

January 25, 2017

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

SUBJECT: NORTHWEST MEDICAL ISOTOPEs, LLC – REQUEST FOR ADDITIONAL
INFORMATION FOR CONSTRUCTION PERMIT APPLICATION REGARDING
EMERGENCY RESPONSE PLAN (TAC NO. MF6138)

Dear Ms. Haass:

By letter dated July 20, 2015 (NWMI-LTR-2015-006, Agencywide Documents Access and Management System (ADAMS) Accession No. ML15210A114), Northwest Medical Isotopes, LLC. (NWMI) filed with the U.S. Nuclear Regulatory Commission (NRC), pursuant to Section 103 of the Atomic Energy Act of 1954, as amended (the Act), and Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," the second part of its two-part application for a construction permit (CP) for a medical radioisotope production facility. If granted, the CP would allow NWMI to construct a production facility in Columbia, Missouri.

By letter dated December 24, 2015 (ADAMS Accession No. ML15341A112), the NRC staff completed its acceptance review of part two of NWMI's application for a CP. The NRC staff determined that this second and final portion of NWMI's two-part CP application contained the remainder of the preliminary safety analysis report (PSAR) required by 10 CFR 50.34(a), and was submitted in accordance with the requirements of 10 CFR 2.101(a)(5). Therefore, the application was determined to be complete for docketing and was assigned Docket No. 50-609.

In the course of reviewing NWMI's CP application, the NRC staff has determined that additional information is required to complete the review of NWMI's PSAR. This request for additional information (RAI) supports the development of the NRC staff's safety evaluation report that evaluates the requisite findings for the issuance of a CP.

This RAI supplements the NRC's previous RAIs sent by letters dated November 2, 2015, January 19, 2015, March 28, 2016, June 16, 2016, and September 29, 2016 (ADAMS Accession Nos. ML15288A102, ML16020A366, ML16056A122, ML16152A019, and ML16236A013 respectively). The specific information requested is addressed in the enclosure to this letter. It is requested that SHINE respond to this request within 30 days of the date of this letter. Timely responses to RAIs contributes toward an efficient and effective review of the application.

In accordance with 10 CFR 50.30(b), "Oath or affirmation," NWMI must execute its response in a signed original document under oath or affirmation. NWMI's response must be submitted in accordance with 10 CFR 50.4, "Written communications." Information included in this response that NWMI considers sensitive or proprietary must be marked in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." Any information related to security should be submitted in accordance with 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

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

Sincerely,

/RA/

Michael F. Balazik, Project Manager
Research and Test Reactors Licensing Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Docket No. 50-609

Enclosure:
As stated

NORTHWEST MEDICAL ISOTOPES, LLC – REQUEST FOR ADDITIONAL INFORMATION
FOR CONSTRUCTION PERMIT APPLICATION REGARDING EMERGENCY RESPONSE
PLAN (TAC NO. MF6138) DATED January 25, 2017

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REQUEST FOR ADDITIONAL INFORMATION

NORTHWEST MEDICAL ISOTOPES, LLC.

PRELIMINARY EMERGENCY PLAN

CONSTRUCTION PERMIT APPLICATION

DOCKET NO. 50-609

By letter dated February 5, 2015 (NWMI-LTR-2015-003, Agencywide Documents Access and Management System (ADAMS) Accession No. ML15086A262), Northwest Medical Isotopes, LLC. (NWMI) submitted part one of its two-part construction permit (CP) application, primarily consisting of NWMI's environmental report. By letter dated July 20, 2015 (NWMI LTR-2015-006, ADAMS Accession No. ML15210A114), NWMI submitted the second and final part of its application for a CP. With this submittal, NWMI provided an emergency response plan.

In the course of reviewing NWMI's CP application, the U.S. Nuclear Regulatory Commission (NRC) staff has determined that additional information is required to complete the review of the NWMI preliminary safety analysis report (PSAR) submitted on July 20, 2015 (ADAMS Package No. ML15210A182), in support of the development of its safety evaluation report.

