UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE COMMISSION

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

NRC STAFF RESPONSES TO COMMISSION PRE-HEARING QUESTIONS

Pursuant to the Commission Order (Transmitting Pre-Hearing Questions), dated December 13, 2017, the U.S. Nuclear Regulatory Commission (NRC) staff (Staff) hereby files its responses to the questions posed to the Staff by that Order.

Respectfully submitted,

/Signed (electronically) by/

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Executed in accord with 10 CFR 2.304(d)

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this 2nd day of January, 2018

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1. 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)] 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.

Staff Response: SECY-17-0116, "Staff Statement in Support of the Uncontested Hearing for Issuance of a Construction Permit for the Northwest Medical Isotopes, LLC [NWMI] Production Facility," dated November 16, 2017 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML17313A037), cited examples of where the NRC staff (Staff) exercised its judgment in determining what regulatory guidance was applicable to the proposed NWMI production facility and in determining the level of detail needed for a preliminary versus a final design during in the safety review of the Northwest Medical Isotopes, LLC (NWMI) 10 C.F.R. Part 50 construction permit application. The examples were (1) determining the acceptance criteria based on guidance developed for completed designs of non-power reactors and fuel cycle facilities (at 6), (2) the identification of probable subjects of technical specifications (TSs) (at 6), and (3) determining design sufficiency based on NWMI describing its methodology and ability to provide reasonable assurance that its final design will conform to the design basis (at 7). Additional examples of where the Staff determined which aspects of facility design needed to be analyzed before a construction permit could be granted or could be reserved for the Staff's review of the operating license (OL) application included: (4) the establishment of a sufficient margin of subcriticality, (5) the design of the criticality accident alarm system (CAAS), and (6) the facility's seismic design response spectrum.

Examples 1 and 3: Acceptance Criteria

The guidance for the content and Staff review of an application for a radioisotope production facility under 10 C.F.R. Part 50 is set forth in "Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," (ADAMS Accession No. ML12156A069) and "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors" (ADAMS Accession No. ML12156A075) (ISG Augmenting NUREG-1537). Although 10 C.F.R. § 50.34(a) specifies the required content of a construction permit application and 10 C.F.R. §§ 50.35, 50.40, and 50.50 specify the requisite findings to issue a construction permit, the level of detail in these areas involves the exercise of some discretion. Because the acceptance criteria in the ISG Augmenting NUREG-1537, Part 2, were primarily developed based on the completed design of a production facility and do not distinguish

between the information needed for a construction permit versus an OL, the staff used its technical judgment, informed by regulatory requirements, and the detail provided in the NWMI application, in deciding which acceptance criteria should be used in the construction permit review. For example, the Staff considered whether SSCs could significantly impact construction of the proposed production facility and evaluated the preliminary safety analysis report (PSAR) information to determine if an applicable acceptance criterion was satisfied.

Because a construction permit can be issued if, among other things, (1) the application describes a preliminary design, including the principal architectural and engineering criteria for the design and (2) further technical information needed to complete the safety analysis that can reasonably be left for later consideration, will be supplied in the final safety analysis report (FSAR), the Staff determined that NWMI could defer providing many details until the submission of its FSAR with an OL application. Thus the Staff evaluated the sufficiency of the NWMI preliminary design based on NWMI's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases and allow for adequate margin for safety. The Staff also concluded that it was reasonable to review NWMI's methodology, in part, because, as indicated by 10 C.F.R. § 50.35(b), an acceptance of NWMI's preliminary design for the issuance of a construction permit does not constitute approval of the safety of any design feature or specification. Such approval would be made following the evaluation of NWMI's final design and analysis submitted in support of an NWMI OL application.

Additionally, the Staff used its engineering judgment to determine the extent that established guidance and acceptance criteria were relevant to the review of NWMI's construction permit application, as much of this guidance was originally developed for completed designs of non-power nuclear reactors and fuel cycle facilities. For example, taking into consideration the design and operational similarities of separating radioisotopes between production facilities and fuel cycle facilities licensed under 10 C.F.R. Part 70, applicable non-reactor guidance contained in NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," the Staff determined that the use of certain methodologies as described in NUREG-1520, are an acceptable way of demonstrating adequate safety for a radioisotope production facility.

Engineering judgment was also used in determining where it was appropriate to apply non-power reactor guidance to a production facility, such as NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," (ADAMS Accession No. ML042430055) and NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," (ADAMS Accession No. ML042430048). Consistent with the statement in the ISG Augmenting NUREG-1537, Part 2 (at xi), when applying non-power reactor guidance to a production facility where the term "reactor" appears it can be interpreted to mean "radioisotope production facility," as appropriate, for areas of siting, design, operation, and decommissioning that are not specific to a particular production or utilization facility technology.

As appropriate and based on applicability to a production facility, the Staff used additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers [IEEE] standards, American National Standards Institute/American Nuclear Society [ANSI/ANS] standards, and NRC office instructions) in the review of NWMI's application. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG Augmenting NUREG-1537, Parts 1 and 2; and the NWMI application.

Example 2: Technical Specifications

Section 14b of the ISG Augmenting NUREG-1537, Part 2, provides the acceptance criteria for establishing TSs. As required by 10 C.F.R. § 50.34(a)(5), an applicant must identify and justify those variables and conditions, or other items selected (based on the results of the preliminary safety analysis and evaluation), as probable subjects of TSs. As listed in PSAR Table 14-1 (at 14-1), NWMI identified systems and variables as probable subjects of technical specifications based on their role in preventing releases of radioactive materials during normal operations or in the event of an accident. NWMI stated in the PSAR (at 14-2) that items relied on for safety (IROFS) will likely be translated into TSs as limiting conditions for operation (LCOs).

The ISG Augmenting NUREG-1537, Part 2 (at 134), states that TSs can include IROFS that were identified in the PSAR and the integrated safety analysis (ISA). In determining if the requirements of 10 C.F.R. § 50.34(a)(5) were met, the Staff exercised judgment in applying the acceptance criteria in the ISG Augmenting NUREG-1537 because the criteria addressed the content of TSs for the issuance of an OL and not the probable TS subjects for the issuance of a construction permit. Therefore, instead of using the explicit acceptance criteria in the ISG Augmenting NUREG-1537, the Staff reviewed NWMI's methodology (see PSAR at 14-6) and found that NWMI's identification and justification of the proposed TSs methodology is sufficient for the issuance of a construction permit. Because the NWMI PSAR (at 14-1 and 14-2) indicates that IROFS will be a likely subject of TSs and that NWMI will provide TSs for the proposed NWMI production facility in its OL application, the Staff finds that NWMI met 10 C.F.R. §50.34(a)(5).

Example 4: Margin of Subcriticality

Section 6b.3 of the ISG Augmenting NUREG-1537, Part 2, provides the acceptance criteria for an applicant's criticality safety program, including the establishment of a sufficient margin of subcriticality. Among these criteria is the expectation that an applicant include a summary description of a documented, reviewed, and approved validation report (by nuclear criticality safety (NCS) function and management) for each methodology that will be used to perform an NCS analysis. The summary description of a reference manual or validation report should include the following: a summary of the theory of the methodology that is sufficiently detailed and clear to be understood, including the method used to select the benchmark experiments, determine the bias and uncertainty in the bias, and determine the upper subcritical limit (USL).

As described in the Staff's safety evaluation report (SER), section 6.4.5, given the relative lack of critical benchmarks for the chemical forms and enrichments expected at the proposed NWMI facility, the Staff used its technical judgement to determine what information was needed to establish an USL in a construction permit review versus what could be deferred to an OL review. In particular, the Staff found it challenging to determine whether a properly benchmarked criticality code with sufficient margin to ensure subcriticality was used in the design of the production facility.

Therefore, the Staff requested that NWMI provide additional information to justify its choice of subcritical margin and to justify its choice of benchmarks for its proposed facility operations (ADAMS Accession No. ML17069A408). In response to Staff requests for additional information (RAIs), NWMI included additional criticality benchmarks and revised its USL to provide additional safety margin (ADAMS Accession No. ML17128A067). Based on NWMI's use of

conservative modeling practices, and its conservative validation methodology, the Staff has reasonable assurance that its margin of subcriticality is acceptable to ensure subcriticality of the proposed production facility under normal and credible abnormal conditions.

However, with this reduction in USL, it is possible that some of NWMI's criticality calculations and design analysis will need to be redone to incorporate the revised USL. Therefore, in order to confirm that NWMI will integrate the revised USL in the criticality calculations and design analysis of the facility for its final design, the Staff recommends that a construction permit, if issued, include a license condition to ensure that, prior to the completion of construction, all nuclear processes are evaluated to be subcritical under all normal and credible abnormal conditions. The condition would terminate once NWMI finalizes its design and submits its FSAR as part of an OL application.

Example 5: Criticality Accident Alarm System

Section 6b.3 of the ISG Augmenting NUREG-1537, Part 2, provides the acceptance criteria for an applicant's criticality safety program, including the design of a CAAS. Among these criteria is the expectation that (1) the CAAS is capable of detecting a criticality that produces an absorbed dose in soft tissue of 20 rads of combined neutron and gamma radiation at an unshielded distance of 2 meters from the reacting material within one minute; (2) coverage of all areas is provided by two detectors; (3) the applicant describes a facility CAAS that uses gamma- or neutron-sensitive radiation detectors which will energize clearly audible alarm signals if accidental criticality occurs; and (4) the applicant provides a description of a CAAS that is appropriate for the facility for the type of radiation detected, the intervening shielding, and the magnitude of the minimum accident of concern.

As described in the Staff's SER, section 6.4.5 (at 6-18), since the presence of permanently-installed shielding for the facility could interfere with the ability of detectors to detect the minimum accident of concern, the Staff used its technical judgement to determine what information was needed to establish a preliminary CAAS design for a construction permit review versus what information could be deferred to an OL review. In particular, the Staff found this aspect of the review challenging because if the evaluation of the CAAS is not completed prior to the installation of permanent shielding or other structural materials, there is a potential that the final design may not satisfy the detector coverage requirements of 10 C.F.R. § 70.24(a), which are also described in the acceptance criteria for section 6b.3 of the ISG Augmenting NUREG-1537, Part 2.

As discussed in the Staff's SER, section 6.4.5, the Staff found acceptable NWMI's commitment to design the CAAS consistent with ANSI/ANS-8.3, as modified by NRC Regulatory Guide 3.71, consistent with the requirements of 10 C.F.R. § 70.24(a), the guidance in NRC Regulatory Guide 3.71, which endorses ANSI/ANS-8.3, and the acceptance criteria in Section 6b.3 of the ISG Augmenting NUREG-1537, Part 2. NWMI also indicated that its analysis of the CAAS will be based on widely-used one-dimensional deterministic and three-dimensional Monte Carlo methods, as appropriate, which are acceptable to the Staff. However, because NWMI must provide assurance that the CAAS design will have the capability to detect the minimum accident of concern given the installation of SSCs into the facility, the Staff recommended that the construction permit, if issued, include a license condition, that prior to the completion of construction, NWMI provides periodic reports that provide the technical basis for the design of the CAAS. This condition would also terminate once NWMI submits its FSAR.

Example 6: Seismic

Section 2.5 of NUREG-1537, Part 2, provides the acceptance criteria for an applicant's information presented on geology, seismology, and geotechnical engineering. Among these criteria is the expectation that likely seismic activity affecting the site is sufficiently characterized to support the development of applicable design criteria.

To confirm the seismic design of the proposed NWMI production facility, the Staff developed a general seismic design response spectrum incorporating site amplification factors for the proposed NWMI facility site. As stated in the SER (at 2-16), within the 1 to 10 hertz (Hz) range of the design response spectrum, the Staff found that the seismic response was acceptable for the issuance of a construction permit because this frequency range tends to impact large facility structures, components, and equipment. As stated in SER section 3.4.4, the Staff found that (1) the seismic design criteria and design should provide reasonable assurance that SSCs would continue to perform their required safety functions during and following a seismic event and (2) the design to protect against seismic damage provides reasonable assurance that the consequences of credible seismic events will be considered to adequately protect public health and safety.

