September 29, 2016

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

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

Dear Ms. Haass:

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

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

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

This RAI supplements the NRC's previous RAI related to the NWMI Environmental Report and construction permit application sent by letters dated November 2, 2015, January 19, 2015, March 28, 2016, and June16, 2016 (ADAMS Accession Nos. ML15288A102, ML16020A366, ML16056A122, and ML16152A019 respectively). The specific information requested is addressed in the enclosure to this letter. These RAIs were discussed with you on September 20, 2016, and a mutually agreeable date for NWMI response is within 60 days from the date of this letter. Timely responses to RAIs contribute toward an efficient and effective review of the application.

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

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

Sincerely,

/RA/

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

Docket No. 50-609

Enclosure:
As stated

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

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Enclosure:
As stated

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ADAMS Accession No.: ML16236A013 *concurrence via e-mail NRR-088

OFFICE	NRR/DPR/PRLB/PM	NRR/DPR/PRLB/LA*	NRR/DPR/PRLB/BC	NRR/DPR/PRLB/PM
NAME	MBalazik	NParker (ABaxter for) w/comments	AAdams	MBalazik
DATE	9/20/2016	8/26/2016	9/30/2016	9/29/2016

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REQUEST FOR ADDITIONAL INFORMATION

NORTHWEST MEDICAL ISOTOPES, LLC.

REGARDING PRELIMINARY SAFETY ANALYSIS REPORT

CONSTRUCTION PERMIT APPLICATION

DOCKET NO. 50-609

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

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

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

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

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

- NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors" (ADAMS Accession No. ML062190191)

- Regulatory Guide 2.5, Revision 1, "Quality Assurance Program Requirements for Research and Test Reactors," dated June 2010 (ADAMS Accession No. ML093520099)

- ANSI/ANS-I5.8-1995 (R2013), "Quality Assurance Program Requirements for Research Reactors

GENERAL INFORMATION REQUEST

RAI G-2 Section 50.33(h) of 10 CFR Part 50 states that "If the applicant, other than an applicant for a combined license, proposes to construct or alter a production or utilization facility, the application shall state the earliest and latest dates for completion of the construction or alteration."

In "General Information In Accordance With 10 CFR 50.33" of the introduction section of the CP application, NWMI states that it "expects to complete construction of the facility at earliest and latest by the second quarter 2016 and fourth quarter of 2017, respectively."

NWMI's earliest and latest dates for construction completion are not consistent with the CP application review schedule the NRC staff provided to NWMI on March 28, 2016 (ADAMS Accession No. ML16056A122) or the timing of a Commission decision.

Provide revised earliest and latest dates that NWMI expects to complete construction of the facility.

RAI G-3 NUREG-1537, Part 2, Chapter 13, as augmented by the ISG, is applicable to reviewing a description of the accident analyses for the licensing of a radioisotope production facility and a non-power reactor facility. Whenever the term "reactor" appears, it is understood to mean a "non-power reactor facility," a "radioisotope production facility," or both as applicable.

NUREG-1537, Part 2, Chapter 13, "Accident Analyses," Acceptance Criteria, states that:

> For a research reactor, the results of the accident analysis have generally been compared with 10 CFR Part 20 criteria (10 CFR 20.1 through 20.602 and appendices for research reactors licensed before January 1, 1994, and 10 CFR 20.1001 through 20.2402 and appendices for research reactors licensed on or after January 1, 1994). . . . for research reactors licensed on or after January 1, 1994, occupational exposure is discussed in 10 CFR 20.1201 and public exposure is discussed in 10 CFR 20.1301. In several instances, the staff has accepted very conservative accident analysis with results greater than the 10 CFR Part 20 dose limits discussed above.

The ISG Augmenting NUREG-1537, Part 2, Chapter 13, "Accident Analyses," Section 13b.1.2, "Accident Initiating Events," states that among other considerations, the reviewer should confirm several items including: (a) instruments, controls, and automatic protective systems were assumed to be operating normally or to be operable before the initiating event; (b) maximum acceptable non-conservative instrument error may be assumed to

exist at accident initiation; (c) credit was taken during the scenario for normally operating process systems; and (d) protective actions were initiated by either the operating staff, control systems, or engineered safety features.

