

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of

NORTHWEST MEDICAL ISOTOPES, LLC

(Medical Radioisotope Production Facility)

Docket No. 50-609-CP

ORDER

(Transmitting Pre-Hearing Questions)

On November 21, 2017, the Commission issued a notice that it would convene an evidentiary hearing at its Rockville, Maryland headquarters on January 23, 2018, pursuant to section 189a. of the Atomic Energy Act of 1954, as amended, to receive testimony and exhibits in the uncontested portion of the captioned proceeding.¹ In connection with that hearing, pursuant to my authority under 10 C.F.R. § 2.346(a) and (j), Northwest Medical Isotopes, LLC (NWMI) and the NRC Staff should file written responses to the questions provided in the table below. Responses should be filed by **January 2, 2018**.²

¹ Northwest Medical Isotopes, LLC; Notice of Hearing, 82 Fed. Reg. 56,276 (Nov. 28, 2017).

² Today I am also issuing a separate order with additional questions for NWMI and the Staff. This order is being filed on the non-public docket for this proceeding because it contains sensitive unclassified non-safeguards information (SUNSI).

No.	Category	Subject	Directed to	Question
1	Safety	General	Staff	<p>In its pre-filed testimony, the Staff states that its “safety review was tailored to the nature of NWM’s construction permit application and was informed by the . . . ISG [Interim Staff Guidance Document] 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 (<i>id.</i> 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.</p>
2	Safety	SECY-17-0116 SER §§ 1.4, 12.4.8	Staff and Applicant	<p>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 [C.F.R.] Part 50 construction permit application” (SECY-17-0116, at 5-6).</p> <p>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.</p> <p>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</p>

No.	Category	Subject	Directed to	Question
				<p>facility be analyzed to ensure those effects are bounded by the Part 50 production facility accident analyses?</p> <p>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.</p> <p>How will the structures, systems and components (SSCs) 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?</p>
3	Safety	SER Appendix A	Staff and Applicant	<p>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 (<i>id.</i>).</p> <p>Were the RPF design codes, standards, and other referenced documents, including exceptions or exemptions to the identified requirements, finalized?</p> <p>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.</p>
4	Safety	SER Appendix A	Staff and Applicant	<p>The regulatory commitment associated with RAI 11.1-1-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.</p>

No.	Category	Subject	Directed to	Question
				<p>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).</p>
5	Safety	SER Appendix A	Staff	<p>Will more or less conservative operating condition values be used in this alignment? If the less conservative value is utilized, why is this acceptable? 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.</p>
6	Safety	SER § 2.4.2	Applicant	<p>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 errors in crash impact probabilities, and incorrect runway bearings for the Columbia regional airport.</p>
7	Safety	SER §§ 2.3.1, 2.4.5; PSAR § 2.5	Staff and Applicant	<p>Has NWMI identified the causes for these deficiencies? 10 C.F.R. § 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 C.F.R. § 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).</p>
8	Safety	SER § 2.4.5; PSAR § 2.5	Applicant (Subparts a. through d.); Staff and	<p>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</p>

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			Applicant (Subpart e.)	<p>sinkholes (SER at A-4).</p> <ol style="list-style-type: none"> Please describe the sizes and depths of the caves and sinkholes found in Boone County. What methods of geotechnical investigation would NWMI employ to effectively detect potential caves at the site? 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? 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? 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.
9	Safety	SER § 2.4.5	Staff and Applicant	<p>In SER section 2.4.5, the Staff explains that:</p> <p>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</p>

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				<p>the FSAR [(Final Safety Analysis Report)] as part of an [operating license] application.</p> <p>(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?</p> <p>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?</p> <p>For the Staff:</p> <p>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?</p>
10	Safety	SER §§ 2.2, 2.4.4; PSAR §§ 2.1.1.2, 2.4.3	Staff and Applicant	<p>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).</p>
11	Safety	SER § 3.4.2	Staff and Applicant	<p>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.</p> <p>How will the RPF and diesel generator buildings be protected from a) tornado loading, b) maximum wind speed, c) tornado-generated missile impact effects,</p>

No.	Category	Subject	Directed to	Question
				and d) rain, snow, and ice loading?
12	Safety	SER § 6.4.2	Staff and Applicant	<p>Will the safety-related SSCs attached to the outside of the RPF building and the diesel generator building also be protected from meteorological damage?</p> <p>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.</p> <p>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?</p> <p>Historically, the agency has declined to apply 10 C.F.R. § 50.59 to construction permits (Miscellaneous Amendments; Correction, 27 Fed. Reg. 8825 (1962) (removing the words "construction or" from 10 C.F.R. § 50.59)). The Staff states in SER section 6.4.5, "The change process will be consistent with ANSI/ANS-8.19 and the requirements for 10 [C.F.R. §] 50.59, 'Changes, tests, and experiments'" (SER at 6-12).</p>
13	Safety	SER § 6.4.5	Staff and Applicant	<p>What is the basis for this proposed departure from established practice?</p> <p>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?</p> <p>Are all of the criteria and questions that would require prior NRC approval of a change under 10 C.F.R. § 50.59 applicable to the NWMI production facility?</p>
14	Safety	SER § 7.2.3; PSAR § 7.1	Staff and Applicant	<p>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?</p>
15	Safety	PSAR	Staff and	<p>a. In the PSAR, NWMI states that one of the keys to its FPC design is</p>

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		§§ 3.5.1.2, 7.2.3.1, Table 7-1	Applicant	<p>“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 NWNMI plan to design for diversity in the FPC design?</p> <p>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?</p>
16	Safety	PSAR Chapter 7	Staff and Applicant	<p>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 NWNMI 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?</p>
17	Safety	PSAR § 7.3.7	Staff and Applicant	<p>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 meters (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).</p>

No.	Category	Subject	Directed to	Question
18	Safety	PSAR § 6.3.1.1	Staff and Applicant	<p>Because most areas where irradiated fissile material would be processed in the NWM1 facility would be shielded and not normally accessed by personnel, explain how criticality events will be detected in these areas.</p> <p>Section 6.3.1.1 of the PSAR, "Preliminary Criticality Safety Evaluations," states that "[u]sing the source from the minimum accident of concern, NWM1 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, NWM1 will use 3D Monte Carlo analysis to determine adequate CAAS coverage" (PSAR at 6-59).</p>
19	Safety	SER §§ 8.2, 8.4.2	Staff and Applicant	<p>Explain how the one-dimensional deterministic and three-dimensional Monte Carlo analyses for determining CAAS coverage would be validated.</p> <p>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 (UPSs). In SER section 8.2, the Staff describes the July 11, 2017, ACRS NWM1 Subcommittee meeting where NWM1 stated that the exact number and location of the UPSs are yet to be determined.</p> <p>Does the emergency electrical power system incorporate redundancy into the design for the SEP and UPSs?</p>
20	Safety	SER § 8.4.2.4	Staff and Applicant	<p>Does the emergency electrical power system incorporate redundancy into the design for the SEP and UPSs?</p> <p>SER section 8.4.2.4, "Single-Failure Criterion," discusses NWM1's commitment to examine the possible effects of malfunctioning electrical equipment resulting in possible unexpected effects of interaction between otherwise independent and separate circuits.</p> <p>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-</p>

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21	Safety	SER § 8.4.2.5	Staff and Applicant	<p>failure criterion. SER section 8.4.2.5, "Safe Shutdown," states:</p> <p>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.</p> <p>(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.</p> <p>For the Staff:</p> <p>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.</p>

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				<p>For NWM1:</p> <p>Has the discrepancy been corrected?</p>
22	Safety	SER § 8.4.2.5	Staff and Applicant	<p>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 NWM1 PSAR section 8.2.</p> <p>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?</p>
23	Safety	SER § 13.4.1	Staff	<p>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.”</p> <p>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?</p>
24	Safety	SER § 13.5	Staff	<p>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, 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.</p>

No.	Category	Subject	Directed to	Question
				<p>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).”</p> <p>Please discuss the basis for the Staff’s acceptance of NWMl’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. 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 (see, e.g., Regulatory Guide 2.2, “Development of Technical Specifications for Experiments in Research Reactors,” at 2.2-4).</p>
25	Safety	SER Chapter 13	Staff	<p>In the SER, the Staff references the use of the RASCAL code in performing independent confirmation of NWMl’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.</p>
26	Safety	SER § 13.4.3; PSAR	Staff and Applicant	<p>SER Section 13.4.3, “Liquid Spills and Sprays with Radiological and Criticality Safety Consequences,” discusses NWMl’s assessment of the radiological consequences of the release of an irradiated target dissolver product. Based</p>

No.	Category	Subject	Directed to	Question
		§ 13.2.2.7.2		<p>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.</p> <p>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).</p>
27	Safety	SER § 13.4.3	Staff	<p>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 C.F.R. § 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 C.F.R. § 20.1301(d).</p>
28	Safety	SER § 13.4.4; PSAR	Staff	<p>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</p>

No.	Category	Subject	Directed to	Question
29	Safety	§ 13.2.3.8 SER Chapter 13	Staff	<p>As discussed in PSAR section 13.2.3.8, "Identification of Items Relied on for Safety and Associated Functions," NWMl 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, NWMl 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 C.F.R. § 20.1301(a)(1) or if it is expected that based on this accident evaluation NWMl 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 C.F.R. § 20.1301(d).</p> <p>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 [Part 20]" (10 C.F.R. § 50.40(a)). If the Staff determines that NWMl will need to obtain, under 10 C.F.R. § 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 NWMl will comply with 10 C.F.R. Part 20? If not, what would be the expected time frame for NWMl 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?</p>
30	Safety	SER Chapter 13	Staff	<p>Based on NWMl'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 NWMl application. Rather, NWMl states that:</p> <p>The accident analyses in the PSAR are based on (1) use of integrated safety analysis (ISA) methodologies, as described in 10 CFR 70</p>

No.	Category	Subject	Directed to	Question
				<p>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.</p> <p>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.</p> <p>(RAI G-3, at 2 (ML16344A053)). The performance requirements of 10 C.F.R. § 70.61 for radiological accident consequences are considerably higher than those specified in 10 C.F.R. § 20.1301, “Dose limits for individual members of the public.” Please confirm that the acceptance criteria for the NWWMI accident dose consequence analyses, as mitigated by SSCs and administrative safety measures, are evaluated against the requirements of 10 C.F.R. § 20.1301 and not the performance requirements of 10 C.F.R. § 70.61.</p>
31	Safety	Technical Specifications	Staff	<p>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 <i>likely</i> 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?</p>
32	Safety	Research and Development	Staff	<p>10 C.F.R. § 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</p>

No.	Category	Subject	Directed to	Question
33	Environmental	FEIS Chapters 3, 4	Staff	<p>activities listed in SER section 1.1.6 (items 1-3) do not contain completion dates. Were dates provided by NWM? </p> <p>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).</p> <p>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).</p> <p>In section 4.3.1, the Staff states, “At the time they were evaluated by Terracon (2011a), 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).</p> <p>Do high shrink/swell soils or over excavation of the site pose an increased risk for sinkholes or other geologic hazards?</p>
34	Environmental	FEIS § 3.4.2.1	Staff	<p>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 NWM facility site demonstrating saturated conditions at 12 ft bgs. The Staff stated in section 3.4.2.1 of the FEIS that “NWM has indicated</p>

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				<p>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 (NWMWI 2016a)" (FEIS at 3-34).</p>
35	Environmental	FEIS § 4.4.1.1, Appendix B	Staff and Applicant	<p>Has the Staff evaluated NWMWI's statement? As stated in FEIS section 4.4.1.1, NWMWI 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 NWMWI's obtaining either the requisite certification or a waiver of that requirement? 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 NWMWI must still secure?</p>
36	Environmental	FEIS § 4.6.3	Staff	<p>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 NWMWI project" (FEIS at 4-26). Which tribe made the request? How did the Staff respond to the request, and what was the outcome?</p>
37	Environmental	General	Staff	<p>In order to operate the NWMWI 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 NWMWI 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" (<i>id.</i>). Describe the anticipated process and scope of the environmental reviews for</p>

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38	Environmental	General	Applicant	<p>future operating license amendment applications filed by research reactor licensees to irradiate NWMMI targets.</p> <p>10 C.F.R. § 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."</p> <p>Additionally, 10 C.F.R. § 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."</p> <p>On March 1 and September 15, 2017, the NRC Staff notified NWMMI that the provisions in these regulations apply to NWMMI.</p> <p>Has NWMMI sought an exemption from these provisions?</p>

No.	Category	Subject	Directed to	Question
39	Environmental	General	Staff	<p>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 C.F.R. Part 70 license?</p> <p>In SECY-17-0116, the Staff states that “granting the 10 [C.F.R.] Part 50 construction permit will only authorize NWMI to construct the production facility portion of the RPF” (SECY-17-0116, at 12).</p> <p>For the purposes of 10 C.F.R. § 70.21(f), is the “facility” the production facility portion of the RPF or the entire RPF?</p> <p>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?</p> <p>Currently, the draft construction permit is written to authorize construction of “a production facility as defined in 10 [C.F.R. §] 50.2.” Should the construction permit specifically prohibit construction of the target fabrication facility?</p>
40	Environmental	FEIS §§ 2.7.1.2, 4.9.1	Staff and Applicant	<p>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 <i>a/so id.</i> at 4-37). Please explain the basis for this conclusion.</p>
41	Environmental	FEIS § 4.8.2.1	Staff	<p>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 (issued in 1977). Did NUREG-0170 include an assessment of the transportation impacts from the types of materials that NWMI will be transporting?</p>
42	Environmental	FEIS § 4.11.2	Staff	<p>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</p>

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				<p>members of the public” (FEIS at 4-48).</p> <p>What are the protective action criteria for sodium hydroxide? Did the Staff evaluate NWMI’s assumption? If so, what did the Staff conclude?</p> <p>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).</p>
43	Environmental	FEIS § 5.2.1	Staff	<p>Did the Staff evaluate NWMI’s statement? If so, what did the Staff conclude?</p> <p>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 decisionmaking 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).</p> <p>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.</p> <p>b. Discuss the specific considerations that led the Staff to determine that NWMI’s site selection process was reasonable.</p>

No.	Category	Subject	Directed to	Question
44	Environmental	FEIS § 5.4.1	Staff	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.
45	Environmental	FEIS Chapter 5	Staff	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?
46	Environmental	FEIS Chapter 5	Staff	Council on Environmental Quality (CEQ) regulations provide that the significance of impacts be considered in terms of intensity and context (40 C.F.R. § 1508.27). 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?
47	Environmental	FEIS § 4.7.2.3	Staff	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.
48	Environmental	General	Staff	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?
49	Environmental	General	Staff	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

No.	Category	Subject	Directed to	Question
				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?

IT IS SO ORDERED.

For the Commission

NRC SEAL

/RA/

Annette L. Vietti-Cook
Secretary of the Commission

Dated at Rockville, Maryland,
this 13th day of December, 2017.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of)
)
NORTHWEST MEDICAL ISOTOPES, LLC)
) Docket No. 50-609-CP
)
(Medical Radioisotope Production Facility))
)
(Mandatory Hearing))

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing **ORDER (Transmitting Pre-Hearing Questions)** have been served upon the following persons by Electronic Information Exchange.

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[Original signed by Herald M. Speiser]
Office of the Secretary of the Commission

Dated at Rockville, Maryland,
this 13th day of December, 2017