear Regulatory Commission (NRC) pursuant to Section 103 of the Atomic Energy Act of 1954, as amended, and Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR), a portion of an application for a construction permit for a medical radioisotope production facility in Columbia, Missouri. By letter dated February 5, 2015, NWMI withdrew and resubmitted this portion of their construction permit application to include a discussion of connected actions in their environmental report in response to a letter from the NRC (ADAMS Accession No. ML14349A501). By letters dated November 2, 2015 and April 25, 2016, NWMI submitted responses to requests for additional information (ADAMS Nos. ML15328A010 and ML16123A119).

The NRC staff is reviewing information submitted to the NRC, information NWMI provided in teleconference calls documented in meeting summaries (ADAMS Nos. ML16104A043, ML16110A253, ML16124A510, ML16145A018), and information provided via e-mails (ADAMS Nos. ML16117A489, ML16145A004, ML16141A061, ML16153A308). The NRC staff has identified in the enclosure to this letter areas where additional information is needed to complete the environmental review.

NRC staff requests that NWMI provide a response to the enclosed requests for additional information no later than 30 calendar days from the date of this letter. Following receipt of the additional information, NRC staff will continue its evaluation of NWMI's construction permit application. 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."

C. Haass

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If you have any questions, please contact me by telephone at 301-415-6223 or by e-mail at David.Drucker@nrc.gov.

Sincerely,

/RA/

David Drucker, Environmental Project Manager
Environmental Review and Projects Branch
Division of License Renewal
Office of Nuclear Reactor Regulation

Docket No. 50-609

Enclosure:
Requests for Additional Information

cc w/encl: Distribution

C. Haass

- 2 -

If you have any questions, please contact me by telephone at 301-415-6223 or by e-mail at David.Drucker@nrc.gov.

Sincerely,

/RA/

David Drucker, Environmental Project Manager
Environmental Review and Projects Branch
Division of License Renewal
Office of Nuclear Reactor Regulation

Docket No. 50-609

Enclosure:
Requests for Additional Information

cc w/encl: Distribution

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ADAMS Accession No. ML16152A019

*concurred via email

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PERMIT APPLICATION

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

The following questions are based on a review of Chapter 4, 13 and 19 (ADAMS Accession Nos. ML15210A117, ML15210A124, ML15210A122, ML15210A123, ML15210A128, ML15210A129, and ML15210A131) of Northwest Medical Isotopes, LLC's (NWMI's) preliminary safety report (PSAR) and a review of the request for additional information (RAI) responses NWMI provided on November 2, 2015 (ADAMS No. ML15328A010), on January 19, 2016 (ADAMS No. ML16053A221), and on April 25, 2016 (ADAMS No. ML16123A119) using final Interim Staff Guidance (ISG) augmenting NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content," for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors; and Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria" (ADAMS Accession Nos. ML12156A069 and ML12156A075). In accordance with Title 10 of the *Code of Federal Regulation* (CFR) 51.41, provide the following information.

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.

- A. 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.
- B. 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.
- C. 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?

ALT3-1

The ISG augmenting NUREG-1537, Part 1, Section 19.5, "Alternatives," states that the ER should summarize the history and process used to formulate the reasonable alternatives.

Enclosure

- A. 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).
1. Confirm that a below-grade connection to MURR will be needed at the MURR alternative site.
 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.
- B. 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.
1. Identify where the support buildings would be constructed on the MURR alternative site.
 2. Provide an updated figure of the MURR alternative site that identifies the site layout of the RPF building and support buildings.
 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 meters for non-radiological 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.
- C. 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?

- D. 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.

CONN3-1

In support of analyzing the environmental impacts associated with the connected actions, provide the following information:

- A. 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.
- B. 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?
- C. The response to RAI CONN-1 (ADAMS No. ML15328A010) identifies that Ar-41 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 Ar-41 effluents) would be expected from irradiation services at the hypothetical third reactor and provide a basis for this determination.
- D. 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 $3.93\text{E-}06$ 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.

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.

- A. 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 feet tall, and is representative of the tallgrass prairie community. Confirm that Indian grass is the correct species identified in the surveys.

- B. 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.

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.

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 Mo-99 is at a cruising altitude of 20,000 feet. Clarify whether Mo-99 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.

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.

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.

- A. The response to RAI NOI2-1 (ADAMS No. ML6053A221) 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?
- B. The response to RAI NOI2-1 (ADAMS No. ML6053A221) 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.

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.

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.

- A. 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.
- B. 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.

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.

- A. 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.
- B. 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.

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 (⁹⁹Mo) 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 ⁹⁹Mo."

- A. 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.

- B. 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.

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.

- A. 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?
- B. 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.

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 non-radiological hazardous waste. Provide the amount of hazardous, nonradiological waste that will be generated during operation of the proposed RPF facility.

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.