

April 28, 2017 NWMI-LTR-2017-002

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 January 25, 2017

References:

- U.S. Nuclear Regulatory Commission letter to Northwest Medical Isotopes, LLC, dated January 25, 2017, Docket No. 50-609 (ADAMS Accession No. ML16056A122), "Northwest Medical Isotopes, LLC – Request for Additional Information for Construction Permit Application Regarding Emergency Response Plan Regarding Application For Construction Permit (TAC No. MF6138)"
- Northwest Medical Isotopes, LLC Letter NWMI-LTR-2015-006 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"

Dear Mr. Balazik:

Northwest Medical Isotopes, LLC (NWMI) is providing an amended response (Attachment 1) to the U.S. Nuclear Regulatory Commission request for additional information dated January 25, 2017.

NWMI is submitting this response to the NRC in accordance with 10 CFR 50.30(b), "Oath or Affirmation," and 10 CFR 50.4, "Written Communications."

I solemnly declare and affirm that the foregoing information is true and correct under the penalty of perjury; executed on April 28, 2017.

ADZO AX45 NRR Mr. Michael Balazik page 2

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

Sincerely,

Carolyn C. Haass
Chief Operating Officer

Enclosures: Attachment 1

cc: Mr. Alexander Adams

Research and Test Reactors Branch A Office of Nuclear Reactor Regulation



ATTACHMENT 1

U.S. Nuclear Regulatory Commission
Request for Additional Information for Construction Permit Application
Regarding the Emergency Response Plan
(TAC No. MF6138)

Northwest Medical Isotopes, LLC Construction Permit Application Docket No. 50-609

(Document No. NWMI-2017-RAI-001, Rev. 1, April 2017)

Information is being provided via hard copy



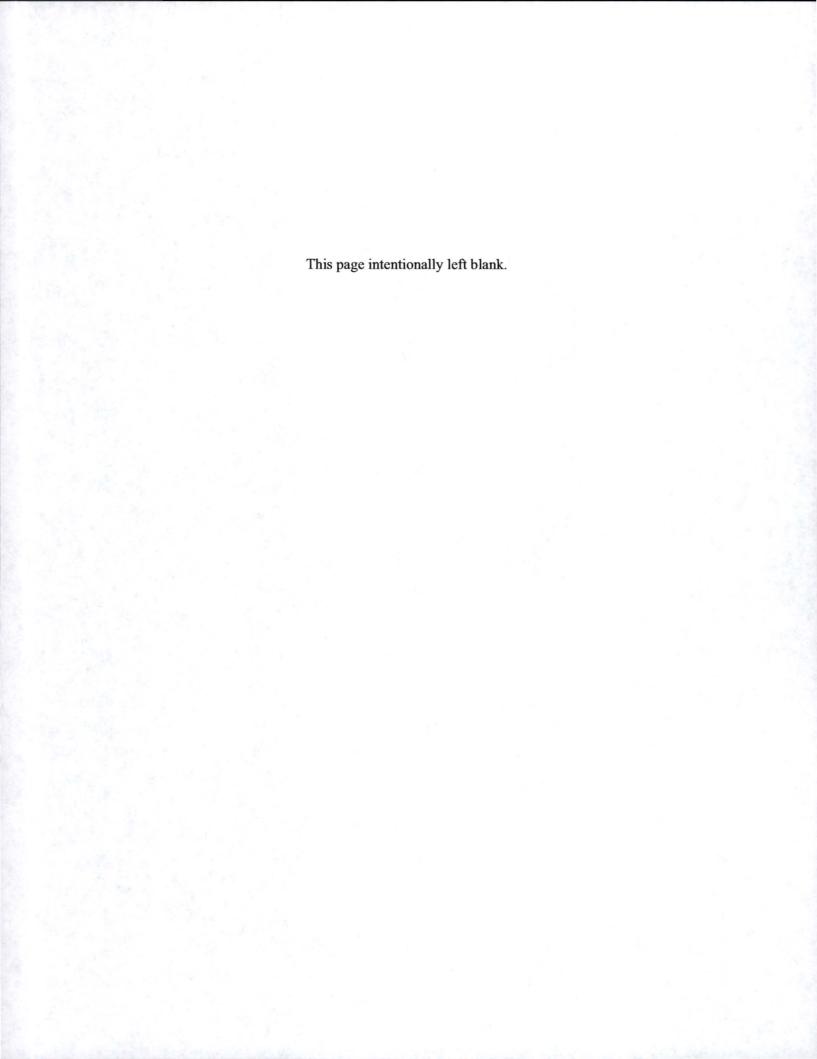
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Response to the
U.S. Nuclear Regulatory Commission
Request for Additional Information
for Construction Permit Application
Regarding the Emergency Response Plan
(TAC No. MF6138)