However, the Staff also identified a potential high-frequency design response that could impact electrical relays, piping, and instrumentation. NWMI committed to evaluate this issue (ADAMS Accession No. ML17265A048). Because the 1 to 10 Hz response was acceptable and the design response of electrical relays, piping, and instrumentation is not expected to impact construction, the Staff found that the application satisfied the requirements and acceptance criteria supporting the issuance of a construction permit with respect to seismology and that additional details may be reasonably left for later consideration in the FSAR. However, the Staff is tracking the issue of the potential high frequency impact in SER Appendix A.4 and will ensure that NWMI evaluates the issue as part of any OL application.

2. 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).

[A] 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.

Staff Response: The NWMI Quality Assurance Program Plan (QAPP) and applicable implementing procedures described in the NWMI QAPP will apply to the NWMI Radioisotope Production Facility (RPF), including the 10 C.F.R. Part 50 production facility and the 10 C.F.R. Part 70 target fabrication area. This includes systems that are shared between the production facility and the target fabrication area. The QAPP includes provisions for safety and reliability during RPF design, construction, and operation activities, including activities related to material processing safety, criticality safety, and engineered safety features.

The NWMI PSAR quality assurance policy statement in PSAR section 12.9 (at 12-17) states that the corporate QAPP meets ANSI/ANS 15.8, "Quality Assurance Program Requirements for Research Reactors," which is endorsed in NRC Regulatory Guide 2.5, "Quality Assurance Program Requirements for Research and Test Reactors," and 10 C.F.R. § 70.64(a)(1). In order to determine whether to issue a 10 C.F.R. Part 50 construction permit, the Staff used the guidance in NUREG-1537, Parts 1 and 2, section 12.9, "Quality Assurance," to evaluate whether the NWMI QAPP satisfied the relevant requirements of 10 C.F.R. § 50.34(a)(7). Because the NWMI 10 C.F.R. Part 50 construction permit application states that NWMI intends to submit a separate 10 C.F.R. Part 70 application for the target fabrication area (see PSAR at 1-1), the Staff also considered in its 10 C.F.R. Part 50 review how the QAPP could be applied to SSCs shared between the 10 C.F.R. Part 50 production facility and the target fabrication area. Specifically, the Staff considered how NWMI addressed the requirements of 10 C.F.R. § 70.64(a)(1) as part of the development of a comprehensive QAPP to be used in the design and construction of the entire RPF, but focused its review on findings related to the construction of the 10 C.F.R. Part 50 production facility.

[B] 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?

Staff Response: No, the Staff would not analyze the effects of accidents or events in the target fabrication area on the production facility to ensure that those effects are bounded by the 10 C.F.R. Part 50 production facility accident analyses. Instead, the Staff would evaluate all accidents within the target fabrication area to ensure that adequate IROFS and management measures are in place to ensure compliance with the performance requirements of 10 C.F.R. § 70.61.

Upon the receipt of an NWMI 10 C.F.R. Part 70 application to possess and use the special nuclear material related to the operation of the target fabrication area, the Staff would evaluate the ISA associated with the target fabrication processes, which should describe the IROFS that would be in place to ensure compliance with the performance requirements of 10 C.F.R. § 70.61. The performance requirements limit the effects of accidents to the public and workers through reducing the likelihood or consequences of accident sequences that can cause intermediate or high consequences. The NWMI accident sequences for the 10 C.F.R. Part 50 production facility are described similarly in terms of reducing likelihood and consequences. Therefore, the Staff's evaluation of the 10 C.F.R. Part 70 application related to the target fabrication area will be separate but will consider the same effects, i.e., likelihood and consequences, as those considered for the 10 C.F.R. Part 50 production facility. The impact of the target fabrication accidents on the 10 C.F.R. Part 50 production facility will also be considered and evaluated.

[C] 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 (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?

Staff Response: As stated in response to Question 2[A], the NWMI QAPP and its applicable implementing procedures will apply to both the production facility and the target fabrication area. This includes systems that are shared between the production facility and the target fabrication area.

3. 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?

Staff Response: No. The final codes, standards, and referenced documents, including exceptions or exemptions to the identified requirements for the production facility SSCs, do not need to be identified and committed to prior to the issuance of the 10 C.F.R. Part 50 construction permit. The regulations at 10 C.F.R. § 50.34 and 10 C.F.R. § 50.35 only require an applicant for a construction permit to describe the preliminary design of the facility and identify the major features or components incorporated for the protection of the health and safety of the public. The requirements in 10 C.F.R. § 50.35 also allow an applicant for a construction permit to provide further technical or design information as may be required to complete the safety analysis (e.g., identification of and commitment to specific codes and standards) in the FSAR submitted as part of an OL application.

NWMI's 10 C.F.R. Part 50 construction permit application included preliminary information about the RPF design, including the principal architectural and engineering criteria to be used. This information was adequate to identify the principal design criteria for major components of SSCs. Further information regarding final codes, standards and references can be reasonably left for later consideration in the FSAR because the preliminary design information was adequate and further design information required to complete the safety analysis does not need to be identified until an NWMI OL application is submitted.

In response to RAI 3.1-1A, NWMI indicated that it would finalize the specific design codes, standards, and other referenced documents, including exceptions or exemptions to the identified requirements, in the RPF final design (ADAMS Accession No. ML16123A119). NWMI has not submitted the referenced information that will support the final design for either its 10 C.F.R. Part 50 production facility or the entire RPF and has not indicated that its final design has been completed.

The Staff will review this information, if submitted, as part of its review of an NWMI OL application for a 10 C.F.R. Part 50 production facility.

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.

Staff Response: As stated in 10 C.F.R. § 50.35(a), a construction permit can be issued when an applicant has not supplied all of the technical information required to approve proposed design features, provided certain findings are made. Further, as stated in 10 C.F.R. § 50.35(b), a construction permit does not constitute Commission approval of the safety of any design feature or specification unless the applicant specifically requests such approval and such approval is incorporated into the permit. NWMI has not submitted nor sought approval of a final design for the 10 C.F.R. Part 50 production facility and the draft construction permit prepared by the NRC staff does not provide such approval. Therefore, the codes, standards, and referenced documents do not need to be identified and committed to prior to the issuance of the construction permit.

4. **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?

Staff Response: NWMI has not specified exactly which conditions of PSAR section 11.1.1.1.2 were more conservative than those of PSAR section 4.1.2.1 or specified how they would be aligned. However, in an August 23, 2017, meeting with the Advisory Committee on Reactor Safeguards Subcommittee (see meeting transcript at 13, ADAMS Accession No. ML17242A236), NWMI indicated that it will update its routine radioactive release calculations in PSAR section 11.1.1.1.2 as part of its FSAR to reflect the maximum number of targets to be processed under its license. As described in the SER (at 11-11), based on NWMI's preliminary design of the offgas system, there is reasonable assurance that the regulatory requirements of 10 C.F.R. § 20.1101 can be met regardless of whether more or less conservative operating conditions are used in this alignment.

The calculations of airborne releases in PSAR section 11.1.1.1.2 were based on the processing of eight targets at the University of Missouri–Columbia Research Reactor (MURR). PSAR Section 4.1.2.1 provides a different discussion of processing capability, stating that the RPF would have a nominal operational processing capability of one batch per week of up to 12 targets from MURR and approximately 30 targets from the Oregon State University TRIGA Reactor (OSTR) or a third university research reactor for eight weeks per year per reactor.

In its response to RAI 11.1-1a (ADAMS Accession No. ML16344A053), NWMI stated that the primary dose contributor for target processing is xenon noble gas and that the NWMI offgas system will be designed to retain the xenon so that releases are below regulatory limits and bound the range of target processing. Further, NWMI stated in PSAR section 11.1.1.1.2 that it will implement as low as is reasonably achievable (ALARA) constraints on air emissions and doses to the public consistent with the requirements of 10 C.F.R. § 20.1101. The Staff will evaluate NWMI's analysis of the dose contributions from the production capacity of the RPF as part of the review of an NWMI OL application.

5. 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.

Staff Response: There is an additional RAI that should be included in SER Appendix A, section A.2. The second RAI labeled as 12A-9b should be labeled as RAI 12A-9c. The Staff will revise SER Appendix A, section A.2 to correct this error by removing the stricken text and inserting the underlined text as follows:

12A-9~~b~~c	April 28, 2017ML17128A065	PSAR Chapter 12.0, Appendix A, Table A-1, will be amended such that the EALs for each emergency class are consistent with that found in ANSI/ANS 15.16.

6. 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.

Has NWMI identified the causes for these deficiencies?

Staff Response: None. This question was for the applicant only.

7. 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).

Staff Response: Based on the Staff's review of NWMI's description and safety assessment of the Discovery Ridge site, the Staff determined that NWMI had satisfied the requirements of 10 C.F.R. § 50.34(a)(1)(i) and that the design basis of the facility described in PSAR Chapter 3 satisfied the requirements of 10 C.F.R. § 50.34(a)(3). In essence, the Staff concluded that NWMI had given appropriate attention to site features affecting the design.

As described in PSAR Chapter 2, NWMI prepared its description and safety assessment of the Discovery Ridge site on which the facility is to be located based on published and un-published reports, studies, maps, and other documents prepared by various local, State, Federal, and private organizations. In particular, NWMI considered the results of the 2011 Phase I Environmental Site Assessment conducted by Terracon Consultants, Inc. (Terracon) for Discovery Ridge Lot 2 and Lots 5 through 18 (see ADAMS Accession No. ML15328A010 at Appendix H). The proposed NWMI Discovery Ridge site is to be located on Lot 15, which is within the investigation area of this assessment. The purpose of the assessment was to provide preliminary geotechnical recommendations concerning earthwork and the design and construction of foundations, floor slabs, and pavements for Discovery Ridge properties. The results of this assessment were documented in the "Preliminary Geotechnical Engineering

Report-Discovery Ridge" (see ADAMS Accession No. ML15328A010 at Appendix K). The assessment, which included nine shallow borings, concluded that, with proper site preparation and any necessary subgrade repairs, typical commercial buildings could be supported on shallow footings bearing on stiff to very stiff native clay or on compacted structural fill. With respect to geotechnical considerations, NWMI reviewed information available from the facilities in the proximity of the proposed Discovery Ridge site, including the MURR, located 6 miles away, and the Calloway Nuclear Power Station, located approximately 36 miles away. NWMI noted that areas of known karst topography are present west and southwest of the proposed Discovery Ridge site. Specifically, according to the 2015 Boone County Hazards Mitigation Plan, the Discovery Ridge site is located to the north and east of potential sinkhole and collapse areas, as mapped by the Missouri Department of Natural Resources (MoDNR).

In light of the potential for unidentified sinkholes, NWMI has committed to performing a site-specific geotechnical investigation to confirm the results presented in the Terracon and MoDNR reports (see SER section 2.4.5 (at 2-17) and SER Appendix A, section A.2 (at A-4)). If further site-specific investigation identifies the potential for sinkholes, NWMI indicates that design alternatives are to be addressed during the construction of the facility, including: (1) excavation of the site both vertically and horizontally to remove the sinkhole potential and backfill with structural fill, or (2) installation of piers in the bedrock to support the structure if a sinkhole was to occur. Any design changes would be implemented consistent with NWMI's QAAP, which the Staff has found to be satisfactory. The Staff would verify the adequacy of the management and implementation of such design changes through its construction inspection program and its review of the results of the site-specific geotechnical investigation as part of a review of an OL application.

8. 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.

Staff Response: None. This item was for the applicant only.

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

Staff Response: None. This item was for the applicant only.

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?

Staff Response: None. This item was for the applicant only.

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?

Staff Response: None. This item was for the applicant only.

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.

Staff Response: Because (1) a construction permit does not constitute final approval of the adequacy of any design feature and (2) NWMI provided sufficient geotechnical survey information to satisfy the applicable regulatory requirements for the issuance of a construction permit, the Staff determined that it would be appropriate to track NWMI's additional site-specific geotechnical survey information in regulatory commitments to be verified as part of the Staff review of an FSAR, rather than as permit conditions.

However, based on the issues raised by Commission questions 7-9 regarding whether the application contained sufficient information and whether commitments are sufficient to provide reasonable assurance that NWMI will complete a further site-specific investigation to confirm whether there are any site features that could impact the final design bases of the facility, the Staff will revise its SER (at 2-15, A-2, and A-4) and draft construction permit (at 3) to reflect the inclusion of the following permit condition requiring the completion of the planned site-specific geotechnical investigation prior to the beginning of construction:

> Prior to the beginning of construction, NWMI shall (a) complete a geotechnical investigation to identify sinkhole potential, soil characteristics, and liquefaction potential at the site and (b) submit the results of this investigation, including any design changes made to the facility based on the findings of the investigation, in a report to the NRC. This condition terminates once NWMI submits the results of the geotechnical investigation in either this report or as part of its final safety analysis report, whichever occurs first.

Consistent with other proposed NWMI construction permit conditions, this condition would be confirmatory in nature. The results of NWMI's planned site-specific geotechnical investigation will inform the Staff's construction inspection program and confirm the adequacy of the production facility design basis. The Staff will not approve the safety of the design until after NWMI submits a final design for its facility and the Staff concludes that the design satisfies NRC requirements. The Staff's construction inspection program will confirm that the facility is constructed as described in NWMI's construction permit application, including any design changes made in accordance with NWMI's QAPP. The OL review will determine whether the final design is adequate for operation of the production facility.

Consistent with the requirements of 10 C.F.R. § 50.34(b)(1), the Staff will also review all information relating to site evaluation factors such as seismology, meteorology, geology, and hydrology that is submitted in the NWMI FSAR and developed after the issuance of the construction permit. As such, the Staff's OL review will specifically include an evaluation of the results of NWMI's planned site-specific geotechnical investigation.

9. 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?

Staff Response: If the site-specific investigation reveals the need for a previously unconsidered design alternative to address potential sinkholes, NWMI may need to modify its design. The Staff would expect NWMI to submit any such design changes to the NRC prior to the beginning of construction to satisfy the proposed construction permit condition described in response to Question 8(e) above. The Staff would expect NWMI to maintain the documents onsite in accordance with the NWMI QAPP, make them available for the Staff's inspection during construction, and to present the selected alternative for the Staff's review and approval in either an FSAR as part of an NWMI OL application or construction permit amendment application.

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?

Staff Response: Based on the results of the site-specific investigation, the Staff would expect NWMI to describe what onsite buildings would be covered by the alternatives, if implemented, in a report submitted to the NRC prior to the beginning of construction to satisfy the proposed construction permit condition described in response to Question 8(e) above, in onsite design change documents, and in an FSAR.

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?

Staff Response: Because license conditions must be ministerial in nature and not subject to dispute, it is not certain whether a permit condition would ensure that site conditions are corrected prior to construction. However, a condition would ensure that NWMI completes the survey and submits the results of the survey as well as any related design changes to the NRC. The Staff would not review the adequacy of the design changes until it reviews the final design submitted in the OL application or, consistent with 10 C.F.R. § 50.35(b), NWMI requests approval of the design changes by amendment to its construction permit, if issued.

10. 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).

Staff Response: As stated in SER section 2.4.4 (at 2-13), the elevation of the proposed RPF site is 815 feet. However, a portion of the site is as low as 805 feet based on U.S. Geological Survey topographical maps. The Federal Emergency Management Agency flood map confirms that the proposed RPF site is outside the 500-year floodplain boundary for Gans Creek to the southeast. Based on this information, the proposed facility would be located above the 500-year floodplain and, therefore, the effects of potential floods would not impact the portion of the site that is as low as 805 feet.

11. 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?

Staff Response: As stated in PSAR Chapter 3, the RFP buildings will be protected from tornados and tornado missiles (at 3-30), extreme winds (at 3-30), and rain, snow, and ice loads (at 3-33) based on PSAR-referenced applicable standards, guides, codes, and criteria, including the international building code and standards such as ACI-349, "Code Requirements for Nuclear Safety Related Concrete Structures," and ASCE 7, "Minimum Design Loads and Associated Criteria for Buildings and Other Structures" as listed in PSAR Table 3-7 (at 3-12). Additionally, NWMI stated in PSAR section 3.5.2 (at 3-51) that safety-related SSCs that are determined to have safety significance for the RPF will be designed, fabricated, erected, and tested as required by the NWMI QAPP. Implementation of the NWMI QAPP ensures that construction of SSCs meets the appropriate quality standards to protect the buildings from meteorological hazards.

Will the safety-related SSCs attached to the outside of the RPF building and the diesel generator building also be protected from meteorological damage?

Staff Response: Yes. NWMI stated in PSAR Chapter 3 that the design of all RPF safety-related structures and support structures will be protected from meteorological damage, including high winds, tornado missiles, and rain, snow, and ice. This would include safety-related SSCs attached to the outside of the RPF building and the diesel generator (DG) building. Although the DG is part of the NWMI non-safety-related standby electrical power (SEP) system designed to reduce or eliminate process downtime due to electrical outages, NWMI stated in PSAR section 3.5.2 (at 3-52) that non-safety-related components and systems, such as the DG building, will be qualified to withstand environmental stress caused by environmental and dynamic service conditions under which their failure could prevent satisfactory accomplishment of the safety-related functions.

12. 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?

Staff Response: PSAR section 3.5.1.3.2 (at 3-47) states that IROFS will be designated as seismic Category I and designed to withstand the effects of natural phenomena (e.g., earthquakes, tornados, hurricanes, floods) without loss of capability to perform their safety functions. PSAR Chapters 3 (at 3-7) and 6 (at 6-7) indicate that the exhaust stack is an IROFS structure.

13. 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).

What is the basis for this proposed departure from established practice?

Staff Response: The Staff is not proposing to depart from established practice and agrees that the regulations related to construction in 10 C.F.R. Part 50 are sufficient to accommodate changes to the NWMI facility as its design matures from a preliminary to a final design.

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?

Staff Response: Although, NWMI developed a set a criteria based on 10 C.F.R. § 50.59 and ANSI/ANS-8.19, "Administrative Practices for Nuclear Criticality Safety," that it plans to use during construction for nuclear criticality control design changes, the Staff does not consider 10 C.F.R. § 50.59 criteria to be applicable during construction. However, the Staff will inspect NWMI's implementation of the NWMI QAPP, including its design change control process, during construction.

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?

Staff Response: Section 50.59 would only apply to the NWMI production facility if it is granted an OL. The regulation applies to each 10 C.F.R. Part 50 OL holder and defines changes in terms of information described in the FSAR or TSs.

14. 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?

Staff Response: As described in PSAR Table 7-1, the principal design criteria that will allow for the independence of the facility process control (FPC) system and the engineered safety feature (ESF) safety functions are provided in IEEE 384-2008, "IEEE Standard Criteria for Independence of Class 1E Equipment and Circuits." This standard provides the independence requirements of circuits and equipment in Class 1E systems at nuclear power plants. NWMI states that it will apply the design criteria of IEEE 384-2008 to the design of the FPC system, ESFs, and other instrumentation SSCs identified as IROFS. For example, as identified in PSAR section 7.1, the ESF system will be a hard-wired analog system while the FPC system will be a digital system. As stated in SER section 7.5, NWMI has described the proposed design of the production facility instrumentation and control (I&C) systems, including, but not limited to, the principal architectural and engineering criteria for the design. The Staff finds that the selected standard provides appropriate methodologies to select criteria for establishing independence between circuits and equipment through physical separation, electrical isolation, and equipment redundancy.

15. 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?

Staff Response: NWMI plans to account for diversity in the FPC design by applying the principal design criteria contained in IEEE 603-2009, "IEEE Standard Criteria for Safety Systems for Nuclear Power Generating Stations," and IEEE 7-4.3.2-2010, "IEEE Standard Criteria for Digital Computers in Safety Systems of Nuclear Power Generating Stations." These standards specify computer-specific requirements for diversity and software verification and validation at nuclear power plants. For example, NWMI indicates in PSAR Table 7-1, "Instrumentation and Control System Design Criteria," that the FPC will be designed as a digital control system and IEEE 7-4.3.2-2010 will be applied to software development. While the NWMI production facility is not a nuclear power plant, the Staff review of PSAR Table 7-1 finds that the selected standards can be applied, as appropriate, to design the FPC system (SER at 7-13) as a digital control system with sufficient diversity.

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?

Staff Response: While the NWMI 10 C.F.R. Part 50 production facility design includes redundant and diverse hardware capability, the use of identical programmable logic controller (PLC) software could lead to a common-cause failure due to a software error. To address this issue, NWMI has established principal design criteria to prevent common-cause failures in the primary and backup control systems of the FPC. Specifically, NWMI has selected the use of IEEE 603-2009 and IEEE 7-4.3.2-2010 as described in PSAR Table 7-1. These standards specify computer-specific requirements for diversity and software verification and validation for nuclear power plants, including the need to address common cause software failures as part of the diversity and defense-in-depth analysis.

As provided in PSAR Table 7-1, NWMI intends to design the FPC digital control system using the criteria in IEEE 7-4.3.2-2010, which could reduce the likelihood of a software common-cause failure. For example, with sufficient diversity, common-cause failures in digital components can be categorized as not credible. Also, if digital components can be shown to be sufficiently simple and deterministic in performance, measures such as online error checking and exhaustive testing can be used to demonstrate that the component is not a significant source of software common-cause failure. As stated in SER section 8.4.2.4, the Staff finds that the design bases consider functional diversity, diversity in component design, and principles of operation to protect against single failure. The NWMI construction permit application describes sufficient redundancy and diversity in its FPC hardware and contains appropriate principal design criteria to address potential software common-cause failures. The Staff will further evaluate the diversity of the RPF systems, including potential common-cause failures related to the use of identical PLC software systems, as part of its review of an NWMI OL application.

16. 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?

Staff Response: Because the Staff generally does not use this power reactor guidance in the review of a non-power facility and because of the preliminary nature of the NWMI design, the Staff did not specifically consider Branch Technical Position (BTP) 7-18, "Guidance on the use of Programmable Logic Controllers in Digital Computer-Based Instrumentation and Control Systems," or the Electric Power Research Institute (EPPRI) Topical Report TR-107330, "Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants," in its review of NWMI's construction permit application. However, the Staff considered the guidance documents NWMI used to establish a design basis for its PLC systems. Some of these guidance documents are referenced in BTP 7-18. The ISG Augmenting NUREG-1537, Part 2, section 7b does not specifically reference BTP 7-18 or EPPRI Topical Report TR-107330. The Staff evaluated the preliminary design and performance of NWMI's I&C systems against the criteria in the ISG Augmenting NUREG-1537, Part 2, section 7b. As stated in SER section 7.4.2, the Staff found that the description of the NWMI production facility FPC systems contains a sufficient level of detail for an overall understanding of the functions and relationships of the I&C systems to the preliminary design. NWMI established an adequate design basis for its PLC systems by using the following guidance documents referenced in BTP 7-18:

- NUREG/CR-6463, "Review Guidelines on Software Languages for Use in Nuclear Power Plant Safety Systems,"

- NUREG/CR-6090, "The Programmable Logic Controller and Its Application in Nuclear Reactor Systems," and

- EPRI Topical Report TR-106439, "Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications."

If NWMI submits an OL application, the Staff will review NWMI's digital-based I&C systems by following the ISG Augmenting NUREG-1537, Parts 1 and 2, Chapter 7, which includes guidelines for preparing and reviewing radioisotope production facility license applications with respect to digital I&C systems. Consistent with the objectives of BTP 7-18, the Staff's OL application review of NWMI's PLCs will ensure that: (1) embedded and operating systems software, programming tools, and peripheral components are reviewed, and the appropriate acceptance criteria are applied, and (2) the PLC application software (e.g., ladder-logic software) are developed using an appropriate software development process.

17. 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).

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.

Staff Response: PSAR section 6.3.1.1 states that the CAAS will comply with ANSI/ANS-8.3, "Criticality Accident Alarm System," as modified by NRC Regulatory Guide 3.71, "Nuclear Criticality Safety Standards for Fuels and Material Facilities," which establishes minimum criticality detection and alarm criteria.

In its response to RAI 6.3-18 (ADAMS Accession No. ML17283A109), NWMI reiterated its commitment to follow ANSI/ANS-8.3, as modified by NRC Regulatory Guide 3.71, and stated that it will comply with the criticality accident requirements of 10 C.F.R. § 70.24. Specifically, NWMI stated that "CAAS coverage will be in all areas in which greater than the 10 [C.F.R.] § 70.24 mass limits of special nuclear material (SNM) are handled, used, or stored, and in all shielding areas of the RPF."

Because of the concern that shielding could interfere with the CAAS's ability to detect criticality, and because NWMI's evaluation of CAAS coverage has not been completed, the Staff recommended the inclusion of a construction permit condition requiring the submittal of the technical basis for the CAAS, including a demonstration of CAAS coverage in accordance with the requirements of 10 C.F.R. § 70.24. SER Appendix A.1 documents this proposed permit condition, which would terminate once NWMI submits its FSAR.

18. 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.

Staff Response: Detailed and rigorous validation of codes for criticality alarm placement has not historically been performed in the nuclear fuel industry. In addition, the criticality code validation acceptance criteria in the ISG Augmenting NUREG-1537, Part 2, section 6b.3 pertain to neutron multiplication calculations and not to radiation dose calculations for criticality alarm coverage.

Both the one-dimensional point-kernel and three-dimensional Monte Carlo methods (e.g., MCNP) are widely accepted analysis tools in the nuclear industry. While some limited shielding benchmark data is available (e.g., in the Idaho National Lab International Handbook of Evaluated Criticality Safety Benchmark Experiments), these methods have not been validated to the same extent as neutron multiplication calculations.

Once NWMI has completed its evaluation for criticality alarm placement, the Staff will consider the margins in NWMI's calculations and NWMI's analysis methods presented in any periodic reports submitted under proposed permit condition 3.D.(2) (ADAMS Accession No. ML17313A100) and determine the acceptability of the margins and analysis methods when it reviews an NWMI OL application.

19. 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 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?

Staff Response: No, redundancy is not incorporated into the preliminary design of the SEP DG. However, NWMI plans to include some level of redundancy in design of the uninterruptible power supplies (UPSs). PSAR section 8.1 states that the UPSs will be backed up by the on-site DG to extend the duration of power availability to connected loads. PSAR section 8.1.2 states that the UPSs will be designed to operate for a period of up to 120 minutes. Additionally, as documented in the PSAR (at 8-1), a combination of UPSs and SEP would provide emergency electrical power. PSAR section 8.1 (at 8-4) states that the UPS systems locations on the electrical one-line diagram will be defined in the final design and provided in an NWMI OL application.

20. 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.

Staff Response: No. NWMI's preliminary electrical design does not contain enough information about wiring and cable tray locations for the Staff to complete a failure modes and effects analysis for the construction phase of the project. However, as stated in PSAR section 3.5.2.3, NWMI plans to account for single-failure criteria in its electrical power systems by applying the guidance in IEEE 379, "Standard for Application of the Single-Failure Criterion to Nuclear Power Generating Station Safety Systems," and NRC Regulatory Guide 1.53, "Application of the Single-Failure Criterion to Safety Systems." Additionally, as documented in a letter dated September 18, 2017 (ADAMS Accession No. ML17265A048) and in SER Appendix A.4, NWMI committed to identify all fire-induced circuit failures that could directly or indirectly cause single or multiple spurious actuations that could compromise safety.

The Staff finds that NWMI's use of relevant guidance and its commitment to identify fire-induced circuit failures establishes an adequate design basis and design criteria for the normal electrical power system to address single-failure criteria in the final facility design. Thus, NWMI has provided sufficient information about its preliminary design to support the issuance of a construction permit.

The Staff will consider open-phase conditions, as described in NRC Information Notice 2012-03, "Design Vulnerability in Electric Power System," as part of its evaluation of the single-failure criterion during the review of the final design in the NWMI FSAR.

21. 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.

Staff Response: The Staff finds the discrepancy between the SEP DG peak power estimates in PSAR Table 8-1 and PSAR section 8.2.2 compared with the estimate in PSAR section 8.2 to be acceptable for the issuance of a construction permit because the SEP DG provides an economical and defense-in-depth function, but not a safety function. The SEP DG is part of the non-safety SEP system designed to reduce or eliminate process downtime due to electrical outages. Therefore, additional details on the SEP DG, including peak power estimates, may be reasonably left for later consideration in the FSAR.

In its response to RAI 8.2-2, NWMI did not commit to changing the SEP DG power capacity; therefore, the Staff did not document it as a regulatory commitment. However, the Staff documented the SEP DG power capacity discrepancy in the SER (at 8-11).

For NWMI:

Has the discrepancy been corrected?

Staff Response: None. This question was for the applicant only.

22. 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?

Staff Response: As stated in PSAR Table 8-1, the 11-14 hour diesel runtime is a conservative estimate based on industry average fuel consumption rates for DGs for a peak load of 1178.6 kilowatts. The Staff concluded that the NWMI facility design is not yet mature enough to determine the facility-specific required mission times for the standby DG.

The Staff finds that NWMI's estimated diesel runtime figure is acceptable for a preliminary design because it provides a conservative estimate of anticipated fuel consumption rates and describes the operating characteristics of a source of emergency power, consistent with the guidance in NUREG-1537, Part 2, section 8.2. Thus, NWMI has provided sufficient information to support the issuance of a construction permit.

Once the make and model of the DG have been chosen, an accurate, full-load, fuel consumption rate can be determined, which will then dictate the amount of available/usable diesel fuel needed to support the required mission time, and the minimum usable capacity of the fuel tank. As part of its review of an NWMI FSAR, the Staff will assess the lube oil consumption rates at the peak load values for the specified duration.

23. Page 13-[1]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?

Staff Response: No. As stated in the SER (at 13-18), during irradiated target shipping cask unloading preparations, the shield plug fasteners are removed and worker radiation exposures could occur if the cask is tipped over during a seismic event while it is being unloaded. In PSAR section 13.2.6.5 (at 13-74), NWMI indicated that as a passive engineered control, the irradiated target cask lifting fixture will be designed to prevent the cask from tipping within the fixture and prevent the fixture itself from toppling during a seismic event (IROFS FS-04).

Without a final design and the accompanying analysis in an FSAR, it is difficult for the Staff to determine what scenarios would lead to a criticality event. However, the Staff does not consider a cask tip over to be the primary criticality concern because the material is in a solid form and of lower risk of criticality than other areas reviewed, such as the processing of solutions following target dissolution in the RPF.

In order to determine whether to issue a construction permit, the Staff only reviewed fissile solution leaks that could lead to an inadvertent criticality, regardless of whether they resulted from a seismic event or some other cause. Because of their small critical masses and dimensions, and their ability to migrate and change geometric configuration, solutions are the main criticality concern at the proposed NWMI facility. Other accident scenarios resulting from a seismic event and necessary controls will be evaluated as part of the Staff's review of NWMI's final criticality safety evaluations (CSEs) supporting its review of an NWMI OL application. As part of its review of NWMI's final CSEs, the Staff will determine whether all scenarios by which a seismic event could lead to a criticality have been considered. It is expected that, consistent with the double contingency principle, NWMI will implement provisions and controls to prevent criticality.

During its construction permit application review, the Staff also evaluated NWMI's criticality analysis for hot cell uranium purification, to ensure that the principal design criteria applicable to nuclear criticality safety were appropriately applied. The uranium purification process relies on the use of passive geometry equipment and fixed spacing for criticality control. Fissile solution leaks from favorable geometry process equipment and changes to fixed spacing could result from a seismic event and lead to a criticality. However, in the event of a leak, fissile solution would collect in a safe slab geometry configuration on the floor of the facility. As described in SER section 6.4.5, the Staff determined that, even in the event of the catastrophic failure of all process vessels, the depth of solution on the floor would be much less than a minimum critical slab height. Therefore, the Staff concluded that the information was sufficient for the issuance of a construction permit.

The Staff will review other abnormal scenarios, including those resulting from a seismic event, during its review of the NWMI CSEs when NWMI submits an OL application.

24. 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.

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. 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).

Staff Response: The Staff accepted NWMI's atmospheric dispersions factors because, based on the preliminary nature of NWMI's design and proposed facility operation, the Staff found that the dose calculation input parameters, including atmospheric dispersion factors, used by NWMI and provided in the application were sufficiently representative of anticipated site conditions and facility operation.

As discussed in PSAR section 13.2.2.7.2, NWMI used the RASCAL code to calculate doses from a uranium separations feed spray release for its construction permit application. In PSAR Table 13-19, NWMI provided its RASCAL inputs, including meteorological assumptions, and stated that it selected meteorological conditions (Pasquill F stability, 4 mile per hour (1.8 meter per second (m/s)) wind) to maximize the dose to near-field receptors. As discussed in PSAR sections 13.2.2.7.2 and 13.2.3.7, NWMI used the RSAC 6.2 (RSAC) code to calculate the doses from other radiological releases (e.g., dissolver product spray leak and target dissolver offgas accidents). In PSAR section 19.4.11.1.1, NWMI discussed assumptions used for RSAC calculations performed for its environmental report, and stated that it used Pasquill F stability and 2 m/s wind, similar to the RASCAL inputs listed in PSAR Table 13-19. Because the RSAC target dissolver accident consequences discussed in PSAR 13.2.3.7 are scaled from the PSAR 19.4.11.1.1 RSAC calculation, the meteorological assumptions used were the same.

Until NWMI provides more detailed information describing the validation of models, codes, assumptions, and approximations used to estimate radiological release consequences as part of its final design in an FSAR as part of an OL application, the Staff finds that it is not necessary for NWMI to provide a dose calculation model that necessarily predicts worst-case values such as the 95th percentile values commonly used for power reactor design basis dose consequence accident analyses. As discussed in response to Question 25 below, the Staff's independent verification of NWMI's preliminary dose calculations allowed the Staff to conclude that there is reasonable assurance that NWMI will develop appropriate models to estimate dose

consequences as the design of the facility matures. The Staff will perform a more thorough analysis of NWMI's dose calculations as part of its review of an FSAR as part of an NWMI OL application.

25. 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.

Staff Response: During its review of the construction permit application, the Staff used the RASCAL code to perform an independent verification of preliminary dose calculations presented in PSAR Chapter 13. In its calculations, the Staff used similar meteorological assumptions as NWMI had used in the RASCAL calculation provided in its application (NWMI stated in PSAR Table 13-19 that its RASCAL meteorological conditions were chosen to maximize the dose to near-field receptors). In order to determine whether a construction permit should be issued, the Staff used the RASCAL code to verify the adequacy of NWMI's approach to calculating dose consequences for a preliminary facility design. Until NWMI provides more detailed information describing the validation of models, codes, assumptions, and approximations used to estimate radiological release consequences as part of its final design in an FSAR, the Staff finds that it is not useful to develop and use its own model for performing confirmatory calculations that necessarily predicts worst-case values, such as values based on a 95th percentile confidence level because of the preliminary nature of the information that may change in the final design.

Considering the preliminary nature of NWMI's design and proposed facility operation, which may change in the final design, the Staff found that the dose calculation input parameters used by NWMI and provided in the PSAR were reasonably representative of anticipated site conditions and facility operation. As described in SER section 13.4.9, the Staff's independent verification of NWMI's preliminary dose calculations allowed the Staff to conclude that there is reasonable assurance that the applicant will develop appropriate models to estimate dose consequences as the design of the facility matures. The Staff will perform a more thorough analysis of NWMI's dose calculations as part of its review of an NWMI OL application.

26. 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).

Staff Response: The RASCAL code utilized by NWMI and the Staff uses an algorithm which outputs receptor doses based on the inputs provided by the user, but the code does not directly output the numerical values of the atmospheric dispersion factors used within the code for a given calculation. As such, the Staff did not use numerical atmospheric dispersion factors as inputs to its RASCAL runs and, thus, cannot provide a comparison for 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.

As discussed in PSAR section 13.2.2.7.2, NWMI used the RASCAL code to calculate doses from a uranium separations feed spray release for its construction permit application. PSAR section 13.2.2.7.2 also discusses NWMI's use of the RSAC coded to calculate the consequences of an unmitigated dissolver product spray leak as resulting in doses of 300 mrem and 1.8 rem at the 432 meter and 1,100 meter locations, respectively. However, as discussed in response to Question 24 above, the Staff expects that the meteorological assumptions used for the RSAC dissolver product spray leak calculations are similar to those used for the RASCAL uranium separations feed spray release calculations.

For NWMI's RSAC calculations, the Staff did not consider it necessary to request that NWMI provide numerical values of the atmospheric dispersion factors because, based on the preliminary nature of NWMI's design and proposed facility operation, the Staff found that the dose calculation input parameters used by NWMI and provided in the application were reasonably representative of anticipated site conditions and facility operation. Until NWMI provides more detailed information describing the validation of models, codes, assumptions, and approximations used to estimate radiological release consequences as part of its final design in an FSAR, the Staff finds that it is not necessary for NWMI to provide a dose calculation model that necessarily predicts worst-case values such as the design basis dose consequence values for similar close-in, short-term accident evaluations such as those performed for nuclear power plants. As discussed in response to Question 25 above and in SER section 13.4.9, the Staff's independent verification of NWMI's preliminary dose calculations enabled the Staff to conclude that there is reasonable assurance that the applicant will develop appropriate models to estimate dose consequences as the design of the facility matures. The Staff will perform a more thorough analysis of NWMI's dose calculations as part of its review of an NWMI OL application.

27. 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).

Staff Response: Section 20.1301 establishes dose limits for individual members of the public as a result of normal operations. As described in PSAR section 11.1.2, the NWMI production facility will be designed such that under normal operating conditions a member of the public would receive a dose within the 0.1-rem limit in 10 C.F.R. § 20.1301(a). SER section 13.4.3, on the other hand, discusses dose to the public from an accident scenario. The regulations do not require that an evaluation show that acute doses resulting from an accident scenario remain within the 0.1-rem dose limit described in 10 C.F.R. § 20.1301(a). Therefore, NWMI would not need to seek NRC authorization to operate its facility 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).

The standards in 10 C.F.R. § 20.1301 protect members of the public against ionizing radiation received from the normal operation of an NRC-licensed facility by establishing annual dose limits. These dose limits do not apply to emergency or accident conditions. For nuclear power plants and testing facilities licensed under 10 C.F.R. Part 50, accident dose reference values are described for individuals located at the boundary of the reactor exclusion area in 10 C.F.R. § 50.34(a)(1)(ii)(D) and 10 C.F.R. Part 100, respectively. For facilities other than nuclear power plants or testing facilities licensed under 10 C.F.R. Part 50 (e.g., research reactors and radioisotope production facilities), no accident dose reference values have been established by regulation (see 10 C.F.R. § 50.34(a)(1)(i)). In the absence of such reference values for certain non-power production or utilization facilities, the Staff developed guidance establishing accident dose criteria to inform the facility design and accident analysis for the prevention and mitigation of acute radioactive releases. As described in NUREG-1537, Part 1, Chapter 6, the Staff has generally evaluated acute radioactive releases resulting from emergency or accident conditions at research reactors against the occupational and public dose limits in 10 C.F.R. §§ 20.1201 and 20.1301, respectively.

As described in the ISG Augmenting NUREG-1537, Part 1, section 13b, the Staff has determined that applicants for radioisotope production facilities to be licensed under 10 C.F.R. Part 50 may propose alternate accident assessment methodologies and consequence criteria to account for the design and operational differences between reactors and production facilities. For example, the Staff has determined that the use of ISA methodologies as described in 10 C.F.R. Part 70 Subpart H and NUREG-1520, “Standard Review Plan for Fuel Cycle Facilities License Applications”; application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 C.F.R. § 70.61; designation of IROFs; and establishment of management measures are an acceptable way of demonstrating adequate safety at radioisotope production facilities. The performance requirements in 10 C.F.R. § 70.61 ensure that the risk of each credible high- and intermediate-consequence accident sequence is limited through the implementation of engineered or administrative controls and the use of management measures to reduce the likelihood or consequences (e.g., dose) of the event. The acceptability of the risk of a credible accident sequence is determined based on the severity of the consequence level and the likelihood of occurrence.

As stated in PSAR section 1.2.2, NWMI intends to design its facility such that “[p]otential doses to workers and the public from postulated accident[s] are within the limits of 10 C.F.R. §§ 20.1201 and 10 C.F.R. § 20.1301, respectively.” With respect to offsite dose consequences, NWMI intends to select IROFS and appropriate management measures based on the results of its ISA and consideration of 10 C.F.R. § 70.61 performance requirements to mitigate potential radioactive releases resulting from accident conditions. As described in PSAR

section 13.2, and consistent with 10 C.F.R. § 20.1301(d), such releases would be mitigated to an acute dose limit of 0.5 rem for an individual member of the public.

In order to determine whether a construction permit should be issued, the Staff reviewed the sufficiency of NWMI's accident analysis methodology, as presented in PSAR Chapter 13.0. Specifically, the Staff's review focused on whether NWMI's use of an ISA methodology adequately addressed the systems and operating characteristics of the NWMI production facility that could affect safe operation or shutdown. Additionally, the Staff evaluated whether PSAR Chapter 13.0 and the ISA Summary demonstrated that the applicant used the ISA methodology to appropriately identify limiting accidents, analyze the evolution of the scenarios, evaluate event consequences, and identify preliminary IROFS. In SER section 13.4.1 (at 13-8), the Staff concluded that the ISA processes presented by NWMI demonstrated an adequate basis for a preliminary design and satisfied the applicable acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, section 13b.1.

In light of the preliminary nature of NWMI's current facility accident analysis and the use of ISA methodologies, the Staff acknowledges that NWMI may, consistent with the NRC's regulations and guidance, ultimately decide to meet the performance objectives of 10 C.F.R. § 70.61 to demonstrate the safety of the facility under accident conditions rather than the dose criteria of 10 C.F.R. § 20.1201 and 10 C.F.R. § 20.1301 applicable to normal operations. In its review of an NWMI OL application, the Staff will verify that NWMI's use of the ISA methodologies; evaluation of accident sequences; selection of engineered and administrative controls; and choice of dose and consequence limits demonstrate acceptable radiological and chemical risks to the public health and safety under accident conditions.

28. 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 C.F.R. § 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 C.F.R. § 20.1301(d).

Staff Response: As described in response to Question 27 above and as described in PSAR sections 1.2.2 and 13.2, NWMI intends to select IROFS, such as IROFS RS-03 and IROFS RS-09, and appropriate management measures based on the results of its ISA to mitigate potential radioactive releases resulting from accident conditions to be within the normal operational dose limits of 10 C.F.R. § 20.1301(d) (i.e., 0.5 rem). Additionally, the Staff acknowledges that NWMI may, consistent with the NRC's regulations and guidance, ultimately decide to meet the performance objectives of 10 C.F.R. § 70.61 to demonstrate adequate safety of the facility under accident conditions. In its review of an NWMI OL application and FSAR, the

Staff will verify that NWMI's use of the ISA methodology; evaluation of accident sequences; selection of engineered and administrative controls; and choice of dose and consequence limits demonstrate acceptable radiological and chemical risks to the public health and safety under accident conditions. Therefore, the mitigated dose for the target dissolution off-gas release accident could exceed 0.1 rem. However, since there are no regulatory requirements that acute doses resulting from postulated accident conditions identified by NWMI remain within the 0.1-rem normal operational dose limit described in 10 C.F.R. § 20.1301(a), NWMI would not need to seek NRC authorization to operate its facility 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).

29. 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 C.F.R. § 50.40(a)). If the Staff determines that NWMI 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 NWMI will comply with 10 C.F.R. 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?

Staff Response: As described in PSAR section 11.1.2, the NWMI production facility will be designed such that under normal operating conditions a member of the public would receive a dose within the 0.1-rem limit in 10 C.F.R. § 20.1301(a). As such, the Staff does not anticipate that NWMI will need to obtain NRC authorization to operate up to an annual dose limit under normal operating conditions of 0.5 rem under 10 C.F.R. § 20.1301(d). Therefore, as stated in SER section 1.2, the Staff found that issuance of the construction permit would be consistent with 10 C.F.R. Part 20, as required by 10 C.F.R. § 50.40(a).

The standards in 10 C.F.R. Part 20 protect workers and members of the public against ionizing radiation received from normal operation of an NRC-licensed facility by establishing annual dose limits. These dose limits do not apply to emergency or accident conditions. Since there are no regulatory requirements that acute doses resulting from postulated accident conditions identified by NWMI remain within the 0.1-rem dose operational limit described in 10 C.F.R. § 20.1301(a), NWMI would not need to seek NRC authorization to operate its facility up to an annual dose limit for an individual member of the public of 0.5 rem for any analyzed accidents. In its review of an NWMI OL application, the Staff will verify that NWMI's use of the ISA methodology; evaluation of accident sequences; selection of engineered and administrative controls; and choice of dose and consequence limits demonstrate acceptable radiological and chemical risks to the public health and safety under accident conditions.

30. 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 C.F.R. 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 C.F.R. 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 C.F.R. 70.61. The safety measures are designated as IROFS.

(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 NWMI 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.

Staff Response: As explained in response to Question 27 above, the NWMI accident dose consequences are not required to be evaluated against 10 C.F.R. § 20.1301. As part of its review of the construction permit application, the Staff considered the mitigated accident dose criteria against the dose limits in 10 C.F.R. § 20.1301, as committed to by NWMI in PSAR sections 1.2.2 and 13.2 and as described in PSAR sections 13.1.1.1 and 13.3, and consistent with guidance in the ISG Augmenting NUREG-1537, Part 1, section 13b. The Staff also considered the 10 C.F.R. § 70.61 performance requirements related to soluble uranium intake and acute chemical exposures in its evaluation of NWMI's accident analysis. However, the Staff acknowledges that NWMI may, consistent with the NRC's regulations and guidance, ultimately decide to meet the performance objectives of 10 C.F.R. § 70.61 to demonstrate the safety of the facility under postulated accident conditions rather than the normal operations dose criteria of 10 C.F.R. § 20.1201 and 10 C.F.R. § 20.1301. In its review of an NWMI OL application and FSAR, the Staff will verify that NWMI's use of the ISA methodology; evaluation of accident sequences; selection of engineered and administrative controls; and choice of dose and consequence limits demonstrate acceptable radiological and chemical risks to the public health and safety under accident conditions.

31. 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?

Staff Response: Yes. There could be IROFS that would not be translated into limiting conditions for operation (LCOs) in NWMI's technical specifications, but would, instead, be translated into safety limits, limiting safety system settings, limiting control settings, surveillance requirements, administrative controls, or design features in NWMI's technical specifications.

Pursuant to 10 C.F.R. § 50.34(a)(5), a construction permit applicant need only identify probable subjects of technical specifications, with special attention to those items which may significantly influence the final design. The ISG Augmenting NUREG-1537, Part 2, section 14b states that

the technical specifications for a radioisotope production facility are acceptable if, in part, the technical specifications include a list of all IROFS for all processes involving special nuclear material, radioisotopes, and hazardous chemicals that prevent or mitigate accident consequences. As described in SER section 14.4, the Staff found that NWMI satisfied these provisions by identifying probable subjects of technical specifications in PSAR Table 14-1. Per 10 C.F.R. § 50.34(b)(6), the Staff will review NWMI's proposed technical specifications, including the translation of IROFS into technical specifications, during the review of an NWMI OL application.

32. 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 activities listed in SER section 1.1.6 (items 1-3) do not contain completion dates. Were dates provided by NWMI?

Staff Response: No, NWMI has not provided completion dates for items 1-3 in SER section 1.1.6. However, the NRC staff is tracking these activities as regulatory commitments in Appendix A, section A.5 (at A-37) and will verify their resolution as part of its construction inspection program and review of an OL application.

As stated in PSAR section 1.3.4 (at 1-36):

> The RPF does not include experimental facility SSCs that require research and development (R&D) to:
>
> - Confirm the adequacy of the facility design
> - Identify and describe the R&D program that will [be] completed to resolve any safety questions associated with such SSCs
> - Schedule the R&D program to show that such safety questions will be resolved at or before the latest date stated in the application for completion of construction of the facility.

33. 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 (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). Do high shrink/swell soils or over excavation of the site pose an increased risk for sinkholes or other geologic hazards?

Staff Response: Yes, in part, as over excavation could affect existing sinkholes. In particular, over excavation and removal of existing site soils would have the potential to alter ground loading, drainage, and other subsurface conditions such that any unidentified sinkholes and similar karst features may be adversely affected. However, the mere presence of high shrink/swell (expansive) soils does not foretell the potential for sinkholes or other features associated with karst topography to exist beneath the site, or to develop in the future. The expansive or plastic clay soils mapped at the site are the product of materials that were transported to and redeposited at the site by natural processes, rather than solely originating from the weathering of the existing site surficial materials and bedrock. Sinkholes and other karst features develop over long periods of time due to the dissolution of carbonate bedrock at depth. Therefore, there is no direct connection between site soils and the nature of the bedrock underlying the site. As the Staff indicates in FEIS section 4.3.2 (at 4-13), and section 4.4.2.1 (at 4-18), the completion of site-specific geotechnical and hydrological studies proposed by the applicant would identify any karst features or related hazards and necessary mitigation measures to support final facility design and construction.

34. 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)" (FEIS at 3-34).

Has the Staff evaluated NWMI's statement?

Staff Response: Yes, the Staff has evaluated NWMI's statement. NWMI provided this statement in response to one of the Staff's two requests for additional information to confirm the depth to perched groundwater or water-table conditions beneath the site (ADAMS Accession Nos. ML15328A071 and ML16053A205). In its later response (ADAMS Accession No. ML16053A205), NWMI offered its own observations and interpretations of the findings presented in a 2011 Preliminary Geotechnical Engineering Report of the Discovery Ridge Research Park prepared for the University of Missouri by Terracon Consultants, Inc. (Terracon) (ADAMS Accession No. ML15328A080) and concluded that "with the high water content of soil and clay near the site surface (24 and 34 percent, respectively), water could have seeped into the hole during the drilling process and was not noticed by the well logger." Specifically, NWMI provided its interpretation of an east-west cross-section it had prepared based on four of Terracon's bore holes to conclude that water observed in the bore holes likely was not perched but that the water observed was introduced during drilling. NWMI further stated that site-specific geotechnical and hydrological studies will better resolve such issues, a position which the Staff reiterated in FEIS section 4.3.1 (at 4-13), and section 4.4.2.1 (at 4-18 and 4-19). While NWMI presents a reasonable explanation, it also remains possible that the water observed by Terracon was the result of perched groundwater. Further, the introduction of water from the

surface into the borings was not among the observations or conclusions offered by Terracon in its report to account for the observed water in the subsurface.

In its 2011 report, Terracon initially raised the issue of the possible presence of perched groundwater conditions across the Discovery Ridge property, stating that sandy zones in the glacial soils in the area of the site can contain water of "variable quality and quantity." As part of its environmental review, the Staff reviewed this report, including the boring logs contained in the report. The presence of water as observed in the two borings completed by Terracon personnel circumstantially supports the presence of either a perched groundwater condition in the upper subsurface or a seasonally high water table. The results from the preliminary survey do not conclusively establish current site-specific subsurface conditions at the proposed NWMI site. This is because there is uncertainty due to the limited scope of the study performed by Terracon, including the number of borings completed, the short period of time allowed by Terracon for observations to be made for the presence of water until the borings were abandoned, and the conditions under which the borings were drilled.

After reviewing NWMI's statement and the Terracon report, the Staff concluded that the presence of perched groundwater or seasonally high water-table conditions should be further evaluated by NWMI prior to construction. As stated in the concluding paragraph of FEIS section 3.4.2.1 (at 3-34), available site characterization data suggests that any lenses or pockets of perched groundwater underlying the Discovery Ridge site are likely to be of limited lateral and horizontal extent.

35. 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?

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

Staff Response: As noted in the Draft Record of Decision prepared by the Staff (ADAMS Accession No. ML17313A338), by letter dated September 15, 2017 (ADAMS Accession No. ML17268A303), the Missouri Department of Natural Resources (MoDNR) issued a Clean Water Act section 401 water quality certification for the NWMI production facility. The 401 certification includes several conditions relating to NWMI's compliance with applicable provisions of the Clean Water Act including permitting and compliance with applicable water quality standards. In light of the issuance of the 401 certification, there are no other environmental permits required prior to final NRC action on the construction permit application.

What is the status of other environmental permits that NWMI must still secure?

Staff Response: Table B-4 in Appendix B of the FEIS lists the permits and the status (as of its date of publication) of those permits that NWMI plans to obtain from Federal, State, and local authorities to construct and operate the proposed facility. The Staff expects NWMI to obtain the necessary permits.

36. 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?

Staff Response: As discussed in FEIS section 4.6.3, six Tribes provided input to the Staff regarding the scope of the NWMI environmental review. One of these Tribes asked that its communications be non-public, but requested consulting party status on the NWMI project and asked that a cultural resource survey be conducted. Therefore, as reflected in Appendix C (at C-6 and C-7) and as noted in Table D-2 in Appendix D (at D-6 and D-7) of the FEIS, neither the Tribe's name nor its communications were made publicly available at the request of the sender.

The Staff initially responded to the request by contacting the Tribe via both email and telephone to discuss its request and to better understand any concerns that it may have. The Staff also notified NWMI of the Tribe's cultural resource survey request, which NWMI fulfilled (at its own discretion) by providing the Tribe with the cultural resource survey that NWMI had previously completed in support of its construction permit application.

In conjunction with the distribution of the DEIS, the Staff issued a letter to the Tribe notifying it of the Staff's preliminary determination that no historic properties would be affected by the proposed project, and inviting the Tribe to submit any comments that it may have. In its response, the Tribe indicated that the NRC had fulfilled its NHPA section 106 consultation requirements with respect to the Tribe, and that the Tribe did not anticipate that the proposed project would adversely impact any cultural resources or human remains protected under the NHPA, NEPA, or other Federal or Tribal laws. As a result, the outcome of the consultation request was that the FEIS (at 4-26 and 4-27) maintained the determination that no historic properties would be affected.

37. 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.

Staff Response: If NWMI were to submit an application for an operating license for its proposed 10 C.F.R. Part 50 production facility, the Staff would prepare a supplement to the construction permit FEIS that would document its environmental review of operation of that facility as required by 10 C.F.R. § 51.95(b). Section 51.95(b) directs the Staff to prepare a supplement to the final EIS "on the construction permit for the facility" that updates the environmental review conducted for the issuance of the construction permit. The supplement would only cover matters that differ from the construction permit FEIS or that reflect significant new information concerning matters discussed in the FEIS.

As described in 10 C.F.R. § 51.53(b), an operating license applicant must submit with its application a separate document entitled "Supplement to Applicant's Environmental Report – Operating License Stage." In this supplement, the applicant shall discuss the same matters described in 10 C.F.R. §§ 51.45, 51.51, and 51.52, but only to the extent that they differ from those discussed or reflect new information in addition to that discussed in the final EIS prepared in connection with the construction permit.

As required by 10 C.F.R. § 51.95(b), the Staff would independently evaluate the information provided in the supplemental environmental report to prepare a supplement to the final EIS. In addition, the Staff would conduct its own independent evaluation of any significant new information that has become available since publication of the final EIS. The Staff would follow the environmental review process described in 10 C.F.R. Part 51 in preparing the supplement to the FEIS, including scoping, publishing a draft supplemental EIS, requesting comments on the draft supplemental EIS, updating the supplemental EIS based on public comments received, and publishing a final supplemental EIS.

If NWMI were to submit an application for a license to possess and use special nuclear material for target fabrication and scrap recovery, the requirements of 10 C.F.R. § 70.21(f) would apply to the NWMI 10 C.F.R. Part 70 license application. In accordance with 10 C.F.R. § 70.21(f), an application for a license to possess and use special nuclear material for processing and fuel fabrication, scrap recovery, or conversion of uranium hexafluoride should be accompanied by an environmental report. Section 51.20(b)(7) directs the Staff to prepare an EIS on issuance of a license to possess and use special nuclear material for processing and fuel fabrication, scrap recovery, or conversion of uranium hexafluoride pursuant to 10 C.F.R. Part 70. As stated in SECY-17-0116 (ADAMS Accession No. ML17313A037) (at 18 n.10), because the potential environmental impacts related to target fabrication and scrap recovery activities have been addressed in the 10 C.F.R. Part 50 construction permit FEIS, the Staff expects that a similar approach of supplementing the FEIS, as described above for the environmental review of a 10 C.F.R. Part 50 operating license application, could be adopted to meet its NEPA obligations with respect to the 10 C.F.R. Part 70 application. The supplement would cover matters that differ from the 10 C.F.R. Part 50 construction permit FEIS or that reflect new and significant information concerning matters discussed in the FEIS based on the Staff's independent evaluation of the applicant's environmental report required to accompany the 10 C.F.R. Part 70 license application.

> **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.**

Staff Response: The Staff will conduct a separate environmental review for each license amendment application submitted by research reactor licensees to the NRC. In accordance with 10 C.F.R. § 51.25, the Staff will determine whether the proposed action is of the type listed in 10 C.F.R. § 51.22(c) as being subject to a categorical exclusion or whether an environmental assessment should be prepared in accordance with 10 C.F.R. § 51.21. This determination and the scope of the environmental review would be based upon the proposed activities and actions, such as receipt, handling, and irradiation of LEU targets and/or facility modifications to support irradiation services, described in each license amendment application. The environmental review for each license amendment application will leverage the information and environmental analyses contained in sections 3.10 and 4.13 of the NWMI 10 C.F.R. Part 50 construction permit FEIS. The Staff will identify any new information and environmental impacts relevant to environmental concerns bearing on the proposed irradiation activities that differ from those discussed in the NWMI construction permit FEIS. The appropriate NEPA document for each license amendment application could cover matters that differ from those disclosed in the NWMI construction permit FEIS and could incorporate by reference applicable environmental impacts previously analyzed in the NWMI construction permit FEIS.

38. 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."

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."

On March 1 and September 15, 2017, the NRC Staff notified NWMI that the provisions in these regulations apply to NWMI.

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 C.F.R. Part 70 license?

Staff Response: None. This question was for the applicant only.

39. 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).

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?

Staff Response: Section 70.21(f) states, in relevant part, that "[a]n application for a license to possess and use special nuclear material for processing and fuel fabrication [or] scrap recovery … shall be filed at least 9 months prior to commencement of construction of the plant or facility in which the activity will be conducted…." In these circumstances, where a 10 C.F.R. Part 50 construction permit application has been submitted for the production facility portion of the RPF, the Staff interprets the term "facility" in 10 C.F.R. § 70.21(f) to mean the portion of the RPF in which the target fabrication process is to occur, not the production facility portion of the RPF or the entire RPF. This interpretation acknowledges that NWMI's construction permit would only

authorize construction of the production facility portion of the RPF. If the Staff were to instead interpret the term "facility" to mean the entire RPF, this would create uncertainty as to the authority granted under the 10 C.F.R. Part 50 construction permit because 10 C.F.R. § 70.21(f) includes separate provisions regarding the timing of construction.

NWMI's 10 C.F.R. Part 50 application describes processes that are to occur in separate portions of the RPF building and notes that these processes would be governed by either a 10 C.F.R. Part 50 or a 10 C.F.R. Part 70 license. The majority of the building would house the area where NWMI plans to conduct activities that meet the definition of a 10 C.F.R. § 50.2 production facility (i.e., the processing of irradiated materials in large batches). The 10 C.F.R. Part 50 construction permit would authorize construction of this portion of the RPF. The remainder of the building would house the area where NWMI plans to conduct activities under a 10 C.F.R. Part 70 license (i.e., target fabrication processes that include target fabrication and scrap recovery, processes that are similar to those used in fuel fabrication). The 10 C.F.R. Part 50 construction permit would not authorize construction of this portion of the RPF; instead, the separate requirements of 10 C.F.R. Part 70 would apply to this portion of the RPF.

Construing "facility" as referring to the portion of the facility where target fabrication processes would occur recognizes that the construction permit would be issued under 10 C.F.R. Part 50, not Part 70. Further, it provides regulatory certainty by allowing NWMI to commence construction of the 10 C.F.R. Part 50 production portion of the RPF upon issuance of a construction permit.

> **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?**

Staff Response: If construction work commences on portions of the site where target fabrication activities would occur, the staff's ability to conduct its environmental and safety review of a NWMI 10 C.F.R. Part 70 application to possess and use material for target fabrication processes would not be affected. However, the commencement of construction of the portion of the facility in which the target fabrication process is to occur may be grounds for the denial of a 10 C.F.R. Part 70 application if the requirements of 10 C.F.R. § 70.21(f) and 10 C.F.R. § 70.23(a)(7) are not met. *See Nuclear Fuel Services, Inc.* (Erwin, Tennessee), CLI-03-3, 57 NRC 239, 246-47 (2003). *See also* 10 C.F.R. § 70.23(a)(7) (providing that, before the commencement of construction, the Director of Nuclear Material Safety and Safeguards or his/her designee must conclude "that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values").

> **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?**

Staff Response: The construction permit should not specifically prohibit construction of the portion of the RPF in which the target fabrication process is to occur. The scope of a construction permit is the construction of a 10 C.F.R. Part 50 production facility. Authority to construct a facility for an activity that falls within the activities enumerated in 10 C.F.R. § 70.21(f) and 10 C.F.R. § 70.23(a)(7) is not within the scope of a 10 C.F.R. Part 50 construction permit. Further, the purpose of 10 C.F.R. § 70.21(f) and 10 C.F.R. § 70.23(a)(7) is not to require regulatory approval of the design of a proposed facility, analogous to the requirements for the issuance of a construction permit, but to discourage the commencement of construction before

the completion of the Staff's environmental review. *See NFS*, CLI-03-3, 57 NRC at 246-247 (providing that 10 C.F.R. §§ 51.101(a)(2), 70.21(f), and 70.23(a)(7) discourage, but do not prohibit, construction before completion of the NRC's environmental review). Therefore, the 10 C.F.R. Part 50 construction permit should not contain conditions related to the construction of a facility that is not the subject of the construction permit.

In addition, a specific prohibition in the 10 C.F.R. Part 50 construction permit regarding construction of the portion of the RPF where NWMI plans to conduct target fabrication is not necessary. The provisions regarding the commencement of construction of facilities in which fabrication and scrap recovery activities are to occur are set forth in the NRC's regulations at 10 C.F.R. § 70.21 and § 70.23 and do not need to be restated as conditions in a license or permit. As noted in SECY-17-0116 (at 12 n.7), the Staff informed NWMI of these regulations. See emails from NRC to NWMI (Mar. 1, 2017, and Sept. 15, 2017) (ADAMS Accession Nos. ML17312A989 and ML17313A978, respectively). On December 18, 2017, NWMI submitted a request for an exemption from 10 C.F.R. § 70.21(f) (ADAMS Accession No. ML17362A040).

40. 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.

Staff Response: As discussed in FEIS section 2.7.1.2 (at 2-17), 10 C.F.R. § 61.55 classifies solid low-level radioactive waste as Class A, Class B, Class C, or greater than Class C (GTCC) waste, depending on the types and concentrations of radionuclides in the waste. As also discussed in FEIS section 2.7.1.2 (at 2-17), the radioactive waste generated at the NWMI facility would be Class A, B, or C. The Staff estimates that because of the relatively short half-life of molybdenum-99 (about 66 hours), the quantity of molybdenum-99 in irradiated targets would reach about 83 percent or 97 percent of its maximum level after approximately 1 week or 2 weeks of irradiation, respectively (i.e., after about 2.5 or 5 molybdenum-99 half-lives have passed, respectively). Therefore, the burnup of irradiated targets would be relatively low when they are removed for shipment back to the NWMI facility. The Staff notes that the relatively low burnup of the irradiated targets processed at the NWMI facility will help limit the activity and concentration of medium- to long-lived radionuclides (i.e., radionuclides with half-lives greater than 5 years) that will ultimately be contained in radioactive waste. Since, in accordance with 10 C.F.R. § 61.55, medium- to long-lived radionuclide concentrations primarily determine whether radioactive waste is Class B, Class C, or GTCC, lower concentrations of these radionuclides in waste will ensure that NWMI can dispose of its high-activity waste as Class B or C (NWMI will also produce low-activity waste, which will be Class A). In PSAR sections 11.2.3 and 11.2.3.1 (at 11-39 and 11-40), NWMI states that it will manage waste, and analyze waste samples, to ensure that the waste meets the acceptance criteria of the commercial disposal facility to which the waste will be shipped. The disposal facility that NWMI will use does not accept GTCC waste. Based on the low burnup of the processed targets, and NWMI's plan to manage its waste such that it will meet commercial disposal facility criteria, the Staff found that NWMI's determination that its facility would not produce GTCC waste is reasonable.

41. 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?

Staff Response: Yes, NUREG-0170 (ADAMS Accession No. ML12192A283) assessed the transportation impacts from types of material that are the same as, or are reasonably similar to, the materials that would be transported in connection with the operation of the NWMI facility. As discussed in FEIS section 2.8.1.1 (at 2-20), radioactive material that would be shipped to or from the NWMI facility would include radioactive waste, fresh LEU, unirradiated LEU targets, irradiated LEU targets, molybdenum-99 product solution, and take-back LEU. The assessment in NUREG-0170 included the transportation of radioactive waste; medical radioisotopes (including molybdenum-99); nuclear fuel cycle material, such as fresh and reprocessed LEU, and unirradiated and irradiated reactor fuel; and other materials. Reprocessed LEU is similar to take-back LEU in that both contain small amounts of residual fission products and transuranics, but both pose a radiological hazard that is much lower than that of material such as irradiated reactor fuel or targets. The radioactive material content in unirradiated reactor fuel is also relatively similar to the radioactive material content in unirradiated targets, and both pose a low radiological hazard. Although irradiated targets would contain a higher proportion of short-lived radionuclides than irradiated reactor fuel, which contains a higher proportion of longer-lived radionuclides (because reactor fuel is typically irradiated longer (e.g., for 12-24 months) than the targets and has decayed longer before being transported), both would contain large quantities of fission products posing a significant radiological hazard; both would have a similar form with a fission product boundary (i.e., cladding) containing uranium and fission products; and both would similarly require robust packaging and shielding during highway transportation, in accordance with NRC regulations in 10 C.F.R. Part 71 and Department of Transportation regulations in 49 C.F.R. Subchapter C, that apply to transportation of radioactive material. Based on these similarities, the Staff believes that NUREG-0170 includes a sufficient assessment of the transportation impacts from the types of materials that NWMI will be transporting.

42. 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?

Staff Response: The protective action criteria (PAC)-1, PAC-2, and PAC-3 values for sodium hydroxide (based on the American Industrial Hygiene Association Emergency Response Planning Guidelines) are 0.5 milligrams per cubic meter (mg/m^3), 5 mg/m^3, and 50 mg/m^3, respectively. The Staff evaluated NWMI's assumption that a sodium hydroxide release could cause PAC-2 limits to be exceeded at locations occupied by members of the public and found it to be reasonable. As stated in FEIS section 4.11.2 (at 4-48), for sodium hydroxide, the material at risk (MAR) is 1,900 liters of highly concentrated aqueous solution. The Staff found that this MAR is sufficiently large that a spill of the solution could produce vapors that could cause the PAC-2 value to be exceeded at locations potentially occupied by members of the public.

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?

Staff Response: The Staff also evaluated NWMI's statement 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, and found it to be reasonable. As discussed in FEIS section 4.11.2, the release scenario NWMI assumed for aqueous solutions, such as nitric acid, is a breach in a chemical tank resulting in an unconfined spill and subsequent evaporation. In this scenario, the Staff expects that the vapor concentration in areas near the breached tank, which could potentially be occupied by NWMI facility workers, could be significantly greater than in areas beyond the facility boundary. This is a reasonable assumption because the vapors would be diluted by the facility ventilation system and/or the atmosphere before they reached the location of the maximally exposed offsite individual.

43. 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.

Staff Response: The Staff determined that the two sites examined in the FEIS covered the full spectrum of alternatives, even though both sites are located in relatively close proximity to one another, for two main reasons. First, the spectrum of likely environmental impacts from the proposed action was relatively limited due to the small size of the proposed facility, the limited footprint and excavation required, and the use of county water rather than surface water or ground water resources. Second, both sites had different baseline environmental conditions. The baseline environmental conditions were different because the MURR alternative site had a higher population surrounding the site, currently existing buildings on site, academic facilities surrounding the site, surface water features that flowed nearby, and mature stands of trees adjacent to the site. In contrast, the Discovery Ridge site had been cleared due to past decades of agricultural use and there are no standing buildings on site and no mature trees adjacent to the site. Therefore, examining the relatively limited impacts at two different sites with different baseline conditions allowed the Staff to analyze the potential impacts at two sites that cover the spectrum of possible sites.

The Staff's alternatives analysis is consistent with the ISG Augmenting NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content," (ADAMS Accession No. ML12156A069), section 19.5.2, which states that

"[i]f new construction is proposed, at least one alternative location should be analyzed. Additional sites should be analyzed depending on the context, degree, and intensity of potential impacts." Given the impacts determinations at both the Discovery Ridge and MURR sites (e.g., SMALL for all resources, except SMALL to MODERATE for noise at the MURR site and a potential adverse effect to historic property at the MURR site), in FEIS section 5.2, the Staff determined that one alternative site was reasonable for sound decision making based on the relatively limited environmental impacts due to the small size of the proposed facility, the limited footprint and excavation required, the use of county water rather than surface water or ground water resources, and the absence of high quality habitat at either site.

b. Discuss the specific considerations that led the Staff to determine that NWMI's site selection process was reasonable.

Staff Response: The Staff evaluated the site-selection methodology described in NWMI's Environmental Report and summarized in FEIS section 5.2.1 and concluded that the process for selecting and evaluating alternative sites, including the proposed site at Discovery Ridge, was reasonable because it was consistent with guidelines in NUREG-1537 and the associated ISG. Specifically, the Staff determined that NWMI had followed the guidance in Part 1 of the ISG Augmenting NUREG-1537 by providing information related to the site selection methodology in its Environmental Report and in its responses to the Staff RAIs (in ALT-2, ALT3, ALT2-1, ALT2-2, and ALT2-3, ADAMS Accession No. ML15328A071). Based on the data provided, the Staff was able to follow its environmental standard review plan as described in section 19.5, "Alternatives," of Part 2 of the ISG Augmenting NUREG-1537 (ADAMS Accession No. ML12156A075).

For example, Part 1 of the ISG Augmenting NUREG-1537 lists several specific data needs including that "[t]he applicant should summarize the history and process used to formulate the reasonable alternatives," and that the applicant should:

- Describe the process used to determine reasonable alternatives to the proposed action;
- Describe all alternatives considered;
- Indicate which alternatives were eliminated from further study and which alternatives are described in further detail; and
- Briefly describe any alternatives considered that would reduce or avoid adverse effects.

NWMI provided this information in its Environmental Report and its responses to the Staff RAIs, such as a description of the site selection process used to determine the reasonable alternatives (i.e., following the U.S. Department of Energy's (DOE's) Guidebook to Decision-Making Methods), a description of all four of the alternative sites considered, and a discussion of the two alternative sites that were eliminated from further study (i.e., Oregon State and McClellan Business Park) and the alternative site (i.e., MURR) that was analyzed in detail.

The information NMWI provided was sufficient for the Staff to conduct its review as described in the environmental standard review plan, section 19.5, of Part 2 of the ISG, which states that:

> The reviewer should identify the criteria used in evaluating the reasonableness of the alternatives and explain which alternatives would not be considered for detailed analysis and why. The reviewer should identify the alternatives that would be carried forward for comparison with the proposed action.

FEIS section 5.2.1 (at 5-2 to 5-7) specifically describes the criteria that NWMI used to evaluate and determine reasonable alternatives, discusses which alternatives were eliminated from detailed study and why, and identifies the MURR site as the alternative site carried forward for detailed study.

Therefore, the Staff's ISG provided the specific considerations that led the Staff to determine that NWMI's site selection process was reasonable, including a description of the process, a description of each alternative site considered, and a discussion of the criteria NWMI used to determine which sites were reasonable and evaluated for further study and which sites were eliminated from detailed study.

44. 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.

Staff Response: Section 5.4.1 of the FEIS, "Benefit and Costs of Alternatives," does not compare the cumulative impacts of the two sites because those impacts would occur irrespective of whether the NWMI facility is constructed or operated and would not inform the Staff's consideration of environmental costs from the environmental degradation associated with the proposed action. Instead, FEIS section 5.4.1 compares the direct contributory environmental impacts of the proposed NWMI facility with those that would be associated with the use of an alternative site or alternative technology in accordance with 10 C.F.R. § 51.71(d). Section 51.71(d) states that "the draft environmental impact statement will include a consideration of the economic, technical, and other benefits and costs of the proposed action and alternatives." The Staff also applied the guidance provided in section 19.5.3, "Cost-Benefit Analysis," of Part 2 of the ISG Augmenting NUREG-1537 for the cost-benefit analysis, which identifies how to obtain and review information on the potential costs and benefits of the proposed action and alternatives. The ISG states that the scope of the analysis should include the potential costs and benefits associated with the proposed action and does not specifically state that the cumulative impacts should be included. Rather, the ISG says to describe the costs, such as the environmental degradation, from the proposed action. The cumulative impacts, on the other hand, are other Federal or non-Federal activities that would occur regardless of whether the NWMI facility is constructed and operated. For example, the cumulative impacts to terrestrial and ecological resources would be MODERATE (for both locations) due to runoff from agricultural fields and urban areas and climate change (see FEIS section 4.16.5 [at 4-80]), whereas the incremental contribution from the NWMI facility would be minimal. In order to focus the cost-benefit analysis on the direct environmental degradation from the proposed action, FEIS Table 5-12 (at 5-86) presents a summary of the environmental impacts that would be directly attributable to the construction, operation, and decommissioning of the proposed NWMI facility at the Discovery Ridge site and the MURR alternative site.

Although the cumulative impacts are not directly compared in a table in FEIS section 5.4.1, the cumulative impact analysis of the proposed Discovery Ridge site and the MURR alternative site are presented in FEIS sections 4.14 and 5.2.2.13, respectively. The Staff applied the guidance in sections 19.4.13, "Cumulative Impacts," and 19.5.2, "Environmental Consequences of Alternatives," of Part 2 of the ISG Augmenting NUREG-1537 in developing the analysis and assessment of these cumulative impacts. Specifically, section 19.5.2 states that the Staff should "[d]escribe the impacts in sufficient detail so that reviewers may compare the adverse and beneficial impacts of the alternatives with those of the proposed actions…The impact analyses should include direct, indirect, and cumulative impacts." In accordance with

sections 19.4.13 and 19.5.2 of Part 2 of the ISG Augmenting NUREG-1537, FEIS sections 4.14 and 5.2.2.13 considered the direct, indirect, and cumulative impacts in sufficient detail so that reviewers may compare the adverse and beneficial impacts of the proposed Discovery Ridge site with the MURR alternative site. For example, FEIS Table 4-11 (at 4-66) describes the past, present, and reasonably foreseeable future projects and other actions considered within the cumulative analysis for the proposed Discovery Ridge site and FEIS Table 5-5 (at 5-37) provides the same information for the MURR alternative site. Similarly, the Staff analyzed the level of cumulative impacts for 12 resource areas at the proposed Discovery Ridge site and for the same 12 resource areas at the MURR alternative site. The cumulative impacts for each resource area would be the same at both sites, except for accidents, where the cumulative impacts would be SMALL to MODERATE at the MURR alternative site, and SMALL at the Discovery Ridge site. Therefore, the Staff conducted similar cumulative impact analyses at both the proposed and alternative sites such that the information provided in FEIS sections 4.14 and 5.2.2.13 allows for a comparison between the two sites, as described in the ISG, even though that comparison is not provided in a side-by-side table.

In FEIS section 5.5 (at 5-88), the Staff determined that the environmentally preferable site would be Discovery Ridge because the MURR alternative would entail potentially greater impacts (i.e., impacts from noise for constructing the NWMI facility at the MURR site would be SMALL to MODERATE, and adverse effects to historic properties could also occur). If the Staff were to explicitly compare the cumulative impacts between the proposed Discovery Ridge site and the MURR alternative site, the conclusion regarding the environmentally preferred site (i.e. the proposed Discovery Ridge site) would not change, because the cumulative impacts would be greater at the MURR alternative site as compared to the proposed Discovery Ridge site (i.e., the cumulative impacts for accidents would be SMALL to MODERATE at the MURR alternative site, and SMALL at the Discovery Ridge site).

45. 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?

Staff Response: As described in FEIS section 5.2.1.2 (at 5-3), NWMI's weighted ranking of the 10 criteria used in its secondary screening of potential sites was informed by NWMI's business plan.

Specifically, NWMI weighted each criterion based on its relative importance in terms of NWMI's business plan. Criteria that were most important to NWMI's business plan received the highest weight and those least important to the business plan received the lowest weight. The specific rationale for the weight for each of the criteria was provided in NWMI's Environmental Report, NWMI's responses to RAIs, and was summarized in FEIS section 5.2.1.2 (at 5-3 to 5-6) as follows:

1. *Political and Local Logistic Support (Weight = 10):* This criteria was very important to NWMI's business plan because local support depends on regional politics, and the importance to local economic development will likely play a large role in the financial success of the company.
2. *Facility Operations (Weight = 10):* This criteria was very important to NWMI's business plan because NWMI's sole responsibility for operations and for the building design is important to prevent logistical complications.

3. *Production Logistics (Weight = 10):* This criteria was very important to NWMI's business plan because minimizing transportation time, and the associated (Mo-99) decay, is critical to ensure that NWMI delivers the maximum amount of product to the distributor.
4. *Transportation (Weight = 8):* This criteria was important to NWMI's business plan because longer transportation routes would likely be more costly because of the longer transportation time, especially with inclement weather delays.
5. *Radioactive, Hazardous, and Mixed Secondary Waste Generation (Weight = 8):* This criteria was important to NWMI's business plan because the proposed facility must comply with Federal, State, and local radioactive and hazardous waste requirements, which may have various impacts on NWMI's business plan based on the State and/or locality.
6. *Federal, State, County, and Local Requirements (Weight = 5):* NWMI determined that differences in State, county, and local environmental permitting requirements could influence the initial start date for operations, which could in turn affect NWMI's business plan.
7. *Federal and State Taxes and Incentives (Weight = 3):* This criterion could have some impact on NWMI's business plan because State and local taxes, employment hiring credits, and incentives may slightly differ among locations, which could affect the cost of construction, equipment, and operations.
8. *Available Space (Weight =3):* NWMI assigned available space a low weight because all four sites have the minimum amount of space required for the production facility, but differences in the available space could influence NWMI's ability for future expansion and the complexity of construction activities.
9. *Construction Costs (Weight =2):* NWMI assigned construction costs a low weight because local labor rates, materials costs, and the current site condition could have a small influence on the total construction cost, and concomitantly a small impact on the business plan.
10. *Natural or Human-Made Disaster Potential (Weight =1):* NWMI assigned this criterion a low weight because each site is adjacent or close to an existing reactor, which was likely sited in an area with low potential for natural or human-made disasters.

46. 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?

Staff Response: Yes. As stated in FEIS section 5.0 (at 5-1), the Staff considered both "context" and "intensity," as defined in the CEQ regulations at 40 C.F.R. § 1508.27, including the potential duration and extent when assessing the impacts of site alternatives.

The Staff reviewed the information provided in NWMI's Environmental Report and responses to RAIs; received from other Federal, State, and local agencies; provided in scoping comments; and gathered during the visits to the proposed and alternative sites to identify potential projects and activities to be considered in the impacts analysis. The Staff then determined whether the project would occur within the noted geographic areas of interest and within the NWMI facility's proposed 30-year operating period, whether it was reasonably foreseeable, and whether there would be potential spatial and temporal overlapping effects with the proposed project, in

accordance with section 19.4.13, "Cumulative Impacts," of Part 2 of the ISG Augmenting NUREG 1537. FEIS Tables 4-11 (at 4-66) and 5-5 (at 5-37) list the past, present, and reasonably-foreseeable future projects and other actions identified by the Staff and considered in the impacts analysis for the Discovery Ridge and MURR sites, respectively. Although the effects of past actions were generally included in the description of the affected environment, past actions that would continue to have an overlapping effect on a resource potentially affected by the proposed action were also carried forward in the analysis.

The duration and extent of impacts were considered on a resource-specific basis for the proposed and the alternative site. For example, in FEIS section 4.14.2 (at 4-72 to 4-73), the Staff addresses the potential short- and long-term effects on both local and regional air quality relative to the proposed Discovery Ridge site. Similarly, in FEIS section 5.2.2.13 (at 5-40 to 5-41), the Staff addresses these factors relative to the MURR alternative site.

47. 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.

Staff Response: In the FEIS, the Staff stated, in part, that "[the] increase in tax revenue may have a noticeable effect in the ROI. [h]owever, given the small number of workers, overall tax revenue impacts in the ROI during operations would be SMALL" (FEIS at 4-29). The Staff's use of the term "noticeable" in this context was not intended to indicate that the Staff thought that this impact should have been designated as MODERATE. Instead, the Staff concluded that the impacts of the anticipated increase in tax revenue for the proposed NWMI facility during operations would be SMALL because the estimated total tax revenue generated during NWMI facility operations would be small when compared to the total amount of tax revenue collected from other businesses and development interests in the ROI. For instance, the total annual tax payment from NWMI (approximately $2.5 million) would comprise less than 1 percent of the City of Columbia's total tax revenue in 2015 (approximately $325 million). Additionally, NWMI would only have a small number of employees. Therefore, although the additional tax revenue could contribute toward public infrastructure improvements in the City of Columbia, Boone County, or Columbia Public Schools, or toward city, county, or school employee salaries and benefits, the Staff believes that, overall, it would not be sufficient to noticeably alter these socioeconomic conditions.

48. 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?

Staff Response: The Staff did not receive any comments on the DEIS that resulted in significant revisions to the FEIS or that led the Staff to rethink its approach. However, the EIS was revised in response to comments provided by the U.S. Environmental Protection Agency (EPA) and the Sierra Club. Appendix A, section A.2, of the FEIS provides the EPA and Sierra Club comments and the Staff responses to these comments.

EPA comments led the Staff to revise the EIS as follows: (1) clarify that krypton-85, metastable xenon-131, and xenon-133 are the primary radionuclides of interest in the gaseous effluent from

a public dose standpoint in section 2.7.1.1 (at 2-15); (2) clarify that only Class A (low activity concentration) radioactive waste would be handled and stored in the detached waste management building, and no processing of waste would be performed in that building so any activity available for release would be limited in section 2.8.1.1 (at 2-20); (3) clarify that the Staff will perform a detailed review of potential accidents related to target irradiation at the research reactor facilities as part of its review of the research reactor license amendment requests, and that, if the consequences of potential accidents remain below 10 C.F.R. Part 20 dose limits, then no significant additional environmental impact is expected from accidents at the research reactor facilities in sections 4.13.1.2 (at 4-57), 4.13.2.2 (at 4-61), and 4.13.3.2 (at 4-64); and (4) clarify that the existing research reactor accident dose analyses (for previously evaluated accidents, not related to target irradiation) are not discussed in section 3.10 because activities related to target irradiation at the research reactors are not anticipated to result in significant changes in impacts of potential research reactor accidents in section 3.10 (at 3-67).

The Sierra Club comments led the Staff to revise the EIS as follows: (1) the description of the Gans Creek Recreation Area in section 4.14 was added to sections 3.1.1.3 (at 3-4) and 3.5.4.5 (at 3-47); (2) a discussion of native grasses within Rock Bridge Memorial State Park was added to section 3.5.4.5 (at 3-46 to 3-47); and (3) a discussion of ecological features (i.e., the cherrystone snail and the Topeka shiner) within the Three Creeks Conservation Area was added to section 3.5.4.5 (at 3-47).

49. 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 C.F.R. 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?

Staff Response: No, the conditional conclusions stated in the FEIS for human health and accidents are accurate, and no changes to the FEIS are needed now that the Staff has completed the SER.

Based on NWMI's discussion of its radiation protection program in PSAR sections 11.1.2, 11.1.3.2, and 11.1.5.5.3, the Staff expects that the NWMI production facility will be designed such that under normal operating conditions, the maximum doses to workers and members of the public would be within the limits in 10 C.F.R. § 20.1201(a) and § 20.1301(a), respectively. With regard to accident consequences, as described in PSAR section 1.2.2, NWMI intends to design its facility such that "[p]otential doses to workers and the public from postulated accident[s] are within the limits of 10 CFR 20.1201 and 10 CFR 20.1301, respectively." Chemical accident consequences would be mitigated consistent with the performance requirements of 10 C.F.R. § 70.61. NWMI intends to select IROFS and appropriate management measures based on the results of its integrated safety analysis to mitigate potential radioactive and chemical consequences resulting from accident conditions. Therefore, because the Staff concluded in its SER that NWMI would comply with applicable NRC regulations regarding the radiological impacts from normal operation, and the radiological and chemical consequences from potential accident conditions at its proposed facility, no changes are needed in the FEIS.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE COMMISSION

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

CERTIFICATE OF SERVICE

Pursuant to 10 C.F.R. § 2.305, I hereby certify that copies of the foregoing "NRC STAFF RESPONSES TO COMMISSION PRE-HEARING QUESTIONS," dated January 2, 2018, have been served upon the Electronic Information Exchange, the NRC's E-Filing System, in the above-captioned proceeding, this 2nd day of January, 2018.

/Signed (electronically) by/

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Dated at Rockville, Maryland
this 2nd day of January, 2018