These requests for additional information (RAIs) have been developed based on the following requirements and guidance applicable to the NWMI production facility, specifically the emergency response plan, as described in the NWMI PSAR:

- Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50
- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (ADAMS Accession No. ML042430055)
- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (ADAMS Accession No. ML042430048)
- "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ADAMS Accession No. ML12156A069)
- "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production

Enclosure

Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012 (ADAMS Accession No. ML12156A075)

- NUREG-0849, “Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors,” dated October 31, 1983 (ADAMS Accession No. ML062190191)
- Regulatory Guide 2.6, Revision 1, “Emergency Planning for Research and Test Reactors,” dated March 1983 (ADAMS Accession No. ML003740234)
- ANSI/ANS-15.16-1995 (R2013), “Emergency Planning for Research Reactors
- NUREG-1520, Revision 2, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility” dated June 2015 (ADAMS Accession No. ML15176A258)

CHAPTER 12 – CONDUCT OF OPERATIONS

The following requests for additional information (RAIs) are based on a review of Chapter 12, Appendix A, of the Northwest Medical Isotopes (NWMI) Preliminary Safety Analysis Report (PSAR) (ADAMS Accession Package No. ML15210A182). The NRC staff evaluated the NWMI emergency response plan (ERP) against the applicable regulatory requirements using the regulatory guidance and standards listed to assess the sufficiency of the ERP. The NRC staff has determined that additional information is needed to complete our review of the ERP.

Appendix A – Emergency Response Plan

RAI 12A-1 As required in Appendix E.II to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, the PSAR should address the site layout and location, consideration of access routes, surrounding population distribution, land use, and jurisdictional boundaries. Guidance in the ISG augmenting NUREG-1537, Section 12.7.1, "Introduction," states that the application should include a general area map covering a radius of approximately 16.1 km (10 mi); a U.S. Geological Survey topographical quadrangle (7.5-minute series, including the adjacent quadrangles if the site is located less than 1.61 km (1 mi) from the edge of the quadrangle); and a map or aerial photograph indicating on-site and near-site structures within a radius of approximately 1.61 km (1 mi). PSAR Chapter 12, Appendix A, Section A6.0, "Emergency Planning Zone," Figure A-3, "Radioisotope Production facility Complex in the Columbia Area," is not legible and does not provide sufficient details of the area.

Additional information is needed to meet the requirement of Appendix E.II to 10 CFR Part 50, and conform to the guidance of NUREG-0849, Section 1.0, Evaluation Item 1.b., and the ISG augmenting NUREG-1537, Part 2, Chapter 12, Section 12.7.1, "Emergency Planning."

- a. Provide a legible figure of the facility and/or an electronic copy that could be manipulated to facilitate resolution of building names/numbers and labels, roads and parking lots, site boundaries showing fences and gates, major site features, access routes, and water bodies within approximately 1 mile of the site.
- b. Provide a general area map covering a radius of approximately 16.1 km (10 mi) consistent with the information discussed above. The map should also include the location of sensitive facilities near the site, such as hospitals, schools, nursing homes, nearest residence, fire department, prisons, environmental sampling locations, and other structures and facilities that are important to emergency management.

RAI 12A-2 As required in Section II.B to Appendix E of 10 CFR Part 50, the PSAR should address contacts and arrangements made and documented with local, State, and Federal governmental agencies with responsibility for coping with emergencies, including identification of the principal agencies. Concerning this requirement, the ISG augmenting Section 12.7.3, "Organization and Responsibilities," to

NUREG-1537, Part 2, provides the guidelines for reviewing applications and references in NUREG-0849. Section 3.0, "Organization and Responsibilities," to NUREG-0849 states, in part, that the plan should describe the emergency organization that would be activated to cope with radiological emergencies.