NWMI-2017-RAI-001, Rev. 1 April 2017

Prepared by: Northwest Medical Isotopes, LLC 815 NW 9th Ave, Suite 256 Corvallis, OR 97330





Response to the **U.S. Nuclear Regulatory Commission Request for Additional Information** for Construction Permit Application Regarding the Emergency Response Plan (TAC No. MF6138)

NWMI-2017-RAI-001, Rev. 1

Date Published: April 28, 2017

Document Number: NWMI-2017-RAI-007

Revision Number: 1

Title: Response to the U.S. Nuclear Regulatory Commission Request for Additional Information for Construction Permit Application Regarding the Emergency Response Plan (TAC No. MF6138)

Approved by: Carolyn Haass

Signature: Canolys CHauss



REVISION HISTORY

Rev	Date	Reason for Revision	Revised By
0	3/6/2017	Issued for submittal to the NRC	N/A
1	4/28/2017	Incorporated clarifications to responses.	C. Haass



TERMS

Acronyms and Abbreviations

ANS American Nuclear Society

ANSI American National Standards Institute

CFR Code of Federal Regulations
EPZ emergency planning zone
ERP Emergency Response Plan
ISG Interim Staff Guidance

NRC U.S. Nuclear Regulatory Commission
NWMI Northwest Medical Isotopes, LLC
PSAR preliminary safety analysis report
RPF Radioisotope Production Facility

U.S. United States

Units

km kilometer mi mile



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CHAPTER 12.0 – CONDUCT OF OPERATIONS

No.	Request for additional information
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 indicting 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."
RAI 12A-1a	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.

A legible copy of the proposed Northwest Medical Isotopes, LLC (NWMI) Radioisotope Production Facility (RPF) is provided in Figure 1. This figure will replace Figure A-3 in NWMI-2013-021, Construction Permit Application for Radioisotope Production Facility, Chapter 12.0, "Conduct of Operations," Appendix A, "Emergency Response Plan." In addition, Figure 2 and Figure 3 on subsequent pages provide additional detail of the RPF site (including roads, fences, gates, access routes) (Chapter 19, Figure 19-7) and water bodies within 1 kilometer (km) (1-mile [mi]) of the RPF, respectively.



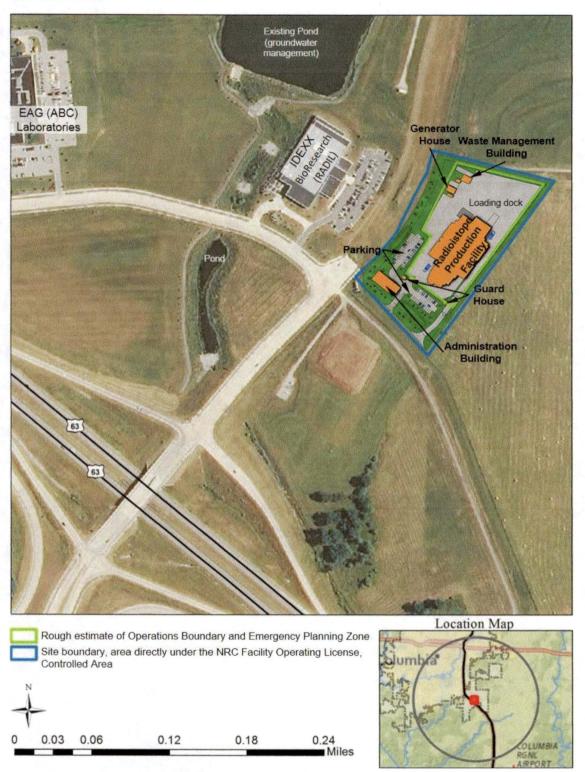


Figure 1. Radioisotope Production Facility Complex in the Columbia Area (Replacement for Figure A-3)





Figure 2. Radioisotope Production Facility Site Plan





Source: Google Maps, 2017

Figure 3. Water Bodies within 1.6 kilometers (1 mile) of the Site

No.	Request for additional information
RAI 12A-1b	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.

An area map covering a radius of 8 km (5-mi) was provided in Chapter 19, Figure 19-41. Figure 4 is a new area map covering a radius of 16.1 km (10 mi). The map includes the location of sensitive facilities near the RPF site, such as hospitals/medical facilities, schools, nursing homes/retirement communities, nearest residence, fire stations, and other structures and facilities that are important to emergency management. A U.S. Geological Survey 7.5 series map is provided in Figure 5.



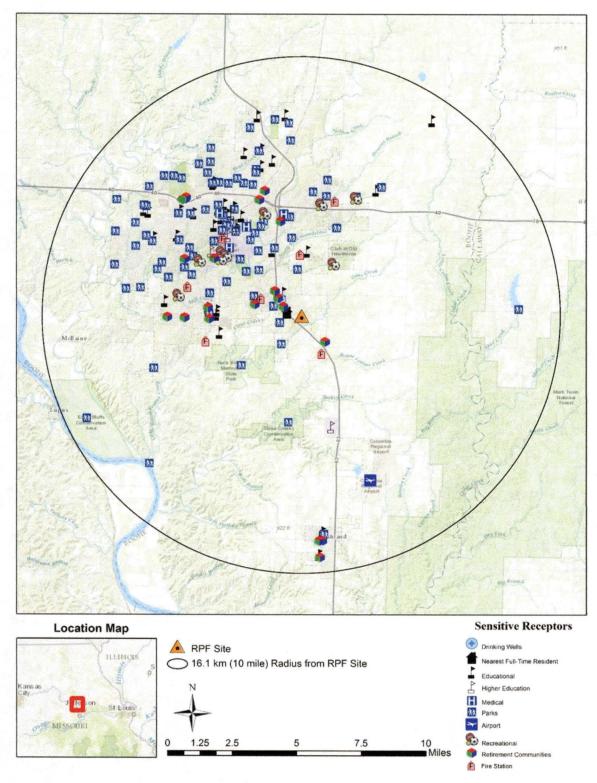


Figure 4. Sensitive Receptors within 16.1km (10 mile) Radius of the Radioisotope Production Facility Site



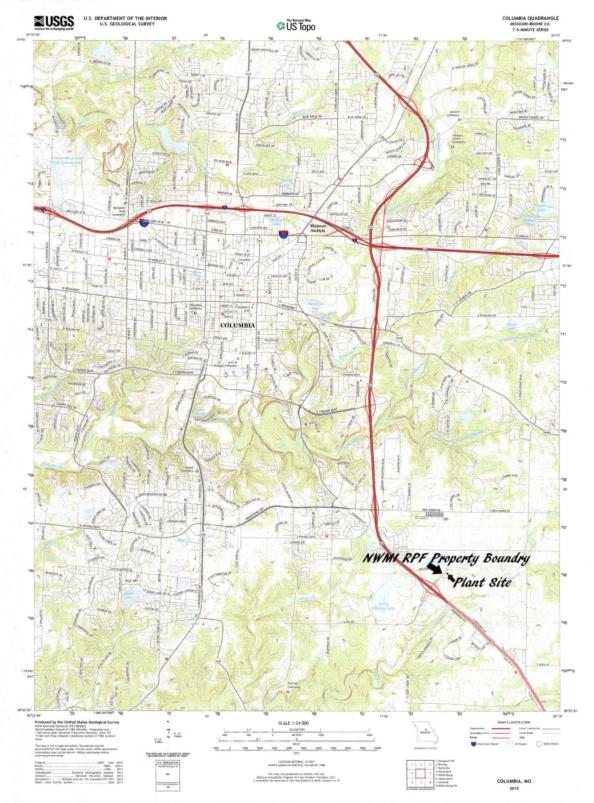


Figure 5. U.S. Geological Survey 7.5-Minute Topographic Quadrangle with Property Boundary



No.	Request for additional information
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.
RAI 12A -2a	Describe what contacts and arrangements have been made and documented with local, State, and Federal governmental agencies with responsibility for coping with emergencies.

No formal arrangements have currently been made with any responding agency listed in Chapter 12, Appendix A, Section A3.0. With respect to local agencies, introductory conversations have taken place with the City of Columbia Fire Department, the emergency preparedness department of the University of Missouri Hospital (also involved with the ambulance service), and the Boone County Office of Emergency Management. These discussions have been limited to a description of the NWMI RPF and draft emergency plan for the RFP. The Federal government agency, the U.S. Nuclear Regulatory Commission (NRC), by virtue of this application, is aware of the facility but no formal contacts or arrangements have been made. Continued interactions, discussions, and agreements are anticipated with these organizations before the Operating License Application is submitted.

RAI 12A-2b	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 a formal radiological emergency preparedness program.

The listing of the Missouri Office of Emergency Coordination as the primary contact for radiological emergencies is in error. The Missouri Office of Emergency Coordination will be replaced with the Missouri State Emergency Management Agency in Section A3.1.2 of Appendix A.

RAI 12A-2c 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.

The Missouri State Emergency Management Agency has responsibility for the State's formal radiological emergency preparedness program. Sections A3.1.2 and A3.3.3 of Appendix A will be updated to include the organization responsibility of this agency.



No.	Request for additional information
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.

The staff positions were intended to be by title, not by individual. The individuals who fill these staff positions will be identified in implementation procedures, which will be developed and submitted as part of the NWMI Operating License Application. The 24-hour on-shift positions identified in Section A3.3.2 include:

- Emergency Director Plant Manager, Chief Operating Officer, and Operations Manager
- Emergency Coordinator Operations Manager, Safety Health and Licensing Manager, and Radiation Protection Manager
- Radiation Safety Officer Radiation Protection Manager, Safety Health and Licensing Manager, and Shift Supervisor
- Radiological Assessment Team Radiation Protection Manager and Shift Supervisor.

The Radiological Assessment Team will also comprise the hot cell operators, supervisors, health physicists, or process technicians on shift at the time.

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.

The following sentence will be added to the first paragraphs of Sections A4.2 and A4.3, "The appropriate off-site agency described in Section A3.1 (depending on the nature of the emergency), should be notified within 15 minutes of the emergency being declared. Notification shall be made to the NRC Operations Center as soon as is reasonably possible, but no later than one hour after the declared emergency."

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.

The eighth bullet under the responsibilities of the Emergency Director will be deleted in Section A3.3.2. Authorization for reentry after an evacuation will rest with the Emergency Coordinator only.



No.	Request for additional information
RAI 2.5-2 [RAI 12A-6]	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.
RAI 12A-6a	Provide the details of the training program to include the above criteria.

In Section A3.3.1, a second paragraph will be added to read, "The Safety, Security and Emergency Preparedness Manager will have organizational responsibility for maintenance and implementation of an emergency preparedness program, including this plan, for facility equipment and personnel, including the scheduling and performance of equipment maintenance, personnel training, coordination with off-site

support organizations, and drills associated with the emergency plan." The last three bullets in Section A3.3.2 under the responsibilities of the Emergency Coordinator will be deleted.

The first item in Section A10.1 will be amended to read, "Initial and annual retraining will be conducted for emergency response personnel to maintain the ability to perform their assigned functions during an emergency event."

The third item in Section A10.1 will be amended to read, "Training will also include, as appropriate, information on the use of protective equipment, protective clothing, and monitoring devices used in emergency response relevant to the personnel listed above. Initial training on the emergency plan should nominally take two hours and annual retraining should take one hour to perform."

RAI 12A-6b Describe the training to be provided for first aid and rescue personnel.

Training for first aid responders is described in Section A8.3.1. Additionally, because they are members of the RPF emergency organization, first aid personnel would participate in annual training, as described in Section A10.1. Rescue personnel are not specifically identified in the emergency plan but are assumed to include individuals whose training is described in Section A10.1.



No.	Request for additional information
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.
	 Offsite 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.

Item one of Section A10.2 will be amended to read, "Annual on-site emergency drills will be conducted as action drills, with each required emergency measure being executed as realistically as is reasonably possible. Drills should be conducted such that:

- Qualified individuals for each position in the emergency response organization demonstrate taskrelated knowledge through periodic participation.
- Emergency drills demonstrate that resources are effective and 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."

The following will be added to Section A10.4.2 (1.), "The ability to communication with off-site responding agencies shall be checked quarterly."

The participation with off-site emergency response organizations is described in item three of Section A10.2.



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.
setpoints for manufacturer	itors used to project dose rates and radiological effluent releases and any associated such systems will be identified in the NWMI Operating License Application. The t, detection methodology, and (therefore) instrument setpoints will also be identified in the cense Application.
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.
RAI 12A-9a	Clarify the basis for the inclusion of a General Emergency classification in PSAR Chapter 12, Appendix A, Section A5.0.
reach the eme Therefore, Se the RFP beca emergency in	-021, Chapter 13.0, as amended, shows that the maximum dose to the general public will not ergency action levels defined for a Site Area Emergency or a General Emergency. ection A4.4 and A4.5 will be amended to read, "This class of emergency is not credible for use the doses predicted in Chapter 13.0 do not exceed the action levels specified for this a ANSI/ANS 15.16, Emergency Planning for Research Reactors." The references to these cy classification will also be removed from Table A-1.

Request for additional information

RAI 12A-9b Explain why the Site Area Emergency and General Emergency EALs are identical in Table A-1 of the NWMI ERP.

Table A-1 will be amended such that the EALs for each emergency class are consistent with that found in ANSI/ANS 15.16.

RAI 12A-9c 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.

Table A-1 will be amended such that the EALs for each emergency class are consistent with that found in ANSI/ANS 15.16. Security-related action levels are described in this standard.



REFERENCES

- 10 CFR 50, "Domestic Licensing of Production and Utilization Facilities," *Code of Federal Regulations*, Office of the Federal Register, as amended.
- ANSI/ANS-15.16, *Emergency Planning for Research Reactors*, American Nuclear Society, La Grange Park, Illinois, 2008 (W2015).
- NRC, 2012, Final Interim Staff Guidance Augmenting NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," Parts 1 and 2, for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors, Docket Number: NRC-2011-0135, U.S. Nuclear Regulatory Commission, Washington, D.C., October 17, 2012.
- NUREG-0849, Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors, U.S. Nuclear Regulatory Commission, Office of Inspection end Enforcement, Washington, D.C., October 1983.
- 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.