As stated in Chapter 13b, “Radioisotope Production Facility Accident Analyses,” of the ISG Augmenting NUREG-1537, Part 1, the NRC staff has determined that the use of Integrated Safety Analysis methodologies as described in 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material,” and NUREG-1520, “Standard Review Plan for Fuel Cycle Facilities License Applications,” as well as application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of items relied on for safety, and establishment of management measures, are acceptable ways of demonstrating adequate safety for the radioisotopes production facility. Applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequences and likelihood criteria, alternate safety features, and alternate methods of assuring availability and reliability of the safety features.

NWMI PSAR Section 13.2.1, “Maximum Hypothetical Accident,” provides a description and analyses of the maximum hypothetical accident (MHA) at the NWMI facility. The PSAR states that the event is not credible and assumes that the off-gas treatment system that releases all radioiodine and noble gas radioisotopes retained in that system from the radioisotopes production facility stack without mitigation. Additionally, the PSAR states that the dose consequences from the event are within the intermediate consequence level as defined in 10 CFR 70.61, “Performance requirements.”

PSAR Section 13.2.1 contains a mix of MHA and 10 CFR 70.61 methodologies. It is not apparent which accident analysis philosophy is being used for the RPF. The accident analysis in PSAR Section 13.2.1 makes overly conservative assumptions relative to the accident analysis methodology that was discussed in ISG Augmenting NUREG-1537, Part 1, Chapter 13b that was derived from NUREG-1520, “Standard Review Plan for Fuel Cycle Facilities License Applications,” for fuel facilities, or the methodology that has been applied for non-power reactors. For example, the MHA analyses assumes that safety systems, such as, the offgas dissolver train and mitigating offgas treatment are not functional (note that the items relied on for safety (IROFS) is called Primary Offgas Release System). Furthermore, the MHA dose acceptance criteria used by NWMI is significantly greater than the requirements of 10 CFR Part 20 which are generally applied to the MHA for non-power reactors.

Demonstrate that the MHA in PSAR Section 13.2.1, including the items stated in the ISG Augmenting NUREG-1537, Part 2, Section 13b.1.1, such as appropriately functioning instruments, controls, automatic protective systems normally operating process systems and protective actions initiated by either the operating staff, control systems, or engineered safety features meets the generally accepted dose requirements of 10 CFR Part 20.

Otherwise, provide an accident analysis that is either consistent with the requirements of 10 CFR 70.61 (e.g., application of items relied upon for safety to prevent or mitigate the event) or propose an alternate methodology.

RAI G-4 Subparagraph 50.35(a)(1) of 10 CFR Part 50 requires that the applicant describe the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and identifies the major features or components incorporated therein for the protection of the health and safety of the public.

NWMI PSAR Section 3.5.1.3.1, "Safety-Related Structures, Systems, and Components," describes those structures, systems and components (SSCs) that are relied on to remain functional during normal conditions and during and after design-basis events (DBEs) will ensure that acute chemicals exposures to an individual produced from licensed material or hazardous chemicals will not lead to:

- Irreversible or other serious, long lasting health effects to workers
- Mild transient health effects to individuals located outside [radiological production facility] RPF [radiologically controlled area] RCA

It is not clear in the PSAR if the SSCs will protect for high consequences which could lead to endangerment of the life of a worker and/or lead to irreversible or other long lasting health effects to individual outside the controlled area.

Provide additional information explaining why the SSCs will be designed to protect against intermediate consequences, and not for high consequences.

CHAPTER 2.0 – SITE CHARACTERISTICS

The following RAIs on this chapter are based on the NRC staff review of Chapter 2.0 of the NWMI PSAR (ADAMS Accession Nos. ML15210A113 and ML15210A116) using NUREG-1537, Parts 1 and 2, in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

Section 2.2 – Nearby Industrial, Transportation, and Military Facilities

RAI 2.2-1 NUREG-1537, Part 1, Section 2.2.2, "Air Traffic," states that factors such as frequency and type of aircraft movement, flight pattern, local meteorology, and topography should be considered for sites located within 8 kilometers of an existing or projected commercial or military airport and that the analysis should demonstrate that there is a low potential that any aircraft could affect the [RPF] reactor or that the consequences from any aircraft-associated accident are already bounded or considered in the accident analysis.

NWMI PSAR Section 2.2.2.1, "Airports," describes three helicopter ports (University Hospitals, Missouri University (MU), and Clinics heliports) within 8 km of the radioisotope production facility (RPF), and two small private airports (Cedar Creek Airport and Sugar Branch Airport) within 16 km of the RPF site. The $200d^2$ calculation uses a shorter distance of 10.4 km than the stated in the first paragraph of 10.5 km. NWMI does not provide an analysis of possible effects to the RPF to evaluate any potential radiological risks to the facility staff, the public, and the environment. This information is needed to determine the potential radiological risks, if any, to the facility staff, the public, and the environment resulting from aircraft-associated accidents

a. Provide an analysis that demonstrates the risk to be low potential from hazards posed by activities associated with the referenced heliports and airports; or how the RPF design can accommodate any possible hazards associated with these heliports and airports and impact with the facility.

b. Justify using 10.4 km in the $200d^2$ calculation when the distance to the Columbia Regional Airport to the RPF site is stated as 10.5 km.

RAI 2.2-2 NUREG-1537, Part 1, Section 2.2.3, "Analysis of Potential Accidents at Facilities," states that if a facility (i.e., nearby industrial, transportation, or military facility) "cannot affect the [RPF], the applicant should make a statement to that effect and give the basis for this statement."

Furthermore, NUREG-1537, Part 2, Section 2.2, "Nearby Industrial, Transportation, and Military Facilities," states, in part, that the review:

> …should confirm that any hazards to the [RPF] facility posed by normal operations and potential malfunctions and accidents at nearby manmade stationary facilities…have been described and analyzed to the extent necessary to evaluate the potential

radiological risks to the facility staff, the public, and the environment.

NWMI PSAR Section 2.2.3.1.3, "Flammable Vapor Clouds (Delayed Ignition)," Table 2-19, "Flammable Vapor Clouds and Vapor Cloud Explosion from External Sources," does not include the acceptable distance for diesel at MU South Farm.

PSAR Section 2.2.3.1.2, "Nearby Facilities," Table 2-17 and Table 2-19 only considers a portion of the total amounts of gasoline and diesel storage at the Magellan Facility, and the propane at MU South Farm, to determine the acceptable distance of peak positive incident overpressure of 6.9 kPa (1 lb/in^2). NWMI indicates that an analysis accounting for the total amount of gasoline and diesel stored at the Magellan facility yields a minimum separation distances (i.e., safe standoff distances) greater than its current location to the RPF. Such scenario may pose a risk to the RPF since the location of those tanks are closer than the safe standoff distance. It presents the same potential risk for an analysis accounting for the total amount of propane stored at MU South Farm facility. The PSAR seems to only consider the acceptable distance to the largest tank of gasoline, diesel, or propane, at these nearby facilities which is significantly less than the total inventory. Therefore, additional information is needed for the NRC staff to determine that potential accidents at nearby facilities would not pose sufficient risk to the RPF to render the site unsuitable for construction and operation and to understand the potential radiological risks, if any, to the facility staff, the public, and the environment, resulting from accidents at nearby facilities.

a. Clarify whether the assumptions in PSAR Section 2.2.3.1, "Determination of Design-Basis Events," bound any other possible explosion scenario, such as the explosion of the total inventory at nearby facilities that could potentially affect RPF operations or safe shutdown.

a. Provide the acceptable distance for diesel at MU South Farm and describe potential effects in the RPF, if any.

Section 2.3 – Meteorology

RAI 2.3-1 NUREG-1537, Part 2, Section 2.1, "Geography and Demography," states, in part, that "as part of this review, the reviewer should check the exclusion area distances against distances used in analysis presented in Chapter 11 and 13 of the SAR [safety analysis report]."

NWMI PSAR Section 2.3.2, "Site Meteorology," states, in part, that "conservative assumptions were used, in both the Radiological Safety Analysis Computer code to support 10 CFR 100.11, "Determination of Exclusion Area, Low Population Zone, and Population Center distance." However, the exclusion area is not specifically described in this Section 2.1 or in Chapter 11 and 13 of the PSAR.

Confirm that the exclusion area boundary is what is described in Chapter 11 of the PSAR as the "controlled area." If not the same, describe the exclusion area boundary for the RPF.

RAI 2.3-2 NUREG-1537, Part 1, Section 2.3.1, "General and Local Climate," states that historical seasonal and annual frequencies of severe weather phenomena, including hurricanes, tornadoes, waterspouts, thunderstorms, lightning, and hail, should be stated. The applicant should give the known and maximum annual frequency of occurrence and time duration of freezing rain (ice storms) and dust (sand) storms where applicable. The applicant should estimate the 100-year return wind speed.

NWMI PSAR, Section 2.3.1.7, "Extreme Weather," states that the RPF location area exhibits significant atmospheric instability, heavy precipitation, and many intense thunderstorms and is located in a tornado prone area, but did not provide annual frequencies of severe weather phenomena. This information is needed to determine if a weather-related event of credible frequency or consequences at the site render it unsuitable for operation, as designed, and likely to cause damage to the RPF facility during its lifetime that could release uncontrolled radioactive material to the unrestricted area.

a. Provide the seasonal and annual frequencies of tornadoes, thunderstorms, lighting, and hail.

b. Provide the maximum annual frequency of occurrence and time duration of freezing rain and discuss the potential effects of these meteorological events on the RPF.

Section 2.5 – Geology, Seismology, and Geotechnical Engineering

(Applies to RAIs 2.5-1 through 2.5-5)

NUREG-1537, Part 1, Section 2.5, "Geology, Seismology and Geotechnical Engineering," states that the applicant should detail the seismic and geologic characteristics of the site and region surrounding the site. The degree of detail and extent of considerations should be commensurate with the potential consequences.

NUREG-1537, Part 1, Section 2.5.2, "Site Geology," states that the applicant should discuss in detail the structural geology at the facility site and should pay particular attention to specific structural units of significance to the site such as folds, faults, synclines, anticlines, domes and basins.

In Sections 2.5.3, "Seismicity," 2.5.4, "Maximum Earthquake Potential," 2.5.5, "Vibratory Ground Motion," 2.5.6, "Surface Faulting," and 2.5.7, "Liquefaction Potential," the NUREG states, in part, that:

> The applicant should list all historically recorded earthquakes….of Modified Mercalli intensity of greater than IV or magnitude (Richter) greater than 3.0…[in the list]...the applicant should evaluate the largest earthquake that could occur… and isoseismal maps for the earthquakes should be presented" … the applicant should assess the ground motion at the site from the maximum potential earthquakes…and the applicant should establish the vibratory ground motion design spectrum [and] the applicant should discuss soil structure and prepare an appropriate state-of-the–art analysis for liquefaction at the site.

NUREG-1537, Part 2, Section 2.5 further states the review should confirm that the information presented has been obtained from sources of adequate credibility and is consistent with other available data such as the final safety analysis report (FSAR) of a nearby nuclear power plant."

RAI 2.5-1 NWMI PSAR Section 2.5.1.3, "Local Topography and Soils of Boone County," states that several areas of the county contain well developed cave and sinkhole formations. PSAR, Section 2.5.2.3, "Mississippian Age Osagean Series Burlington Formation," references a report by Terracon Consultants, Inc. (Terracon) that states that "no caves or sinkholes are known to exist, or are published to exist within approximately 1 mile of [this project site] … However, several areas of known karst activity are present …"

a. Confirm by reference or investigation that no new sinkhole formations have developed at the project site since the Terracon preliminary report was issued in 2011.

b. Clarify and identify measures to be taken to preclude potentially detrimental effects of sinkhole formations on the foundations in the future.

RAI 2.5-2 NWMI PSAR Section 2.5.2.1, "Quaternary Age Holocene Series (Qal)," states, in part, that "highly plastic clays that exhibit volume change with variations in moisture are commonly encountered near the ground surface (Terracon 2011)." This statement is repeated three times in this PSAR section. Additional information is needed to preclude adverse effects of this phenomenon on structural foundations

Clarify any measures to be taken to preclude adverse effects of this phenomenon on the structural foundations.

RAI 2.5-3 NWMI PSAR Section 2.5.3, "Onsite Soil Types," states that:

> Soils with moisture levels above their measured plastic limits may be prone to rutting and can develop unstable sub-grade conditions during general construction operations (Terracon 2011).
> Moderate to high plasticity clays were observed at the site. Such soils are commonly referred to as "expansive" or "swelling soils"…
> Footings, floor slabs, and pavements supported on expansive soil often shift upward or downward causing possible distortions, cracking or structural damage.

Additional information is needed on measures to prevent potential structural damage of the foundation from occurring as a result of these clays.

Clarify any measures to be taken to preclude these potential adverse effects on the structural foundations from occurring.

RAI 2.5-4 NWMI PSAR Section 2.5.4, "Seismicity," presents a listing of recorded earthquakes with a magnitude equal to or larger than 3.0 in Table 2-28, "Recorded Missouri Earthquake History," as required by NUREG-1537, Part 1, Section 2.5.3, "Seismicity." The last listed earthquake, with magnitude 4.6, occurred in 2002.

Clarify that there were no other recorded earthquakes of magnitude 3.0 or larger between 2002 and 2016, and if there were, update the table.

RAI 2.5-5 NWMI PSAR Section 2.5.6, "Vibratory Ground Motion," states that the seismic design parameters for the proposed project are discussed in terms of the 2012 International Building Code (IBC) and associated standards. Later discussions in this section refer to the 2009 IBC and American Society of Civil Engineers (ASCE) 7-05, without any explanation. Additional information is needed to resolve this apparent discrepancy between IBC 2012 and IBC 2009.

Provide justification for this change from IBC 2012 to IBC 2009.

RAI 2.5-6 NUREG 1537, Part 2, Section 2.5 "Geology, Seismology and Geotechnical Engineering" states that "the information on potential seismic effect should be in a form suitable for developing design basis in Chapter 3 for the SSCs, and…..this information presented should be obtained from sources of adequate credibility, and is consistent with other available data, such as data from the USGS or in the FSAR of a nearby nuclear power plant."

NWMI PSAR Section 2.5.6, "Vibratory Ground Motion," states that "for MU facilities the 2012 IBC has been levied as the required building code. Therefore, the seismic design parameters for the proposed project are discussed in terms of the 2012 IBC and associated standards."

However, the University of Missouri Research Reactor (MURR) and Callaway Nuclear Plant, which is in the proximity of the RPF site, adapted the seismic response spectra provided by NRC Regulatory Guide 1.60, "Design Response Spectra for Seismic Design of Nuclear Power Plants," and adjusted to reflect the ground acceleration response of 0.2 g.

NWMI PSAR Section 2.5.5, "Maximum Earthquake Potential," states that Boone County would be severely impacted by a 7.6 magnitude earthquake with the epicenter on or near the New Madrid Seismic Zone, with an estimated intensity of VII at the site, as shown on Table 2-29, "Projected Earthquake Hazards for Boone County." Information is needed to justify that the RPF design and its seismic input parameters are adequate to prevent and mitigate any radiological releases below the 10 CFR Part 20 limits in the event of a postulated earthquake.

a. Provide an estimated maximum ground acceleration at the site, corresponding to this intensity VII earthquake.

b. Justify that the RPF and its seismic parameters are designed to prevent and mitigate any radiological releases below the 10 CFR Part 20 limits in the event of an earthquake.

RAI 2.5-7 NUREG-1537, Part 1, Section 2.5.5, "Vibratory Ground Motion," states that the applicant should assess the ground motion at the site from the maximum potential earthquakes associated with each tectonic province and should consider any site amplification effects. Using the results, the applicant should establish the vibratory ground motion design spectrum.

The vibratory ground motion design spectrum was not provided in the NWMI PSAR, Section 2.5.6, "Vibratory Ground Motion." Information on the vibratory ground motion is needed to assess the adequacy of the ground motion at the RPF site.

Provide the vibratory ground motion design spectrum in PSAR Section 2.5.6.

RAI 2.5-8 Section 50.9, "Completeness and accuracy of information," of 10 CFR Part 50 requires that information submitted, or information required to be maintained by the applicant be complete and accurate in all material respects.

NWMI PSAR Section 2.5.6, states that the Boone County site is a soil Site Class D site. Later in Section 3.4.1.1, "Design Response Spectra" states that the Phase 1 Assessment (Terracon, 2011 a/b) the site is referred to as Class C.

Clarify if the RPF site is a soil Site Class C or D, and correct any discrepancies.

RAI 2.5-9 NUREG 1537, Part 1, Section 2.5.7, "Liquefaction Potential," pertains to the evaluation of soil structure, and states, in part, that:

> If the foundation materials at the site adjacent to and under safety-related structures are saturated soils or soils that have a potential for becoming saturated, the applicant should prepare an appropriate state-of-the-art analysis of the potential for liquefaction at the site. The applicant should also determine the method of analysis on the basis of actual site conditions, the properties of the facilities, and the earthquake and seismic design requirements for the protection of the public.

NUREG-1537, Part 2, Section 2.5, "Geology, Seismology and Geotechnical Engineering," instructs the review to confirm that the information on the geologic features and the potential seismic activity at the site have been provided in sufficient detail and in a form to be integrated acceptably into design bases for structures, systems and operating characteristics of the facility.

NWMI PSAR Section 2.5.8, "Liquefaction Potential," provides information based on preliminary investigations of the RPF site by Terracon, and concludes that the available data is insufficient and contradictory and the liquefaction potential cannot be conclusively determined. It also states that additional geotechnical analysis will be conducted at the RPF site to determine the liquefaction potential of the soils on site. Information is needed to understand if this is part of ongoing research and development (10 CFR 50.34(8)) or will be provided in the FSAR.

Provide the timeframe for the performance of these additional state-of-the-art geotechnical investigations and analyses.

CHAPTER 3.0 – DESIGN OF STRUCTURES, SYSTEMS, AND COMPONENTS

The following RAIs are based on the NRC staff review of Chapter 3 of the NWMI PSAR (ADAMS Accession No. ML15210A117) using NUREG-1537 Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

Section 3.2 – Meteorological Damage

(Applies to RAIs 3.2-1 through 3.2-4)

NUREG-1537, Part 1, Section 3.2, "Meteorological Damage," states that:

> The design criteria should provide reasonable assurance that potential meteorological damage would not significantly affect designed structures, systems and components (i.e., they would continue to perform necessary operational and safety functions).

NUREG-1537, Part 2, Section 3.2, "Meteorological Damage," instructs the review to:

> Examine the description of the site meteorology to ensure that all structures, systems and components that could suffer meteorological damage are considered in this section of the SAR…The reviewer should compare design specifications for structures, systems and components with the functional requirements and capability to retain function throughout the predicted meteorological conditions and…the design to protect against meteorological damage provides reasonable assurance that the facility…will perform the safety functions discussed in this SAR…and to protect the health and safety of the public from radioactive materials and radioactive exposure.

RAI 3.2-1 NWMI PSAR Section 3.2.3.1.3, "Live Loads," and Table 3-13, "Floor Live Loads," listed that the uniform and concentrated loads for the hot cell roof and cover block laydown are to be determined.

These live loads may have effect on the global response of the structure and on the design and sizing of the affected structural members.

If the actual magnitude of these loads is not available at the preliminary design stages, confirm that either conservative estimated loads are used to account for their effects, or the design will be revisited when the loads are available at a later stage, before the designs are finalized.

RAI 3.2-2 NWMI PSAR Section 3.1.3, "U.S. Nuclear Regulatory Commission," states that:

> Table 3-3 lists the NRC design inputs for the RPF identified in NWMI-DRD-2013-030. The RPF system design descriptions identify the specific requirements for that system produced by each applicable reference." PSAR Table 3-3, "Relevant U.S. Nuclear Regulatory Commission Guidance," includes Regulatory Guide 1.76, "Design-Basis Tornado and Tornado Missiles for Nuclear Power Plants, 2007" (Revision 1).

PSAR Section 3.1.7, "Codes and Standards," states that:

> Table 3-7 lists design inputs for the RPF identified in NWMI-DRD-2013-030. The RPF system design descriptions identify the specific requirements for that system produced by each applicable reference.

PSAR Table 3.7, "Design Codes and Standards," includes ANSI/ANS-2.3, "Estimating Tornado, Hurricane, and Extreme Straight Line Wind Characteristics as [at] Nuclear Facility Sites, 2011."

PSAR Section 3.2.4.2, "Tornado Loading," states that:

> To date, the NRC has not endorsed the 2011 revision of American National Standards Institute (ANSI)/American Nuclear Society (ANS) 2.3, *Estimating Tornado, Hurricane, and Extreme Straight Line Wind Characteristics at Nuclear Facility Sites,* for use in design of power reactors. However, considering that the RPF is a production facility as opposed to a power reactor, and the wind field characteristics given in ANSI/ANS 2.3 are more consistent with the target performance goals, the tornado load requirements for the RPF design are based on NUREG-1520 and ANSI/ANS 2.3.

However, the Forward to ANSI/ANS 2.3-2011 states, that:

> This standard is a revision to ANSI/ANS 2.3-1983, "Standard for Estimating Tornado and Extreme Wind Characteristics at Nuclear Power Sites." The revision of the 1983 standard began in May of 2005. In this revision, the scope of the standard was expanded to include hurricane wind characteristics. A change to the Fujita damage scale as a function of wind velocities, adopted in 2007 by the National Weather Service, resulted in the wind speeds associated with the Fujita damage scale being replaced by the Enhanced Fujita Scale as shown in Table 1. Also included in the scope expansion is the applicability of this standard to all nuclear facility sites, not just nuclear power plant sites.

ANSI/ANS 2.3-2011 applies the same criteria to nuclear facilities whether a production facility or a power reactor.

PSAR Section 3.2.4.2, “Tornado Loading,” describes the design basis for tornado winds, atmospheric pressure drop, and tornado-generated missile impact effects.

The NRC staff identified that the information provided in Tables 3-16, “Tornado Wind Field Characteristics,” and 3-17, “Tornado Wind-Driven Missile Criteria,” differs from the data provided in Regulatory Guide 1.76, “Design-Basis Tornado and Tornado Missiles for Nuclear Power Plants,” Revision 1, for the tornado wind velocities, atmospheric pressure drop, tornado-generated missile velocities, and the altitude of automobile missile strikes.

The cited ANSI/ANS 2.3-2011, “Estimating Tornado, Hurricane and Extreme Straight Line Wind Characteristics at Nuclear Facility Sites,” has not yet been endorsed by the NRC, and the referenced NUREG-1520, “Standard Review Plan for Fuel Cycle Facilities License Applications,” states that the tornado occurrence probability be quantified by the applicant. NUREG-1520, Part 3 Appendix D states, “…depending on the geographic location of the facility the effects of a tornado with an annual exceedance probability of 10^{-5} or greater may need to be considered.”

Since the PSAR identified Regulatory Guide 1.76, Revision 1, as a design input to the RPF and because ANSI/ANS 2.3-2011 has not been accepted by the NRC, justify the use of tornado effect parameters which are less conservative than those provided in Regulatory Guide 1.76, Revision 1.

RAI 3.2-3 NWMI PSAR Section 3.2.3.1.1, “Dead Loads,” states, in part, that the “dead loads consist of the weight of all materials of construction … [and] also consist of the weight of fixed equipment, including the weight of cranes.” It is not apparent that the weight and loading from other sub-systems were included in the dead load.

This information is needed to confirm that adequate uniform loading is included in the dead load to account for the piping, cable trays/cable, conduits, heating, ventilation and air conditioning (HVAC) duct and appurtenances tubing, etc. weights in the global structural analysis and the design and sizing of the structural elements.

Confirm that adequate uniform loading is included in the dead load to account for the piping and other sub-systems (i.e., cable trays, conduits, HVAC ductwork and components, tubing) weight and loadings in the design and sizing of the structural elements.

Section 3.3 – Water Damage

RAI 3.3-1 NUREG-1537, Part 1, Section 3.3, "Water Damage," states, in part, that:

> …the applicant should specifically describe the proposed site and facility designs to protect against water damage of the structures, systems and components assumed to function in the SAR. This should include…and (3) the impact on equipment, such as fans, motors, and valves resulting from degradation of the electromechanical function due to water.

NUREG-1537, Part 1, Section 3.3, "Water Damage" states, in part, that:

> …(2) the impact on systems resulting from instrumentation and control electrical and or mechanical malfunction due to water, and (3) the impact on equipment, such as fans, motors and valves resulting from degradation of electromechanical function due to water.

NUREG-1537, Part 2, Section 3.3, "Water Damage," states that the areas of review include the design and design bases for all structures, systems, and components that could be affected by predicted hydrological conditions at site, and states that:

> The design criteria and designs should provide reasonable assurance that structures, systems and components would continue to perform required safety function under water damage conditions. For the design the applicant should use local building codes, as applicable to help ensure that water damage to structures, systems and components at the facility site would not cause or allow uncontrolled release of radioactive material.

NWMI PSAR Sections 3.3.1, "Flood Protection," and 3.3.1.1, "Flood Protection Measures for Structures, Systems, and Components," refer to PSAR Section 2.5.3, "Onsite Soil Types," for additional information on flood protection measures. Section 2.5.3 of the PSAR does not contain this information.

Provide the correct reference in the PSAR for additional detail for flood protection measures.

RAI 3.3-2 NUREG-1537, Part 1, Section 3.3, states, in part, that:

> ...(2) the impact on systems resulting from instrumentation and control electrical or mechanical malfunction due to water, and (3) the impact on equipment, such as fans, motors, and valves, resulting from degradation of the electromechanical function due

to water.

NUREG-1537, Part 2, Section 3.3, states, in part, that:

> the design criteria and designs should provide reasonable assurance that structures, systems, and components would continue to perform required safety functions under water damage conditions … for the design the applicant should use local building codes, as applicable, to help ensure that water damage to structures, systems, and components at the facility site would not cause unsafe reactor operation, would not prevent safe reactor shutdown, and would not cause or allow uncontrolled release of radioactive material.

NWMI PSAR Section 3.3 discusses water damage and Sections 3.3.1.3 and 3.3.1.4.1 deal with flooding due to malfunction of the Fire Protection System, but the NRC staff could not find a discussion of the effects of discharge of the Fire Protection System on structures, systems and components.

This information is needed to determine the adequacy of the measures to be taken for the protection of sensitive safety-related components under the effects of inadvertent discharge of the Fire Protection System sprinklers or rupture of the non-seismic fire protection piping as a result of the postulated seismic event.

Provide information discussing measures to be taken for the protection of sensitive safety-related equipment under the effects of inadvertent discharge of the Fire Protection System water.

Section 3.4 – Seismic Damage

RAI 3.4-1 NUREG-1537, Part 1, