UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
BEFORE THE COMMISSION

In the Matter of	)	**Docket No. 50-609-CP**
NORTHWEST MEDICAL ISOTOPES, LLC	)	
(Medical Radioisotope Production Facility)	)	**January 16, 2018**

RESPONSE TO NRC COMMISSION'S PUBLIC PRE-HEARING QUESTIONS
NORTHWEST MEDICAL ISOTOPES, LLC
EVIDENTIARY HEARING

Northwest Medical Isotopes, LLC (NWMI) is providing the following responses to the Commission's December 13, 2017 Pre-Hearing Questions regarding the mandatory hearing for the Construction Permit Application for NWMI's medical radioisotope production facility. The included responses are limited to those questions directed to NWMI. Questions directed to the NRC staff have been noted in the table that follows.

RESPONSE TO U.S. NUCLEAR REGULATORY COMMISSION PUBLIC PRE-HEARING QUESTIONS

Docket No. 50-609-CP

January 16, 2018

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No.	Question
1	**General** – In its pre-filed testimony, the Staff states that its "safety review was tailored to the nature of NWMI's construction permit application and was informed by the . . . ISG [(Interim Staff Guidance Document[1])] Augmenting NUREG-1537, as well as other relevant guidance cited in the ISG, cited in the application, or used based on the [S]taff's technical judgment" (SECY-17-0116, at 5). The Staff's technical judgment also was used in determining which criteria were applicable for the construction permit review and which could await the final design in a future operating license application (*id.* at 6). Please elaborate on the examples provided in the Staff's pre-filed testimony and provide additional examples where the Staff determined the aspects of the facility design that were necessary to be analyzed before a construction permit could be granted and those that could be reserved for the Staff's review of the operating license application. Please highlight aspects of the review that were challenging for the Staff in this regard and describe the bases for the Staff's decisions in these instances.

Response: NRC staff response only

2	SECY-17-0116 SER §§ 1.4, 12.4.8 – The Radioisotope Production Facility (RPF) building will contain both the Part 50 production facility and the Part 70 target fabrication area. In the SECY paper, the Staff states, "As part of its safety review, the [S]taff considered the anticipated interface between and [the] effect on the production facility from the target fabrication area, to the extent that information on the target fabrication process was available in the 10 [CFR] Part 50 construction permit application" (SECY-17-0116, at 5-6). Please explain whether the quality assurance program plan for the Part 50 production facility will be applied to the construction of the entire RPF structure. If construction and operation of the target fabrication area in the RPF are not covered by the production facility quality assurance program plan, please explain what quality assurance program will govern the interface and target fabrication areas within the RPF. When the design of the target fabrication area is complete, will all potential effects of accidents or events in the target fabrication area on the production facility be analyzed to ensure those effects are bounded by the Part 50 production facility accident analyses? Section 1.4 of the Staff's Safety Evaluation Report (SER) discusses shared facilities and equipment in the RPF, including shared common systems, such as ventilation, cooling water, and waste processing systems. How will the structures, systems and components (SSC) for the shared common systems be covered by the production facility quality assurance program plan? If not, what quality assurance program will cover shared common systems?

Response: Northwest Medical Isotopes, LLC (NWMI) has an all-encompassing Quality Assurance Program Plan (QAPP) for the Radioisotope Production Facility (RPF) based on ANSI 15.8, *Quality Assurance Program Requirements for Research Reactors*.[2]

[1] 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.

[2] ANSI 15.8, *Quality Assurance Program Requirements for Research Reactors*, American Nuclear Society, La Grange Park, Illinois, 2013.

No.	Question
	The QAPP applies to both Title 10, *Code of Federal Regulations*, Part 50 (10 CFR 50), "Domestic Licensing of Production and Utilization Facilities,"[3] and 10 CFR 70, "Domestic Licensing of Special Nuclear Material,"[4] portions of the RPF during design, construction, and operations. NWMI plans to submit a single Operating License Application (OLA) for the entire RPF that will integrate and evaluate both the 10 CFR 50 and 10 CFR 70 portions of the RPF. The comprehensive accident analysis performed as part of the integrated safety analysis (ISA) will also include interactions between target fabrication and the rest of the RPF. The ISA methodology follows the guidance of NUREG-1513, *Integrated Safety Analysis Guidance Document*,[5] and NUREG-1520, *Standard Review Plan for Fuel Cycle Facilities License Applications*.[6] The NWMI QAPP covers structures, systems, and components (SSC) shared by the 10 CFR 50 and 10 CFR 70 portions of the RPF.
3	SER Appendix A – The regulatory commitment associated with Request for Additional Information (RAI) 3.1-1A states, "The specific RPF design codes, standards, and other referenced documents, including exceptions or exemptions to the identified requirements, will be finalized in the RPF final design and provided to the U.S. Nuclear Regulatory Commission (NRC) in late 2016. In addition, the codes, standards, and referenced documents for the RPF safety . . .[SSCs] that are needed to demonstrate compliance with regulatory requirements will be identified and committed to in the Operating License Application" (SER at A-3). RAI 3.1-1B has a similar regulatory commitment (*id.*). Were the RPF design codes, standards, and other referenced documents, including exceptions or exemptions to the identified requirements, finalized? Please explain why the codes, standards, and referenced documents, including exceptions or exemptions to the identified requirements for the RPF SSCs, do not need to be identified and committed to prior to the issuance of the construction permit for constructing the RPF SSCs.

Response: Under the provisions of 10 CFR 50.34, "Contents of Applications; Technical Information," and Part 1 of NUREG-1537, *Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors – Format and Content*,[7] a construction permit application (CPA) must include the principal design criteria for a proposed production facility. The principal design criteria establish the necessary design, fabrication, construction, testing, and performance requirements for SSCs important to safety; that is, SSCs that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public.

[3] 10 CFR 50, "Domestic Licensing of Production and Utilization Facilities," *Code of Federal Regulations*, Office of the Federal Register, as amended.

[4] 10 CFR 70, "Domestic Licensing of Special Nuclear Material," *Code of Federal Regulations*, Office of the Federal Register, as amended.

[5] NUREG 1513, *Integrated Safety Analysis Guidance Document*, Rev. 2, U.S. Nuclear Regulatory Commission, Office of Material Safety and Safeguards, Washington, D.C., May 2001.

[6] NUREG-1520, *Standard Review Plan for Fuel Cycle Facilities License Applications*, Rev. 2, U.S. Nuclear Regulatory Commission, Office of Nuclear Reactor Regulation, Washington, D.C., May 2015.

[7] 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.

No.	Question

NWMI undertook a systematic process to identify all potentially applicable design codes and standards, and other referenced documents for the RPF. This process and the results are described in Chapter 13, Section 3.5, "Systems and Components," of NWMI-2013-021, *Construction Permit Application for Radioisotope Production Facility*.[8] Section 3.5 specifically states that certain systems and components of the RPF are considered safety-related because those items perform safety functions during normal operations or are required to prevent or mitigate the consequences of abnormal operational transients or accidents. In addition, Section 3.5 defines the safety classifications, seismic category classification (i.e., Seismic Category I, Seismic Category II), non-safety-related SSCs, and quality levels (i.e., QL-1, QL-2, and QL-3), and summarizes the design bases for design, construction, and operating characteristics of the RPF safety-related SSCs.

NWMI compared the design bases of the RPF to applicable codes and standards according to good design practice. NWMI's identification of relevant design criteria is more extensive than that specified in NUREG-1537, Part 1, Section 3.1.

Chapter 3, Section 3.1.7 lists the design codes and standard inputs that have been identified for design of the RPF, including the design and operating characteristics, unusual and novel design features, and principal safety considerations. The specific RPF design codes, standards, and other referenced documents, including exceptions or exemptions to the identified requirements, will be finalized in the RPF final design and provided to the U.S. Nuclear Regulatory Commission (NRC).

The 10 CFR 50 requirements that apply to construction permits that were not addressed by NWMI were limited to the regulations specific to power reactors or nuclear power plants (e.g., 10 CFR 50.34(a)(1)(ii), 10 CFR 50.34(a)(11), 10 CFR 50.34(a)(12), and 10 CFR 50.34(a)(13)). Because the NWMI RPF is considered a production facility, these regulations were determined to not be applicable, and therefore no exemptions were required. This conclusion is consistent with NUREG-1537, Part 1, Appendix A, which addresses the applicability of NRC regulations to non-power reactors.

NWMI has committed to the design codes, standards, and reference documents as part of the CPA (NWMI-2013-021). However, during the final design/construction phases, NWMI does expect there will be potential exceptions or exemptions from the design codes and standards that do not adversely affect safety and should not be applied to the RPF. These exceptions or exemptions will be identified and included in the OLA.

NWMI also prepared the CPA to fully address the requirements in 10 CFR 50 that apply to construction permits and that are applicable to the RPF. NWMI sought and was granted an exemption from 10 CFR 2.101(a)(5), "Filing of Application,"[9] that enabled NWMI to submit the CPA in two parts. This exemption addressed the 10 CFR 2.101(a)(5) requirement that CPAs under 10 CFR 50 must be of the type requiring an environmental impact statement (EIS) or a supplement to an EIS, as described in 10 CFR 51.20(b), "Criteria for and Identification of Licensing and Regulatory Actions Requiring Environmental Impact Statements,"[10] to submit the application in two parts.

[8] NWMI-2013-021, *Construction Permit Application for Radioisotope Production Facility*, Rev. 3, Northwest Medical Isotopes, LLC, Corvallis, Oregon, 2017.

[9] 10 CFR 2, "Agency Rules of Practice and Procedure," *Code of Federal Regulations*, Office of the Federal Register, as amended.

[10] 10 CFR 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," *Code of Federal Regulations*, Office of the Federal Register, as amended.

No.	Question
	Since the NWMI CPA was not of the type requiring an EIS or supplemental EIS in 10 CFR 51.20(b), the application could not be submitted in two parts. Therefore, the exemption (Lynch, 2013[11]) allowed NWMI to submit Part One of the CPA (Chapter 19.0, "Environmental Review") up to six months prior to submittal of the remainder of the CPA (Chapters 1.0 through 18.0; the preliminary safety analysis report [PSAR]), regardless of whether an EIS would be prepared for its CPA. The exemption was granted by the Commission and published in the Federal Register (FR) on October 24, 2013 (78 FR 63501, "Request to Submit a Two-Part Application–Northwest Medical Isotopes, LLC"[12]).
4	**SER Appendix A** – The regulatory commitment associated with RAI 11.1-b states that Preliminary Safety Analysis Report (PSAR) Section 11.1.1.1.2 operating conditions were slightly more conservative than those described in PSAR Section 4.1.2.1. Additionally, it states that PSAR Sections 4.1.2.1 and 11.1.1.1.2 operating conditions will be aligned in the FSAR as part of the Operating License Application (SER at A-13). Will more or less conservative operating condition values be used in this alignment? If the less conservative value is utilized, why is this acceptable?
	Response: The normal release calculations in PSAR Chapter 11.0 (NWMI-2013-021) used a higher number of targets processed per year than described in Chapter 4.0 to demonstrate that the RPF normal releases would be below regulatory guidelines (less than 10 millirem [mrem]/year to the public). The normal release calculations will be updated in the OLA to reflect final design/process changes and conservative operating rates. NWMI is committed to remain under the 10 mrem/year threshold per 10 CFR 20.1101, "Radiation Protection Programs."[13]
5	**SER Appendix A** – RAI Number 12A-9b is repeated twice in SER Appendix A, Section A.2. Please explain if this is intentional or if there is an additional RAI that should be included in Section A.2.
	Response: NRC staff response only
6	SER § 2.4.2 – SER Section 2.4.2 states that several deficiencies in NWMI's analyses of aircraft impact frequencies were identified during the Advisory Committee on Reactor Safeguards (ACRS) NWMI Subcommittee meetings, including inconsistent flight operations, incorrect crash rates for specific aircraft, inconsistent non-airport crash frequency, transposition s in crash impact probabilities, and incorrect runway bearings for the Columbia regional airport. Has NWMI identified the causes for these deficiencies?
	Response: NWMI reevaluated the results of the of aircraft impact frequencies and the reasons for the deficiencies in the analysis. We determined that the deficiencies were due to the use of information that was dated (report originally prepared in 2014 using the previous year's data), and when revised with more current data, the results were not adequately peer reviewed by both the author and the reviewer. NWMI used a systematic process to evaluate the root cause in accordance with our Quality Assurance (QA) program and identified corrective actions to fix the deficiencies in the aircraft analysis in the OLA. In addition, we are in the process of identifying corrective actions to prevent the reoccurrence of this type of deficiency during the final design of the RPF.

[11] Lynch, S.T., 2013, *Northwest Medical Isotopes, LLC – Exemption from Certain Requirements of 10 CFR 2.101(a)(5), Regarding the Submission of a Construction Permit Application in Two Parts (TAC NO. MF2288)*, (Letter to N.F. Fowler, Northwest Medical Isotopes, LLC, Corvallis, Oregon, October 8), ADAMS Accession No. ML13238A331 U.S. Nuclear Regulatory Commission, Office of Nuclear Reactor Regulation, Washington, D.C., October 2013.

[12] 78 FR 63501, "Request to Submit a Two-Part Application–Northwest Medical Isotopes, LLC," *Federal Register*, Volume 78, Issue 206, Washington, D.C., October 24, 2013.

[13] 10 CFR 20, "Standards for Protection Against Radiation," *Code of Federal Regulation*s, Office of the Federal Register, as amended.

No.	Question
7	**SER §§ 2.3.1, 2.4.5; PSAR § 2.5** – 10 CFR § 50.34 requires all construction permit applicants, other than stationary power reactor applicants, to include in the PSAR "[a] description and safety assessment of the site on which the facility is to be located, with appropriate attention to features affecting facility design" (10 CFR § 50.34(a)(1)(i)). Please describe the reasoning behind the Staff's determination that the information provided in the PSAR meets the requirement in Section 50.34(a)(1)(i) to provide a site safety assessment, given that NWMI has committed to conduct a site-specific geotechnical survey later, at the operating license application stage (SER at A-4).

Response: In 2011, a preliminary geotechnical investigation (Terracon 2011a[14]) was completed at the Discovery Ridge Research Park (Discovery Ridge). This preliminary investigation encompassed Lot 15, which is the site where NWMI will be constructing the RPF. This preliminary geotechnical investigation, including a borehole on Lot 15, provided necessary information to characterize critical geotechnical features that could influence or affect the RPF.

This geotechnical information was used for NWMI's preliminary design that supported the development of the CPA and provided information on subsurface conditions, groundwater, and soil types, profiles, and stability. These geotechnical features, along with the recommendations identified within the report for design and construction of foundations, floor slabs, and pavement, were used by our design engineers for the preliminary design (NWMI-2013-021, Chapter 19.0).

In addition, the information developed for Chapter 2.0 ("Site Characteristics") and Chapter 19.0 on the regional geology, soils, hydrogeology, and seismological conditions, and the areal and site geotechnical conditions, supports the geotechnical design considerations in the NWMI preliminary design. This information includes local topography, geomorphic setting and history, thickness and engineering character of overburden soils, description of rock types, geologic structure, degree of rock weathering, local ground water conditions, description of potential borrow areas and quarries, and accessibility to sources of construction materials. Using this data, NWMI evaluated conditions that could affect the facility construction, including excavation and dewatering concerns, low-strength soils, and the potential for cavernous foundation rock. In developing the preliminary design, NWMI engineers were conservative in their evaluation of geotechnical conditions that will be verified through a detailed subsurface investigation.

A Phase 2 geotechnical investigation on Lot 15 will be performed by NWMI, in conjunction with the development of the RFP final design, to confirm that the facility design has (1) accounted for the geologic features and the potential seismic activity at the site, and (2) integrated acceptably into the design bases for structures, systems and operating characteristics of the facility. In addition, the Phase 2 geotechnical investigation will verify the design assumptions for the potential of liquefaction at the site. The Phase 2 geotechnical investigation workscope will be finalized in January 2018, with the Phase 2 geotechnical investigation to be completed shortly thereafter.

In summary, NWMI has confidence that the preliminary geotechnical investigation and the other site characteristics evaluations completed in Chapters 2.0 and 19.0 (NWMI-2013-021) ensure that the appropriate attention to geotechnical conditions has been incorporated into the preliminary design and meets the requirements of 10 CFR 50.34(a)(1)(i). The Phase 2 geotechnical investigation should confirm that the areal and site geotechnical conditions are addressed the final design and provide the necessary and critical geotechnical data that could influence or affect the RPF.

[14] Terracon, 2011a, *Preliminary Geotechnical Engineering Report Discovery Ridge–Certified Site Program Lots 2, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, and 18*, Terracon Consultants, Inc., prepared for University of Missouri and Trabue, Hansen & Hinshaw, Inc., Terracon Project No. 09105094.1, February 11, 2011.

No.	Question
8	**SER § 2.4.5; PSAR § 2.5** – In its application, NWMI indicated that limestone solution features, including caves and sinkholes, are commonly present in Boone County ("numerous caves" and "418 documented sinkholes" [PSAR at 2-92]). The most recent sinkhole occurred in May 2014 and was located approximately 1.17 km (0.73 mi) from the RPF site. NWMI has committed to conduct a site-specific geotechnical survey to ensure the site does not have the potential for sinkholes (SER at A-4). a. Please describe the sizes and depths of the caves and sinkholes found in Boone County.

Response: The Missouri Speleological Survey reports that there are more than 7,000 known caves in Missouri (MSS, 2017[15]). Of those recorded, the most famous is the Devil's Ice Box in Rock Bridge State Park. According to the Boone County Stormwater Program (Boone County, 2013[16]), there are 418 documented sinkholes with a depth of 6.1 meters (m) (20 feet [ft]) or greater within the county. All of these sinkholes are relatively stable, although some of the sinkholes discharge into the cave system and groundwater. About 290 of these sinkholes are located between U.S. Interstate 70 and Ashland, Missouri, in the southwestern corner of Boone County. The largest known sinkhole in Missouri encompasses about 283 hectares (ha) (700 acres) in western Boone County southeast of where Highway 63 crosses the Missouri River (near Jefferson City, Missouri), which is approximately 48.3 kilometers (km) (30 miles [mi]) from Discovery Ridge.

The most recent study (Boone County, 2015[17]) shows that the project site is northeast of the nearest areas considered to have the potential for sinkholes. Based on the results of the preliminary geotechnical report, available geological mapping of the area, and our independent review, there are no known caves or sinkholes within approximately 1.6 km (1 mi) of the Discovery Ridge. Karst features are present to the west and southwest of the Discovery Ridge site, and the two nearest sinkholes lie approximately 1.17 km (0.73 mi) and 2.1 km (1.3 mi) to the southwest of the RPF site. To date, no sinkholes have occurred at the RPF site.

8 cont.	b. What methods of geotechnical investigation would NWMI employ to effectively detect potential caves at the site?

Response: There are several geophysical methods available to qualitatively detect anomalies (e.g., caves, sinkholes) at the RPF site; however, these methods will not be sufficient for the final design of the NWMI RPF. Ground penetrating radar is the most common geophysical technique to detect sinkholes. Other methods include electromagnetic mapping, electrical conductivity and resistivity imaging, and microgravity and surface wave spectral analysis. As geophysical methods are somewhat interpretive and can provide useful qualitative data relatively quickly, the geophysical results will support the finalization of the Phase 2 geotechnical investigation.

8 cont.	c. What effects (if any) would a potential cave roof collapse have on the ground surface at the site? What measures would the applicant take to mitigate these effects, if necessary?

Response: The impact to the surface of potential cave collapses would depend on the size and depth of the cave. Based on previous geotechnical investigations in the area and surface observations, there does not appear to be sinkholes on or near the site that would be expected if there were near-surface or large caves in the area.