PSAR Chapter 12, Appendix A, Section A3.0 describes the authorities, responsibilities, and support functions of Federal, State, county, and local government agencies in an emergency situation. It also provides the statement: "Written support agreements have been obtained from the City of Columbia, Police and Fire Departments, Boone Hospital, and University Hospital to ensure a clear understanding of the emergency support responsibilities of key support organizations," but the NRC staff determined additional information is needed.

Information required to meet the requirement of Section II. B to Appendix E of 10 CFR Part 50.

- a. Describe what contacts and arrangements have been made and documented with local, State, and Federal governmental agencies with responsibility for coping with emergencies.
- b. Clarify the organizational responsibility for the support function of the Missouri Office of Emergency Coordination, as stated in Section A3.1.2, "State Agencies," to the NWMI ERP, in relation to the formal radiological emergency preparedness program.
- c. Clarify whether the Missouri State Emergency Management Agency under the Missouri Department of Public Safety has responsibility for the State's formal radiological emergency preparedness program. If applicable, the NWMI ERP should be revised to include the organizational responsibility of the Missouri State Emergency Management Agency, or explain why this is not necessary.

RAI 12A-3 As required in Section II.C to Appendix E of 10 CFR Part 50, the PSAR shall address the protective measures to be taken within the site boundary and within each emergency planning zone (EPZ) to protect health and safety in the event of an accident and the procedures by which these measures are to be carried out. PSAR Chapter 12, Appendix A, Section A6.0 describes the EPZ and provides Figure A-3 to indicate the operations boundary. Protective measures, procedures, and notifications are provided in Section A7.0.

In support of around-the-clock emergency response, identify the 24-hour on-shift staff positions designated and trained to perform the initial responsibilities of the Emergency Director, Emergency Coordinator, Radiation Safety Officer, and Radiological Assessment Team until these positions are filled by responding emergency personnel.

RAI 12A-4 ISG augmenting NUREG-1537, Part 2, Section 12.7.3 "Organization and Responsibilities," specifically calls for prompt notification of off-site response authorities, normally within 15 minutes of the declaration of an emergency classification, and notification of the NRC Operations Center as soon as possible but no later than 1 hour after a declared emergency.

Confirm if these specified notification times are included in the NWMI emergency response plan. If not in the NWMI ERP, revise the NWMI ERP to include these notification times.

RAI 12A-5 PSAR Chapter 12, Appendix A, Section A3.3.2, list the responsibilities of the Emergency Director and Emergency Coordinator. It appears that these positions share similar responsibilities. NUREG-0849, Section 3.0, "Organization and Responsibilities," Evaluation Item 1.0 j, in NUREG-0849, states that the emergency plan should identify the individual who may authorize reentry into the NWMI facility (or portion thereof) that required evacuation during the emergency. This responsibility appears to be assigned to both the Emergency Director and the Emergency Coordinator positions.

Information is required to meet the requirement of Sections II.A and II.C to Appendix E of 10 CFR Part 50, and conform to the guidance of NUREG-0849, Section 3.0.

Clarify if the Emergency Director and Emergency Coordinator share this responsibility, and if so, does the authorization for reentry into the RPF that required evacuation require a joint decision.

RAI 2.5-2 As required in Section II.F to Appendix E of 10 CFR Part 50, the PSAR should address the need for a training program for employees of the licensee. Concerning this requirement, ISG augmenting Section 12.7.10, "Maintaining Emergency Planning," to NUREG-1537, Part 2, provides the guidelines for reviewing applications and references NUREG-0849. Section 10.0, "Maintaining Emergency Planning," to NUREG-0849 states, in part, that the emergency plan should describe the elements necessary for maintaining an acceptable state of emergency preparedness.

PSAR Chapter 12, Appendix B, Section A10.0 describes the elements necessary to maintain an effective emergency preparedness plan which include training, review and updating of the emergency plan and associated implementing procedures, and maintenance and inventory of equipment and supplies that would be used in emergencies.

Section A10.0, "Maintaining Emergency Preparedness," to NUREG-0849 states, in part, that the emergency plan should provide the elements necessary for maintaining an acceptable state of emergency preparedness. While all the elements of NUREG-0849 are listed in Section A10.0 of the NWMI ERP, with the exception of first aid and rescue personnel, Section 12.7.10, "Maintaining

Emergency Preparedness,” of the ISG augmenting NUREG-1537 Part 2, calls for the applicant to provide the following supplemental details and information:

- Administration of the training program, including responsibility for training, pertaining to all required staff members;
 - Schedule for training;
 - Frequency of retraining;
 - Estimated number of hours of initial training and retraining; and
 - Training to be provided on the use of protective equipment, such as respirator, protective clothing, monitoring devices, and other equipment used in emergency response.
- a. Provide the details of the training program to include the above criteria.
- b. Describe the training to be provided for first aid and rescue personnel.

RAI 12A-7 ISG augmenting NUREG-1537, Part 2, Section 12.7, states that an adequate emergency plan should demonstrate the following:

- Qualified individuals for each position in the emergency response organization demonstrate task-related knowledge through periodic participation.
- Emergency drills demonstrate that resources are effectively used to control the site, mitigate further damage, control radiological releases, perform required on-site activities under simulated radiation or airborne and other emergency conditions, accurately assess the facility’s status during an accident, and initiate recovery.
- Emergency drills demonstrate personnel protection measures, including controlling and minimizing hazards to individuals during fires, medical emergencies, mitigation activities, search and rescue, and other similar events.
- Emergency drills demonstrate that on-site communications effectively support emergency response activities.
- Emergency drills demonstrate that the emergency public information organization disseminates accurate, reliable, timely, and understandable information.
- Provisions are made for conducting quarterly communications checks with off-site response organizations.

- Off-site organizations are invited to participate in the biennial on-site exercise, which tests the major elements of the emergency plan and response organizations.

This information is required to meet the requirement of Section II.F to Appendix E of 10 CFR Part 50, and conforms to the guidance of the ISG augmenting NUREG-1537 Part 2, Section 12.7.10.

Clarify how the conductance of drills, as described in PSAR Chapter 12, Appendix A, Section A10.2, "Emergency Drills," demonstrates the above guidance.

RAI 12A-8 As required in Section II.H to Appendix E of 10 CFR Part 50, the PSAR should provide a preliminary analysis reflecting the need to include facilities, systems, and methods for identifying the degree of seriousness and potential scope of radiological consequences of emergency situations. Concerning this requirement, the ISG augmenting NUREG 1537, Part 2, Section 12.7.5, "Emergency Action Levels," provides the guidelines for reviewing applications and references NUREG-0849, Section 5.0, "Emergency Action Levels."

PSAR, Chapter 12, Section A5.0 does not contain action levels with initiating conditions such as effluent monitor set points appropriate to the facility and consistent with NUREG-0849 Appendix I.

Specify the effluent monitors used to project dose rates and radiological effluent releases, and include the set points in the emergency action levels (EALs) to initiate protective actions as per guidance of NURG-0849, or explain why this information is not necessary.

RAI 12A-9 PSAR, Chapter 12, Section A5.0, "Emergency Action Levels" contains Table A-1, "Emergency Classes and Action Levels." NWMI did not provide a basis for the General Emergency classification listed in Table A-1. Additionally, the Site Area Emergency and General Emergency classifications have the same EALs listed in Table A-1. This information is inconsistent with information in Section A4.5 of the NWMI ERP.

This information is required to meet the requirement of Appendix E to 10 CFR Part 50, and conform to the guidance of NUREG-0849, Section 5.0; ISG Augmenting 1537, Part 2, Section 12.7.5; and ANSI-ANS-15.16-2015.

- a. Clarify the basis for the inclusion of a General Emergency classification in PSAR Chapter 12, Appendix A, Section A5.0.
- b. Explain why the Site Area Emergency and General Emergency EALs are identical in Table A-1 of the NWMI ERP.

- c. Explain why there are no security-related action level as discussed in ANSI/ANS-15.16-2015, "Emergency Planning for Research Reactors," associated with an Alert.