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[15] MSS, 2017, Missouri Speleological Survey, www.mospeleo.org/, Rolla, Missouri, accessed December 15, 2017.

[16] Boone County, 2013, "Boone County Stormwater Management Program," www.showmeboone.com/stormwater, Columbia, Missouri, accessed July 16, 2013.

[17] Boone County, 2015, "Boone County Hazards Mitigation Plan 2015," Mid-Missouri Regional Planning Commission, July 20, 2015.

No.	Question
	A Phase 2 geotechnical investigation of the RPF site will be conducted to ensure that the area does not have the potential for sinkholes. If the investigation does identify the potential for sinkholes, the RPF final design would incorporate one of the following alternatives: (1) excavate site both vertically and horizontally to remove that potential and backfill with structural fill, or (2) install piers to bedrock to support the substructure if a sinkhole does occur. If one of these alternatives needs to be implemented, the approach will be determined after the Phase 2 geotechnical investigation is complete, incorporated in the final RPF design, and included in the OLA.
8 cont.	d. What limestone dissolution rate (or estimated range of rates) is anticipated at the site? How will NWMI determine if the potential for dissolution would not be a safety concern over the life of the NWMI facility?

Response: The preliminary geotechnical investigation (Terracon 2011a) conducted at Discovery Ridge identified limestone at 4 to 5 m (13 to 17 ft) below the surface. Based on geological mapping of the region, the formation is assumed Burlington-Keokuk limestone. To date, NWMI has not determined a dissolution rate of this limestone.

The dissolution of limestone is a very slow process. Mean rates range from <0.005 millimeter (mm)/year in arctic terrains with little soil to > 0.1 mm/year in equatorial regions beneath thick soil and plant cover (Trudgill 1976[18]). The widening of cracks within limestone starts very slowly with laminar flow in narrow fissures, and will increase when turbulent flow is initiated in wider cracks from 5 to 10 mm under normal hydraulic gradients (White 1988[19]). Opening a fissure to a few millimeters may take thousands of years. A fissure may grow into a large cave as dissolution wall retreat takes place at around 0.1 mm/year (White 1988). These rates are so low that new cavities cannot be created in limestone within the lifetime of a building structure, and active dissolution of strong limestone is irrelevant to engineering (Waltham et al. 2005[20]). The Phase 2 geotechnical investigation will verify the condition of the limestone below Lot 15, and the information collected will be incorporated into the facility final design.

8 cont.	e. Please explain the rationale for the decision to track NWMI's additional site-specific geotechnical survey information in a series of regulatory commitments associated with RAI numbers 2.5-1b through 2.5-9, rather than as permit conditions.

Response: In 2011, a preliminary geotechnical investigation (Terracon 2011a) was completed at Discovery Ridge. This preliminary investigation encompassed Lot 15, which is the site where NWMI will be constructing the RPF. This preliminary geotechnical investigation, including a borehole on Lot 15, provided necessary information to characterize critical geotechnical features that could influence or affect the RPF.

This geotechnical information was used for NWMI's preliminary design that supported the development of the CPA and provided information on subsurface conditions, groundwater, and soil types, profiles, and stability. These geotechnical features, along with the recommendations identified in the report for design and construction of foundations, floor slabs, and pavement, was used by our design engineers for the preliminary design (NWMI-2013-021, Chapter 19.0).

[18] Trudgill, S., 1976, "The Erosion of Limestone Under Soil and the Long-Term Stability of Soil Vegetation System on Limestone," *Earth Surface Processes and Landforms*, January 1976.

[19] White, W.B., 1988, *Geomorphology and Hydrology of Karst Terrains*, Oxford University Press, 1988.

[20] Waltham, T., Bell, F., and Culshaw, M., 2005, *Sinkhole and Subsidence Karst and Cavernous Rocks in Engineering and Construction*, Praxis Publishing, 2005.

No.	Question
	In addition, the information developed for Chapters 2.0 and 19.0 on the regional geology, soils, hydrogeology, and seismological conditions and areal and site geotechnical conditions supports the geotechnical design considerations in the NWMI preliminary design. This information includes local topography, geomorphic setting and history, thickness and engineering character of overburden soils, description of rock types, geologic structure, degree of rock weathering, local ground water conditions, description of potential borrow areas and quarries, and accessibility to sources of construction materials. Using this data, NWMI evaluated conditions that could affect the facility construction, including excavation and dewatering concerns, low-strength soils, and potential for cavernous foundation rock. In developing the preliminary design, NWMI engineers were conservative in their evaluation of geotechnical conditions that will be verified through a detailed subsurface investigation. Based on the above, NWMI recommends that the additional geotechnical investigation should be tracked via a series of regulatory commitments versus a permit condition associated with requests for additional information (RAI) 2.5-1b through 2.5-9.
9	**SER § 2.4.5** – In SER Section 2.4.5, the Staff explains that: The PSAR states that no sinkholes have occurred at the NWMI facility site since the Terracon report was issued in 2011. The most recent sinkhole formed in May 2014 at East Creek Road, approximately 0.45 km (0.73 mi) to the southwest of the NWMI facility site. The applicant also states that a site-specific investigation of the site will be conducted to ensure that the area does not have the potential for sinkhole formations. If the investigation does identify the potential for sinkholes, the design would incorporate one of the following alternatives: (1) excavate site both vertically and horizontally to remove the potential and backfill with structural fill, or (2) install piers to bedrock to support the structure if a sinkhole was to occur. If one of these alternatives needs to be implemented, it will be determined after the geotechnical investigation is complete, incorporated in the final NWMI facility design, and presented in the FSAR [(Final Safety Analysis Report)] as part of an [operating license] application. (SER at 2-15). What would be required if the site-specific investigation identifies a potential for sinkhole formations and neither of the two alternatives is adequate to address the identified issues? What onsite areas would be covered by the alternatives if they are implemented: the entire NWMI facility site; the four main buildings (RPF building, administration building, waste management building, and diesel generator building); or some subset of buildings? For the Staff: Is a construction permit condition necessary to assure that any issues identified during the site-specific geotechnical investigations for sinkholes, soil characteristics, and liquefaction potential are corrected prior to the construction of the structures on the NWMI site?
	Response: NWMI's position is that either of the two identified alternatives above would adequately mitigate any potential sinkhole formations identified with the Phase 2 geotechnical investigation. All buildings would be covered by the alternatives stated above if the Phase 2 geotechnical investigation identifies the potential for sinkholes on the entire RPF site.

No.	Question
10	**SER §§ 2.2, 2.4.4; PSAR §§ 2.1.1.2, 2.4.3** – In Section 2.4.3, the PSAR states that "[t]he RPF site elevation is 248 m (815 ft)" (PSAR at 2-88). Based on this elevation, NWMI concluded that potential flooding at the site is not a concern. However, the PSAR, in Section 2.1.1.2, also states that "[t]he RPF site is primarily relatively flat surfaces at an elevation of 231 m (758 ft)" (PSAR at 2-4). The SER includes both site elevation values (SER at 2-2, 2-13). Clarify the proposed RPF site elevation and discuss the effects of potential floods if the site elevation is lower than the assumed higher elevation of 248 m (815 ft).

Response: The NWMI RPF 3 ha (7.4-acre) site does have a slope. The 248.4 m (815 ft) elevation used in the flood analysis came from geographic information system (GIS) data and is consistent with the information from the preliminary geotechnical report (Terracon 2011a). The low point of Lot 5 is adjacent to Discovery Ridge access roads (e.g., Discovery Ridge Parkway, Discovery Ridge Drive). The RPF will be centered on the lot where the 248.4 m (815 ft) elevation was estimated.

If the site elevation was assumed to be lower (i.e., 231 m [758 ft]), the elevation would still be outside the 500-year flood plain and would not change the FEMA Flood Zone A evaluation. However, the two ponds that are in Discovery Ridge, north of Lot 15, would require additional evaluation (beyond a simple inspection) to demonstrate the ponds would not affect the RPF.

11	**SER § 3.4.2** – In SER Section 3.4.2, the Staff found that the NWMI production facility design features for coping with meteorological damage are sufficient for a preliminary design and meet the applicable regulatory requirements. How will the RPF and diesel generator buildings be protected from (a) tornado loading, (b) maximum wind speed, (c) tornado-generated missile impact effects, and (d) rain, snow, and ice loading? Will the safety-related SSCs attached to the outside of the RPF building and the diesel generator building also be protected from meteorological damage?

Response: The RPF structure will be designed to withstand the design basis meteorological events, as discussed in Chapters 2.0 and 3.0 of the CPA, to protect the items relied on for safety (IROFS) SSCs. The structure will be hardened to withstand missile impacts and high wind loading. The RPF will also have features to withstand the rain, snow, and ice loadings.

While the diesel generator (and associated building) are not IROFS, NWMI will apply stringent design requirements to withstand operating-based meteorological events to the component due to the economic impacts if the generator is not available when needed.

12	**SER § 6.4.2** – SER Section 6.4.2 states that the exhaust stack height to mitigate process solutions spills and sprays and carbon fire (items relied on for safety [IROFS] FS-05) is credited to disperse the release of radioactive material from the confinement system. Will the exhaust stack be classified as seismic Category I? If not, what seismic category will it be assigned? Will the exhaust stack be protected from meteorological damage, such as tornado loading and maximum wind speed?

Response: The NWMI Zone I exhaust stack will be Seismic Category I and will be protected from the seismic design basis event discussed in Chapters 2.0 and 3.0 (NWMI-2013-021). In addition, the Zone I exhaust stack will be designed to withstand the other meteorological design basis events (e.g., tornado loading, maximum wind speed).

No.	Question
13	SER § 6.4.5 – Historically, the agency has declined to apply 10 CFR § 50.59 to construction permits (Miscellaneous Amendments; Correction, 27 Fed. Reg. 8825[21] [1962] [removing the words "construction or" from 10 CFR § 50.59]). The Staff states in SER Section 6.4.5, "The change process will be consistent with ANSI/ANS-8.19[22] and the requirements for 10 [CFR §] 50.59, 'Changes, tests, and experiments' (SER at 6-12). What is the basis for this proposed departure from established practice? Has an alternate set of criteria that are applicable to the NWMI production facility construction permit been developed to assure that changes which require prior NRC approval are appropriately identified and tracked? Are all of the criteria and questions that would require prior NRC approval of a change under 10 CFR § 50.59 applicable to the NWMI production facility?

Response: The approach for changes that need to be approved by the NRC prior to implementation has been agreed on by the NRC staff and NWMI. This approach evaluates changes to the PSAR following a 10 CFR 50.59-like process during construction. The language and intent of the process described in 10 CFR 50.59 will essentially be followed, replacing references to the final safety analysis report (FSAR) (as updated) with the PSAR (as updated). Construction of the RPF is a unique undertaking, such that there is no established practice for this type of facility. However, a previously approved CPA for a production facility followed this same practice for controlling changes.

By accepting the evaluation process and questions from 10 CFR 50.59, no alternate set of criteria should be needed. Tracking of these changes would fall under the NWMI QAPP.

All of the criteria and questions that would require prior NRC approval of a change under 10 CFR 50.59 are applicable to the NWMI RPF.

14	**SER § 7.2.3; PSAR § 7.1** – Section 7.1 of the PSAR states that the Engineered Safety Feature (ESF) safety functions will operate independently from the Facility Process Control (FPC) systems (PSAR at 7-4). What are the principal design criteria that will allow the FPC and ESF systems to be independent?

Response: The actuation/controls functions of the engineered safety features (ESF) will be "hard wired," in that the ESFs do not rely on the facility process control (FPC) systems to perform the associated safety function. Only the key safety functionality of the ESFs is "independent" from the FPC system. NWMI's principal design criteria will require active IROFS to actuate independent of the FPC systems (e.g., hardwired).

15	**PSAR §§ 3.5.1.2, 7.2.3.1, Table 7-1** a. In the PSAR, NWMI states that one of the keys to its FPC design is "diversity" (PSAR at Table 7-1). In addition, PSAR Section 3.5.1.2, "Classification Definitions," states that the structure and system designs for the RPF are based on defense-in-depth practices, including the use of diverse key safety functions. How does NWMI plan to design for diversity in the FPC design?

Response: An example of NWMI's application of defense-in-depth practices and the use of diverse key safety functions is the iodine removal equipment. In the process offgas systems design, three diverse technologies are used to remove iodine gas from offgas streams. Diversity features of the FPC system will be identified in the OLA.

[21] 27 FR 8825, "Licensing of Source Material; Miscellaneous Amendments; Correction," *Federal Register*, Volume 27, Number 172, Washington, D.C., September 5, 1962.

[22] ANSI/ANS-8.19, *Administrative Practices for Nuclear Criticality Safety*, American Nuclear Society, La Grange Park, Illinois, 2014.

No.	Question
15 cont.	b. PSAR Section 7.2.3.1, "Facility Process Control System," states that "[t]he standby workstations provide redundant hardware with identical [(programmable logic controller)] PLC software systems as automatic backup control systems" (PSAR at 7-14). With identical software, could a common-cause-failure impact both the primary and backup control systems, causing both to fail?

Response: While a common software failure may affect both the primary and backup control system, software QA and testing should make this type of occurrence an unlikely event. Additionally, IROFS instrumentation safety functions do not use the FPC systems to perform their intended safety function.

16	**PSAR Chapter 7** – As described in the PSAR, the Instrumentation and Control (I&C) design makes extensive use of PLCs. Section 7.2.3.1, "Facility Process Control System," states that the FPC primary and backup PLC systems monitor each other. Tables 7-4, 7-6, 7-8, 7-10, and 7-12 describe extensive utilization of PLCs for alarm functions. Section 7.5.3 states that the control room will consist of a master PLC or distributed controller. How did the Staff and NWMI consider Branch Technical Position (BTP) 7-18, "Guidance on the Use of Programmable Logic Controllers in Digital Computer-Based Instrumentation and Control Systems," and EPRI Topical Report TR-107330, "Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants," as part of the design criteria for the development and implementation of the PLC design?

Response: NWMI plans to procure and test FPC primary/backup systems and related programmable logic controllers (PLC) to the appropriate QA level with a documented acceptance process. The FSAR will also identify pertinent inspection, test, analysis, and acceptance criteria to demonstrate that the design commitments have been satisfied for ESF systems. NWMI commits to evaluating Branch Technical Position (BTP) 7-18, "Guidance on the Use of Programmable Logic Controllers in Digital Computer-Based Instrumentation and Control Systems,"[23] and EPRI Topical Report TR-107330, *Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants*,[24] during the final design of the PLC systems. In addition, NWMI will evaluate EPRI TR-106439, *Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications.*[25]

[23] BTP 7-18, "Guidance on the Use of Programmable Logic Controllers in Digital Computer-Based Instrumentation and Control Systems" Rev. 6, NUREG 0800, *U.S. Nuclear Regulatory Commission Standard Review Plan*, Branch Technical Position, U.S. Nuclear Regulatory Commission, Office of Nuclear Reactor Regulation, Washington, D.C., August 2016.

[24] EPRI TR-107330, *Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants*, Electric Power Research Institute, Palo Alto, California, 1996.

[25] EPRI TR-106439, *Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications*, Electric Power Research Institute, Palo Alto, California, November 1996.

No.	Question
17	**PSAR § 7.3.7** – Section 7.3.7 of the PSAR, "Criticality Accident Alarm System" (CAAS), states that "[t]he CAAS will be capable of detecting a criticality accident that produces an absorbed dose in soft tissue of 20 radiation absorbed dose (rad) of combined neutron or gamma radiation at an unshielded distance of 2 m from the reacting material within 1 minute . . ., except for events occurring in areas not normally accessed by personnel and where shielding provides protection against radiation generated from an accidental criticality" (PSAR at 7-43). Because most areas where irradiated fissile material would be processed in the NWMI facility would be shielded and not normally accessed by personnel, explain how criticality events will be detected in these areas.

Response: Subsequent to Part Two of the CPA submission (PSAR) for review, NWMI reassessed the strategy of exempting facility areas not normally accessed by personnel and facility shielded areas from criticality accident alarm system (CAAS) coverage. NWMI will include these facility areas in the CAAS coverage analysis in the OLA to support emergency response activities during RPF operations.

18	**PSAR § 6.3.1.1** – Section 6.3.1.1 of the PSAR, "Preliminary Criticality Safety Evaluations," states that "[u]sing the source from the minimum accident of concern, NWMI will conduct one-dimensional deterministic computations, when practical, to evaluate CAAS coverage. For areas of the facility where the use of one-dimensional deterministic computations is not practical, NWMI will use 3D Monte Carlo analysis to determine adequate CAAS coverage" (PSAR at 6-59). Explain how the one-dimensional deterministic and three-dimensional Monte Carlo analyses for determining CAAS coverage would be validated.

Response: The radiation transport codes used to demonstrate CAAS detector coverage will be validated during the RPF final design based on appropriate benchmark experiments available in published literature, code documentation, and/or from international benchmark efforts such as the Shielding Integral Benchmark Archive and Database (SINBAD).

Alarm thresholds will be set with adequate margin to address code bias and bias uncertainty.

19	**SER §§ 8.2, 8.4.2**– The Staff states in SER Section 8.4.2, "Emergency Electrical Power Systems," that the review included the standby electrical power (SEP) system and several uninterruptible power supplies (UPS). In SER Section 8.2, the Staff describes the July 11, 2017, ACRS NWMI Subcommittee meeting where NWMI stated that the exact number and location of the UPSs are yet to be determined. Does the emergency electrical power system incorporate redundancy into the design for the SEP and UPSs?

Response: The details of the electrical power system are still being evaluated. There are no current plans for additional redundancy of the standby electrical power (SEP) or uninterruptible power supplies (UPS) unless the FSAR accident analysis or a regulatory commitment requires it beyond the Institute of Electrical and Electronics Engineers (IEEE) standards identified in the CPA (e.g., IEEE 603, *Standard Criteria for Safety Systems for Nuclear Power Generating Stations*,[26] for separation and isolation of safety-related systems and components).

[26] IEEE 603, *Standard Criteria for Safety Systems for Nuclear Power Generating Stations*, Institute of Electrical and Electronics Engineers, Piscataway, New Jersey, 2009.

No.	Question
20	**SER § 8.4.2.4** – SER section 8.4.2.4, "Single-Failure Criterion," discusses NWMI's commitment to examine the possible effects of malfunctioning electrical equipment resulting in possible unexpected effects of interaction between otherwise independent and separate circuits. Does the single-failure criterion review of the electrical power systems include review of the open phase condition discussed in NRC Information Notice 2012-03, "Design Vulnerability in Electric Power System"? If not, please explain why this condition does not need to be reviewed as part of the single-failure criterion.

Response: NWMI plans to follow IEEE 379, *Standard Application of the Single-Failure Criterion to Nuclear Power Generating Station Safety Systems.*[27] In addition, NWMI will review the open phase condition discussed in NRC Information Notice 2012-03, "Design Vulnerability in Electric Power System."[28]

No.	Question
21	**SER § 8.4.2.5** – SER Section 8.4.2.5, "Safe Shutdown," states: The Staff finds that the applicant's explanation in its RAI response regarding the SEP DG [(diesel generator)] power estimate of 2,600 kW to bound emissions in NWMI PSAR Chapter 19.0 (Table 19-60) is satisfactory in that this value is conservative as compared to the values provided in NWMI PSAR Chapter 8.0. Changing the power rating cited in NWMI PSAR Section 8.2.2, "Ranges of Emergency Electrical Power Required," to 1,178.6 kW (1,585 hp [horsepower]) to be consistent with Table 8-1 is also satisfactory in that it resolves the identified inconsistency. The Staff reviewed the most recent revision to NWMI PSAR Chapter 8.0 and confirmed that the applicant's proposed resolution was incorporated in the PSAR. However, the first paragraph of PSAR Section 8.2 in Revision 3 of PSAR Chapter 8.0 still states, in part, that "A 1,000-kW (1,341 hp) diesel generator will provide SEP." Thus, neither the capacity of the SEP DG given as 1,000 kW (1,341 hp) in NWMI PSAR Section 8.2 nor the discrepancy between this value and that given in NWMI PSAR Table 8-1 and NWMI PSAR Section 8.2.2 was addressed in response to an RAI or corrected in subsequent revisions to NWMI PSAR Chapter 8.0. (SER at 8-11). The Staff then states that this inconsistency is acceptable for the purposes of issuing a construction permit since the peak power estimates used in NWMI PSAR Chapter 8 are bounded by the SEP DG power estimates used to bound emissions in NWMI PSAR Chapter 19. For the Staff: Please explain in further detail why this discrepancy is acceptable for issuance of a construction permit and why it does not warrant a regulatory commitment. For NWMI: Has the discrepancy been corrected?

Response: NWMI determined there was no discrepancy between Chapters 8.0 and 19.0 (NWMI-2013-021). As part of the ongoing design process, the actual SEP diesel generator size will be determined and updated in Chapter 8.0 of the OLA. If the SEP diesel generator is larger than 2,600 kW (3,487 hp), Chapter 19.0 will also be updated.

[27] IEEE 379, *Standard Application of the Single-Failure Criterion to Nuclear Power Generating Station Safety Systems*, Institute of Electrical and Electronics Engineers, Piscataway, New Jersey, 2014.

[28] NRC Information Notice 2012-03, "Design Vulnerability in Electric Power System," Office of Nuclear Reactor Regulation, Office of Federal and State Materials and Environmental Management Programs, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, D.C., March 1, 2012.

No.	Question
22	**SER § 8.4.2.5** – SER section 8.4.2.5 states that the Staff will review details of the fuel consumption rates at the peak load values in the FSAR in order to ensure that there is sufficient diesel fuel capacity for the complete range of 11-14 hours of operation as stated in NWMI PSAR Section 8.2. What is the basis for a diesel fuel capacity of 11-14 hours? Will a review be conducted to assess the lube oil consumption rates at the peak load values for the specified duration?

Response: There is no safety requirement for the current sizing of the diesel fuel capacity. The current estimate duration, 11–14 hours, was determined from generic fuel consumption charts. The OLA will include final design or actual equipment sizing information to provide a basis for the duration of operation from on-site fuel storage.

23	**SER § 13.4.1** – Page 13-8 of the SER states that, "leaks of fissile solution based on damage from a seismic event could lead to a criticality event. An additional IROFS related to the irradiated target cask lifting fixture was included to address the tip over event." Is this the only scenario under which a seismic event could lead to a criticality? If so, what analysis was performed to rule out other plant locations or configurations? If not, what other measures are in place to prevent these scenarios?

Response: The tipping of the target cask and corresponding IROFS are to prevent a worker radiation event. The leak of fissile solution based on damage from a seismic event that could lead to a criticality scenario is applicable throughout the RPF where special nuclear material is handled or stored. Therefore, the fissile handling systems are designed to withstand the seismic event and must drain to a critical safe geometry.

24	**SER § 13.5** – Section 13.5 of the SER states that "[m]ethods of calculating doses from inhalation or ingestion (or both) and direct exposure to gamma rays from dispersing plumes of airborne radioactive material are applicable and no less conservative than those developed in PSAR Chapter 11.0, 'Radiation Protection and Waste Management'" (SER at 13-31). Dose consequence analyses in Chapter 11 pertain to normal operations in which the use of average 50th percentile atmospheric dispersion factors is appropriate for estimating the annual dose consequences from the routine release of radioactive materials. In this vein, NUREG-1537, Part 2,[29] Section 2.3, states that "[t]he information on meteorology and local weather conditions [should be] sufficient to support dispersion analyses for postulated airborne releases." The analyses should support realistic dispersion estimates of normal releases for Chapter 11 analyses and conservative dispersion estimates of projected releases for Chapter 13 analysis of accidental releases at locations of maximum projected radiological dose and other points of interest within a radius of 8 kilometers." In addition, the Final ISG Augmenting NUREG-1537, Part 1, Section 13b.2 (for analyses of accidents with radiological consequences) states that the application should "[e]valuate . . . potential radiological consequences using realistic methods [and] [d]iscuss the degree of conservatism in the evaluation (e.g., the use of worst meteorological conditions, the use of minimum effects of mitigating circumstances, use of maximum release fractions)." Please discuss the basis for the Staff's acceptance of NWMI's atmospheric dispersion factors in the dose calculations for design basis accidents in Chapter 13, and in particular, why these factors, such as consideration of worst-case meteorological conditions, are appropriately conservative.

[29] 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.

No.	Question
	In addition, discuss the degree of conservatism in the analyses as compared to the 95th percentile values commonly used in power reactor design basis dose consequence accident analyses (e.g., Regulatory Guide 2.2, "Development of Technical Specifications for Experiments in Research Reactors,"[30] at 2.2-4).

Response: In Chapter 13.0, the RSAC computer code was used. In that calculation, the wind was assumed to have traveled 100 percent of the time (rather than the 95 percent value) with Pasquill F values in the direction toward the shortest distance offsite and/or the closest receptor (for the purpose of the calculation, these were both the same direction). Thus, the accident releases were calculated with a more conservative methodology for determining the X/Q values. Additionally, the calculations did not take any credit for the wind rose data and assumed the plume travels in the direction of the receptor 100 percent of the time.

25	**SER Chapter 13** – In the SER, the Staff references the use of the RASCAL code in performing independent confirmation of NWMI's accident dose consequence analyses (SER at 13-23). Generally, atmospheric dispersion factors are calculated based on the examination of at least one year of site-specific meteorological data and the use of a model that predicts the worst-case values based on a 95th percentile confidence level. Please provide additional information describing how the use of the RASCAL code provides an equivalent level of conservatism.

Response: NRC staff response only

26	**SER § 13.4.3; PSAR § 13.2.2.7.2** – SER Section 13.4.3, "Liquid Spills and Sprays with Radiological and Criticality Safety Consequences," discusses NWMI's assessment of the radiological consequences of the release of an irradiated target dissolver product. Based on NWMI's calculations, the unmitigated total effective dose equivalent (TEDE) to the nearest permanent resident at a distance of 432 meters is stated to be 300 mrem. The maximum TEDE is stated to be 1.8 rem at a distance of 1,100 meters. Section 13.2.2.7.2 of the PSAR discusses the input parameters used in these calculations and includes the description of the meteorological conditions evaluated. The exact values for the atmospheric dispersion factors, however, are not provided for the specified distances. For example, in the above-described case, the parameters given for the RASCAL code meteorological inputs are a 4 mile-per-hour wind speed with a Pasquill stability Class of F. Please provide additional information regarding the exact numerical values of the atmospheric dispersion factors used either by NWMI (in its application) or the Staff (in its independent RASCAL runs for these calculations) at 432 meters and 1,100 meters, respectively. In addition, describe how these values would compare to the atmospheric dispersion factors that are typically used in design basis dose consequence values for similar close-in, short-term evaluations (e.g., values used to calculate the exclusion area boundary accident dose consequences at nuclear power plants).

Response: RSAC 6.2 was used to model dispersion and dose rates resulting from an unmitigated spray leak of dissolver product solution. The following parameters were used for the RSAC model runs:

- Mixing depth: 400 m (1,312 ft) (RSAC default)
- Air density: 1,240 grams (g)/cubic meters [m^3] (1.24 ounce [oz]/cubic feet [ft^3]) (sea level)

[30] Regulatory Guide 2.2, "Development of Technical Specifications for Experiments in Research Reactors," U.S. Nuclear Regulatory Commission, Office of Nuclear Reactor Regulation, Washington, D.C., November 1973.

No.	Question

- Pasquill-Gifford σ (NRC Regulatory Guide 1.145, *Atmospheric Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants*[31]), atmospheric dispersion factors χ/Q for Stability Class F (moderately stable) calculated within the RSAC 6.2 code (see Table 1)
- No plume rise (i.e., buoyancy or stack momentum effects)
- No plume depletion (wet or dry deposition)
- No cross-wind
- 1-hr release (constant release of all activity)
- 1-hr exposure
- ICRP-30, *Limits for Intakes of Radionuclides by Workers*,[32] inhalation model
- Finite cloud immersion model
- Breathing rate: 3.42E-4 m^3/second (sec) (1.2E-2 ft^3/sec) (ICRP-30 heavy activity)

Table 1. RSAC 6.2 Atmospheric Dispersion Factors for Pasquill-Gifford Stability Class F

Downwind distance, m	Atmospheric dispersion factor χ/Q, s/m^3
100	5.171E-25
200	3.376E-10
300	4.185E-07
400	5.858E-06
500	2.008E-05
600	3.834E-05
700	5.500E-05
800	6.754E-05
900	7.754E-05
1,000	8.094E-05
1,100	8.294E-05
1,200	8.263E-05
1,300	8.095E-05
1,400	7.851E-05
1,500	7.566E-05
1,600	7.266E-05

X/Q values calculated by RSAC 6.2, listed in code output

NUREG/CR-6410, *Nuclear Fuel Cycle Facility Accident Analysis Handbook*,[33] Section 5, discusses atmospheric dispersion and dose consequence modeling. The Pasquill stability categories are defined in Table 5-1 of that section. Note that Pasquill stability category F comprises the most quiescent atmospheric conditions of lowest wind speed and optimal cloud cover during nighttime. Category F is thus the most conservative category and is typically used to obtain bounding dose consequences for atmospheric radiological releases from nuclear facilities, including power plants.

[31] Regulatory Guide 1.145, *Atmospheric Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants*, Rev. 1, U.S. Nuclear Regulatory Commission, Washington, D.C., February 1983.

[32] ICRP 30, *Limits for Intakes of Radionuclides by Workers*, International Commission on Radiological Protection, Ottawa, Canada, 1979.

[33] NUREG/CR-6410, *Nuclear Fuel Cycle Facility Accident Analysis Handbook*, U.S. Nuclear Regulatory Commission, Washington, D.C., 1998.

No.	Question
27	**SER § 13.4.3** – SER Section 13.4.3 indicates that NWMI credited the Zone I exhaust system filters to mitigate the consequences of the bounding liquid spray accident scenario and estimated the resulting dose consequences to be 0.030 rem to the nearest residence and 0.18 rem to the maximally exposed offsite individual member of the public. Please provide additional information discussing the implications of the 0.18 rem mitigated dose exceeding the 0.1 rem limit in 10 CFR § 20.1301(a)(1) and whether, based on this accident evaluation, NWMI will need to seek NRC authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem, as described in 10 CFR § 20.1301(d).

Response: NRC staff response only

28	**SER § 13.4.4; PSAR § 13.2.3.8** – Section 13.4.4 of the SER states that according to NWMI, the calculated dose consequences for the unmitigated target dissolution off-gas release accident result in an offsite public dose of 6.65 rem TEDE at a distance of 1,100 meters. As discussed in PSAR Section 13.2.3.8, "Identification of Items Relied on for Safety and Associated Functions," NWMI relies on two IROFS to mitigate the consequences of this postulated accident: IROFS RS-03, "Hot Cell Secondary Confinement Boundary," and IROFS RS-09, "Primary Offgas Relief System." According to the Staff, NWMI will provide detailed information, including worker dose estimates and frequency, in the FSAR that will be submitted as part of the operating license application (SER at 13-13). Doses for the mitigated case, however, are not indicated. Please describe the reduction in dose that would be expected as a result of incorporating the above-mentioned IROFS. In addition, please discuss whether the resulting mitigated doses would be expected to meet the acceptance criteria in 10 CFR § 20.1301(a)(1) or if it is expected that based on this accident evaluation NWMI will seek NRC authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem as described in 10 CFR § 20.1301(d).

Response: NRC staff response only

29	**SER Chapter 13** – In making its determination as to whether the construction permit should be issued, the Commission will consider whether there is "reasonable assurance that the applicant will comply with [the NRC's regulations], including the regulations in [P]art 20" (10 CFR § 50.40(a)). If the Staff determines that NWMI will need to obtain, under 10 CFR § 20.1301(d), NRC authorization to operate up to an annual dose limit of 0.5 rem, does this impact the Commission's determination as to whether NWMI will comply with 10 CFR Part 20? If not, what would be the expected time frame for NWMI to submit such a request? Would the authorization apply only to the projected dose from accidents or would it apply to routine annual releases as well?

Response: NRC staff response only

No.	Question
30	**SER Chapter 13** – Based on NWMI's response to the Staff's request for additional information (RAI) G-3, the evaluation of a maximum hypothetical accident will not be a part of the accident analysis for the NWMI application. Rather, NWMI states that: The accident analyses in the PSAR are based on (1) use of integrated safety analysis (ISA) methodologies, as described in 10 CFR 70 Subpart H and NUREG-1520, *Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility*, (2) application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, (3) designation of . . . [IROFS], and (4) establishment of management measures to demonstrate adequate safety. The ISA includes a systematic analysis and discussion of credible accidents for determining the limiting events for several accident categories. The limiting event in each category is analyzed quantitatively to determine consequences. Radiological accident consequences, as mitigated by . . . [SSCs] and administrative safety measures, are evaluated against the performance requirements of 10 CFR 70.61. The safety measures are designated as IROFS. (RAI G-3, at 2 (ML16344A053)). The performance requirements of 10 CFR § 70.61 for radiological accident consequences are considerably higher than those specified in 10 CFR § 20.1301, "Dose limits for individual members of the public." Please confirm that the acceptance criteria for the NWMI accident dose consequence analyses, as mitigated by SSCs and administrative safety measures, are evaluated against the requirements of 10 CFR § 20.1301 and not the performance requirements of 10 CFR § 70.61.

Response: NRC staff response only

31	**Technical Specifications** – Page 7-17 of the SERs states that, "[e]ach IROFS will be examined and translated into a limiting condition for operation (LCO)." Page 14-2 of the SER states that, "[e]ach IROFS will need to be examined and will likely become the subject of a limiting condition for operation (LCO) [technical specification]" (emphasis added). Please clarify this apparent discrepancy. Could there be IROFS that would not be translated into an LCO?

Response: NRC staff response only

32	**Research and Developm**ent – 10 CFR § 50.34(a)(8) states that applicants for a construction permit should provide "a schedule of the research and development program showing that such safety questions will be resolved at or before the latest date stated in the application for completion of construction of the facility." Several of the activities listed in SER Section 1.1.6 (items 1-3) do not contain completion dates. Were dates provided by NWMI?

Response: NRC staff response only

No.	Question
33	**FEIS Chapters 3, 4** – High shrink/swell soils are discussed in both Chapters 3 and 4 of the FEIS. In Section 3.3.2, for instance, the Staff states, "As a building site, the soils are rated as poorly suited for excavation work because of the depth to the saturated zone, high clay content, and instability of excavation walls. In addition, due to the presence of clays with a high/shrink swell potential . . . the soils are rated as very limited for constructing commercial buildings" (FEIS at 3-24). Section 3.3.1 of the FEIS discusses the geologic features of the region, including karst terrane characterized by the presence of springs, caves, and sinkholes. The Staff noted "the nearest documented feature is associated with a sinkhole that collapsed a roadway in southern Columbia in May 2014 . . . approximately 0.7 mi (1.1 km) southwest of the Discovery Ridge site" (FEIS at 3-22). In Section 4.3.1, the Staff states, "At the time they were evaluated by Terracon (2011b)[34], site soils exhibited a high water content with the potential for perched groundwater conditions. Most significantly, the fat clays have a high shrink/swell potential. High shrink/swell soils are difficult to work and undesirable for backfill. Consequently, these conditions may require additional over excavation and removal of site soils in excavations and foundation cuts so that they can be replaced with suitable engineered backfill to properly support and safeguard concrete structures" (FEIS at 4-12). Do high shrink/swell soils or over excavation of the site pose an increased risk for sinkholes or other geologic hazards?
Response: NRC staff response only	
34	**FEIS § 3.4.2.1** – As part of the boring samples taken by Terracon, two borings showed groundwater at a depth of 12 to 18.5 ft below ground surface (bgs), with one boring at the NWMI facility site demonstrating saturated conditions at 12 ft bgs. The Staff stated in Section 3.4.2.1 of the FEIS that "NWMI has indicated that given the high water content of the site soils at the time the borings were completed, the 'groundwater' observed in the boring holes may have been the result of water introduced into the holes during drilling operations (NWMI 2016a[35])" (FEIS at 3-34). Has the Staff evaluated NWMI's statement?
Response: NRC staff response only	

[34] Terracon, 2011b, *Phase I Environmental Site Assessment Discovery Ridge Lots 2, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, and 18*, Terracon Consultants, Inc., prepared for University of Missouri and Trabue, Hansen & Hinshaw, Inc., Terracon Project No. 09117701, March 23, 2011.

[35] Haass, C., 2016, [NWMI 2016a] "Northwest Medical Isotopes, LLC Responses to the U.S. Nuclear Regulatory Commission Environmental Request for Additional information – Letter Dated January 19, 2016," ADAMS Accession No. ML16053A221, Northwest Medical Isotopes, LLC, Corvallis, Oregon, 2016.

No.	Question
35	**FEIS § 4.4.1.1, Appendix B** – As stated in FEIS Section 4.4.1.1, NWMI plans to seek a waiver (or other documentation) from the state of Missouri associated with its Clean Water Act Section 401 certification. What is the status of NWMI's obtaining either the requisite certification or a waiver of that requirement?

Response: NWMI received the Clean Water Act[36] Section 401 Water Quality Certification (WQC) from the Missouri Department of Natural Resources (MDNR), Water Protection Program, on September 15 2017.[37] The WQC certifies that NWMI's "ongoing activities will not cause the general or numeric criteria to be exceeded nor impair beneficial uses established in Water Quality Standards, 10 CSR 20-7.031" provided that all conditions identified in the letter are met. This WQC is provided in Exhibit NWMI-009.

In addition, the MDNR provided documentation via email on October 5, 2017 to the NRC staff (e.g., David Drucker, Michael Balazik) that the required fees ($150) were received from NWMI.

	What is the status of other environmental permits (if any) required prior to final NRC action on the construction permit application? What is the status of other environmental permits that NWMI must still secure?

Response: No other permits are required prior to the NRC approval of the CPA. Table 2 provides an update to Table B-4 of the Final Environmental Impact Statement (FEIS)[38] with the status of other required permits needed to initiate construction and operations of the RPF. The schedule is based on initiation of the RPF construction in August 2018.

[36] *Clean Air Act of 1970*, 42 USC 7401 et seq.

[37] Wieberg, C., 2017, "Clean Water Act Section 401 Water Quality Certification of Northwest Medical Isotopes, LLC Facility in Boone County, NUREG-2209/CEK007189," (Letter to C.C. Haass, Northwest Medical Isotopes, LLC, September 15), Missouri Department of Natural Resources, Jefferson City, Missouri, 2017.

[38] NUREG-2209, *Final Environmental Impact Statement for the Construction Permit for the Northwest Medical Isotopes Radioisotope Production Facility*, ADAMS Accession No. ML17130A862, U.S. Nuclear Regulatory Commission, Office of Nuclear Reactor Regulation, Washington, D.C., May 31, 2017.

Table 2. Regulatory Compliance Status (5 pages)

Agency	Regulatory authority[a]	Permit or approval	Activity covered	Status
Federal				
U.S. Nuclear Regulatory Commission	Atomic Energy Act 10 CFR 50.50	Construction Permit	RPF construction	Addressed in Construction Permit Application
	10 CFR 50.57	Operating License	RPF operation	To be addressed in operation license application
	10 CFR 30	By-Product Material License	Production, possession, and transfer of radioactive by-product material	To be addressed in license application
	10 CFR 70	Special Nuclear Materials License	Receipt, possession, use, and transfer of special nuclear material	To be addressed in license application
	National Environmental Policy Act 10 CFR 51	Environmental assessment or environmental impact statement	Site approval for RPF construction and operation	Addressed in Construction Permit Application
U.S. Army Corp of Engineers	Clean Water Act 33 CFR 323	Dredge and Fill Permit (Section 404)	Discharges of dredged or fill material into U.S. waters	Not required
U.S. Environmental Protection Agency	Resource Conservation and Recovery Act 40 CFR 262	Notification of RCRA Subtitle C activity	EPA identification number for generation of hazardous waste	Notification to be submitted 60 days prior to construction Estimated submission date: 5/1/2018 Estimated receipt date: 7/15/2018
	Clean Water Act 40 CFR 112, Subpart D, Appendix F	SPCC plans for construction and operation[b]	Storage of oil during construction and operation	SPCC plans to be submitted 30 days prior to construction Estimated submission date: 6/1/2018 Estimated receipt date: No approval required
U.S. Department of Transportation	Hazardous Materials Transportation Act 49 CFR 107	Certificate of Registration	Transport of hazardous materials	Registration to be filed no later than June 30 of the calendar year or prior to offering hazardous materials for transport Estimated submission date: 8/30/2018 Estimated receipt date: 1/30/2019

Table 2. Regulatory Compliance Status (5 pages)

Agency	Regulatory authority[a]	Permit or approval	Activity covered	Status
State				
Missouri Department of Natural Resources	Federal Clean Air Act Missouri Revised Statute Chapter 643 10 CSR Division 10	Construction Permit	Construction of an air emissions source	Not required (Verification 2/28/2016)
		Part 70 Operating Permit	Operation of an air pollution emission source that has potential emissions exceeding 100 tons/yr of criterion pollutants	Not required (Verification 2/28/2016)
		Intermediate Operating Permit	Operation of an air pollution emission source that has the potential to emit is above major threshold, but a voluntary "limit of operation" is requested	Not required
		Basic State Operating Permit	Operation of an air pollution emission source that has the potential to emit is between *de minimis* and major levels	Not required
	Clean Water Act Missouri Revised Statute Chapters 640 and 644 10 CSR Division 20	NPDES Construction Stormwater Permit	Land disturbance and discharge of stormwater from the construction site	Applications for general permits (Forms E and G) to be submitted 30 days prior to construction Estimated submission date: 5/1/2018 Estimated receipt date: 7/15/2018
		NPDES Industrial Stormwater Permit	Discharge of stormwater from the industrial site during operations	Permit to be submitted one year prior to operation Estimated submission date: 9/1/2018 Estimated receipt date: 8/31/2019
		Section 401 Water Quality Certification	Certifies that the Section 404 permitted activity complies with all applicable State water quality standards, limitations, and restrictions	Not required Request for a waiver: 12/30/2015 WQC received from MDNR on 9/15/2017

Table 2. Regulatory Compliance Status (5 pages)

Agency	Regulatory authority[a]	Permit or approval	Activity covered	Status
Missouri Department of Natural Resources (continued)	Resource Conservation and Recovery Act Missouri Revised Statute Chapter 260 10 CSR Division 25	Notification of Regulated Activity	Obtain Missouri identification number for generation of hazardous waste	Registration to be filed 90 days prior to generating hazardous waste Estimated submission date: 6/1/2019 Estimated receipt date: 10/1/2019
		Certified Resource Recovery Facility Application	Reuse, reclamation, or recycling 1,000 kg (2,204.6 lb) or more of site-generated hazardous waste in a month	Application to be submitted 90 days prior to operations Estimated submission date: 6/1/2019 Estimated receipt date: 10/1/2019
		Notification to MDNR of Conditional Exemption	Notify MDNR in writing and by certified delivery of the claim of a conditional exemption for LLMW stored and treated in the facility	Notification to be submitted 90 days prior to operations Estimated submission date: 2/1/2019 Estimated receipt date: 5/1/2019
		Hazardous Waste Permit	Treatment, storage or disposal of hazardous waste	Not required
Missouri Department of Health and Senior Services	Atomic Energy Act Missouri Revised Statute Chapter 192 19 CSR Division 20	Registration of sources of ionizing radiation	Protection against ionizing radiation	Radioactive sources will be managed under the NRC license and are excluded from Missouri regulation
Boone County				
Boone County Resource Management Department	Clean Water Act Missouri Revised Statute, Chapter 64 Boone County Stormwater Ordinance	Stormwater Discharge Permit	Stormwater management	Application to be submitted 30 days prior to construction Estimated submission date: 5/1/2018 Estimated receipt date: 7/15/2018
		Land Disturbance Permit	Activity disturbing 0.4 ha (1 acre) or more of land or disturbing 278.7 m^2 (3,000 ft^2) in environmentally sensitive areas	Application to be submitted 30 days prior to construction Estimated submission date: 5/1/2018 Estimated receipt date: 7/15/2018

Table 2. Regulatory Compliance Status (5 pages)

Agency	Regulatory authority[a]	Permit or approval	Activity covered	Status
Boone County Resource Management Department (continued)	Missouri Revised Statute, Chapter 64 Boone County Zoning Regulations	Application for Commercial Building Permit	Construction of a commercial building	Application to be submitted 30 days prior to construction Estimated submission date: 5/1/2018 Estimated receipt date: 7/15/2018
Boone County Regional Sewer District	Clean Water Act Missouri Revised Statute Chapter 250 Chapter 2 of Boone County Sanitary Sewer Use Regulations	Sanitary sewer connection approval	Building connection to District wastewater treatment works	Required information to be submitted 30 days prior to construction Estimated submission date: 5/1/2018 Estimated receipt date: 7/15/2018
City of Columbia				
City of Columbia	Clean Water Act 10 CSR Division 60 Part II City of Columbia Code of Ordinances, Chapter 27	Application for utility service	Allows RPF to connect to Columbia Water Treatment Plant	Application to be submitted 30 days prior to construction Estimated submission date: 5/1/2018 Estimated receipt date: 7/15/2018
	Part II City of Columbia Code of Ordinances Chapter 6, Article II	Building Permit	Approval of building code and standards, including site plan	Application to be submitted 60 days prior to construction Estimated submission date: 4/1/2018 Estimated receipt date: 7/15/2018
	Part II City of Columbia Code of Ordinances Chapter 6, Article III	Electrical plan approval	Electrical Code	Information to be submitted 60 days prior to construction Estimated submission date: 4/1/2018 Estimated receipt date: 7/15/2018
	Part II City of Columbia Code of Ordinances Chapter 6, Article IV	Plumbing plan approval	Plumbing Code	Information to be submitted 60 days prior to construction Estimated submission date: 4/1/2018 Estimated receipt date: 7/15/2018

Table 2. Regulatory Compliance Status (5 pages)

Agency	Regulatory authority[a]	Permit or approval	Activity covered	Status
City of Columbia (continued)	Part II Code of Ordinances Chapter 6, Article V	HVAC plan approval	Mechanical Code	Information to be submitted 60 days prior to construction Estimated submission date: 4/1/2018 Estimated receipt date: 7/15/2018
	Part II City of Columbia Code of Ordinances Chapter 6	Certificate of Occupancy	Facilities meeting Building Code	Information to be submitted on completion of construction Estimated submission date: 9/30/2019 Estimated receipt date: 10/1/2019
	Part II City of Columbia Code of Ordinances Chapter 27, Article II	Fire Prevention Plan Approval	Fire Code	Information to be submitted 60 days prior to construction Estimated submission date: 4/1/2018 Estimated receipt date: 6/15/2018
	Part II City of Columbia Code of Ordinances Chapter 12A, Article II	Land Disturbances Permit	Land disturbance activity, including construction on any site that results in a disturbed area of 1 acre or more.	Application to be submitted 30 days prior to construction Estimated submission date: 6/1/2018 Estimated receipt date: 7/15/2018
	Part II City of Columbia Code of Ordinances Chapter 12A, Article V	Stormwater Management Plan Approval	Approval required prior to approval for Land Disturbance Permit	Information to be submitted 45 days prior to construction Estimated submission date: 5/15/2018 Estimated receipt date: 7/15/2018

[a] Full references are provided in NWMI-2013-021, Chapter 19.0, Section 19.7.

[b] Only required when oil is stored in a tank or shell with a capacity over 1,320 gal, and the oil could reasonably reach navigable water.

CFR = Code of Federal Regulations.
CSR = Code of State Regulations.
EPA = U.S. Environmental Protection Agency.
HVAC = heating, ventilation, and air conditioning.
LLMW = low-level mixed waste.
MDNR = Missouri Department of Natural Resources.
NPDES = National Pollutant Discharge Elimination System.
NRC = U.S. Nuclear Regulatory Commission.
RCRA = Resource Conservation and Recovery Act.
RPF = radioisotope production facility.
SPCC = spill prevention, control, and countermeasure.
U.S. = United States.

No.	Question
36	**FEIS § 4.6.3** – The FEIS discusses the scoping letters that the Staff issued to federally recognized tribes regarding the proposed action and the responses from several tribes. FEIS Section 4.6.3 states that "[o]ne tribe requested consulting party status on the NWMI project" (FEIS at 4-26). Which tribe made the request? How did the Staff respond to the request, and what was the outcome?

Response: NRC staff response only

37	**General** – In order to operate the NWMI facility, additional licensing actions will be required, including review of a future operating license application, review of a Part 70 license application for the fabrication of low-enriched uranium targets, and review of license amendment applications for the research reactors that will irradiate low-enriched uranium targets. The Staff states that if NWMI applies for an operating license, a supplement to the FEIS would be prepared. Describe the anticipated process and scope of that environmental review. The Staff also states that it "will conduct a separate . . . environmental review of each [research reactor] operating license amendment application" (id.). Describe the anticipated process and scope of the environmental reviews for future operating license amendment applications filed by research reactor licensees to irradiate NWMI targets.

Response: NRC staff response only

38	**General** – 10 CFR § 70.21(f) provides, "An application for a license to possess and use special nuclear material for processing and fuel fabrication, scrap recovery or conversion of uranium hexafluoride, or for the conduct of any other activity which the Commission has determined pursuant to Subpart A of Part 51 of this chapter will significantly affect the quality of the environment shall be filed at least 9 months prior to commencement of construction of the plant or facility in which the activity will be conducted, and shall be accompanied by an Environmental Report required under Subpart A of Part 51 of this chapter." Additionally, 10 CFR § 70.23(a)(7) states, "Where the proposed activity is processing and fuel fabrication, scrap recovery, conversion of uranium hexafluoride, uranium enrichment facility construction and operation, or any other activity which the NRC determines will significantly affect the quality of the environment, the Director of Nuclear Material Safety and Safeguards or his/her designee, before commencement of construction of the plant or facility in which the activity will be conducted, on the basis of information filed and evaluations made pursuant to Subpart A of Part 51 of this chapter, has concluded, after weighing the environmental, economic, technical, and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to this conclusion is grounds for denial to possess and use special nuclear material in the plant or facility." On March 1 and September 15, 2017, the NRC Staff notified NWMI that the provisions in these regulations apply to NWMI.

No.	Question
38 cont.	Has NWMI sought an exemption from these provisions? Does NWMI plan on constructing only the portions of the facility that will not contain Part 70 activities (i.e., the diesel generator building, the waste management building, and the administrative building) prior to obtaining a 10 CFR Part 70 license?
	Response: NWMI sought an exemption from 10 CFR 70.21(f) on December 18, 2017 (Exhibit NWMI-010).[39] NWMI will not initiate construction on the RPF until the exemption from 10 CFR 70.21(f) is approved by the NRC. The start of construction on the Administration Building may be initiated prior to approval of the requested exemption (e.g., start of construction in third quarter 2018).
39	**General** – In SECY-17-0116, the Staff states that "granting the 10 [CFR] Part 50 construction permit will only authorize NWMI to construct the production facility portion of the RPF" (SECY-17-0116, at 12). For the purposes of 10 CFR § 70.21(f), is the "facility" the production facility portion of the RPF or the entire RPF? If construction work commences on the portions of the site that would be used for Part 70 activities, how would this impact the review of the Part 70 license? Currently, the draft construction permit is written to authorize construction of "a production facility as defined in 10 [CFR §] 50.2." Should the construction permit specifically prohibit construction of the target fabrication facility?
	Response: NRC staff response only
40	**FEIS §§ 2.7.1.2, 4.9.1** – The FEIS, in sections 2.7.1.2 and 4.9.1, states that "NWMI expects that no GTCC [(greater than Class C)] wastes will be generated" (FEIS at 2-17; see also id. at 4-37). Please explain the basis for this conclusion.
	Response: NWMI has compared the projected waste stream to 10 CFR 61.55, "Waste Classification"[40] limits to demonstrate that the projected waste is low-level Class C waste. The RPF will control the radionuclide content in the solidified waste by varying the concentration step in the waste management process.
41	**FEIS § 4.8.2.1** – In FEIS Section 4.8.2.1, the Staff notes that the NRC has previously evaluated the environmental impacts of transportation of radioactive materials on public roads and by air and cites the conclusion of a SMALL impact finding from NUREG-0170[41] (issued in 1977). Did NUREG-0170 include an assessment of the transportation impacts from the types of materials that NWMI will be transporting?
	Response: NRC staff response only

[39] Haass, C.C., 2017, "Exemption Request Pursuant to 10 CFR 70.17, from Requirement of 10 CFR 70.21(f), "Filing," for Northwest Medical Isotopes, LLC Radioisotope Production Facility," (Letter NWMI-LTR-2017-016 to M. Balazik, U.S. Nuclear Regulatory Commission, December 18), Northwest Medical Isotopes, LLC, Corvallis, Oregon, 2017.

[40] 10 CFR 61, "Licensing Requirements for Land Disposal of Radioactive Waste," *Code of Federal Regulations*, Office of the Federal Register, as amended.

[41] NUREG-0170, *Final Environmental Statement on the Transportation of Radioactive Material by Air and Other Modes*, U.S. Nuclear Regulatory Commission, Washington, D.C., December 1977

No.	Question
42	**FEIS § 4.11.2** – In Section 4.11.2, the Staff notes that NWMI did not provide an analysis of a chemical accident involving a sodium hydroxide release but that NWMI assumed, "based on the MAR [material at risk] quantity and the low PACs [protective action criteria] for sodium hydroxide . . . a sodium hydroxide release could cause PAC-2 limits to be exceeded at locations occupied by members of the public" (FEIS at 4-48). What are the protective action criteria for sodium hydroxide? Did the Staff evaluate NWMI's assumption? If so, what did the Staff conclude? Similarly, the Staff notes, in the same section, that NWMI "did not provide an analysis of possible chemical exposures to workers at the proposed NWMI facility" but that NWMI stated that a chemical accident involving a nitric acid release would result in chemical exposures to workers that would be much higher than exposure to the maximally exposed offsite individual (MOI). Did the Staff evaluate NWMI's statement? If so, what did the Staff conclude?
Response: NRC staff response only	
43	**FEIS § 5.2.1** – The FEIS describes NWMI's screening of four alternative sites, including the proposed site (FEIS at 5-6). Based on NWMI's site-selection scoring criteria, the score for the Oregon State TRIGA Reactor (OSTR) site differs by about ten percent from the score for the University of Missouri Research Reactor (MURR) site. The OSTR site, however, was not selected for further evaluation. The FEIS states that "[t]he NRC staff analyzed [the MURR] site in detail given that the proposed site and alternative site likely cover the full spectrum of alternatives and provide sufficient information for sound decision-making based on the relatively small size of the proposed facility, the limited footprint and excavation required, the use of county water rather than surface or groundwater for withdrawal or discharge, and the ability to site the facility within a previously disturbed area" (FEIS at 5-7). a. Explain the Staff's conclusion that the proposed site and the MURR alternative site "likely cover the full spectrum of alternatives" when both sites are located in Columbia, Missouri and some of the environmental impacts for the two sites are the same.
Response: NRC staff response only	
43 cont.	b. Discuss the specific considerations that led the Staff to determine that NWMI's site selection process was reasonable.
Response: NRC staff response only	
44	**FEIS Chapter 5** – Section 5.4.1 of the FEIS contains a discussion of cumulative impacts associated with both the proposed action and the MURR alternative site, but only compares the environmental impacts of these two sites rather than the cumulative impacts. Please explain why the cumulative impacts of the two sites were not compared.
Response: NRC staff response only	
45	**FEIS Chapter 5** – In its secondary analysis, NWMI developed a set of criteria to score the four potential sites in an effort to identify the preferred site. What informed the weighted rank for each criteria?
Response: NRC staff response only	

No.	Question
46	**FEIS Chapter 5** – Council on Environmental Quality (CEQ) regulations provide that the significance of impacts be considered in terms of intensity and context (40 CFR § 1508.27[42]). CEQ guidance provides that "intensity" refers to the severity of the impact, including its magnitude, duration, and extent (see, e.g., "Considering Cumulative Effects Under the National Environmental Policy Act," Council on Environmental Quality (Jan. 1997), at 44). Page 5-1 of the FEIS indicates that the Staff assessed the impacts of intensity and context. Did the Staff consider duration and extent when assessing the impacts of site alternatives?
Response: NRC staff response only	
47	**FEIS § 4.7.2.**3 – The FEIS states that the increase in tax revenue during the operational period of the proposed facility "may have a noticeable effect in the [Region of Interest] ROI" (FEIS at 4-29). The Staff concluded that the impact in this resource area would be SMALL. A MODERATE impact, however, is defined as an effect that is "sufficient to alter noticeably, but not to destabilize, important attributes of the resource" (FEIS at 4-1). Please explain why the Staff concluded that the impacts of the anticipated increase in tax revenue for the proposed facility during operations would be SMALL rather than MODERATE.
Response: NRC staff response only	
48	**General** – What comments generated the most significant revisions to the EIS? Did any comments lead the Staff to rethink its approach? If so, in what way?
Response: NRC staff response only	
49	**General** – Some of the impact determinations in the FEIS are dependent upon the results of the Staff's safety review. For example, with regard to radiological impacts from operations, the Staff concludes that the "impacts from potential radiological exposures . . . would be SMALL" if the Staff "determines in its SER that the maximum doses to workers and the public are within the dose limits in 10 CFR Part 20" (FEIS at 4-34). The Staff made similar conditional conclusions with regard to consequences from chemical accidents at the proposed site (FEIS at 4-49) and consequences from chemical accidents at the alternative site (FEIS at 5-31). Now that the Staff has completed the SER, has the Staff identified any changes that need to be made to the environmental analysis in the FEIS?
Response: NRC staff response only	

[42] 40 CFR 1508, "Terminology and Index," *Code of Federal Regulations*, Office of the Federal Register, as amended.

Respectfully submitted,
Executed in Accord with 10 C.F.R. § 2.304(d)

Carolyn C Haass
Digitally signed by Carolyn C Haass
Date: 2018.01.16 13:29:53 -07'00'

Signed (electronically) by Carolyn C. Haass

Carolyn C. Haass
Northwest Medical Isotopes, LLC – Chief Operating Officer
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Dated in Denver, Colorado
this 16th day of January 2018

CERTIFICATION AND DECLARATION OF WITNESS

I certify that NWMI's responses to the Commission's public pre-hearing questions were prepared by me or under my direction; that the responses are true and correct to the best of my information, knowledge and belief; and that I adopt these responses as part of my sworn testimony in this proceeding.

I declare under penalty of perjury that the foregoing written testimony is true and correct to the best of my information, knowledge, and belief.

Executed on January 16, 2018.

Respectfully submitted,

Executed in Accord with 10 C.F.R. § 2.304(d)

Carolyn C Haass

Digitally signed by Carolyn C Haass
Date: 2018.01.16 13:30:15 -07'00'

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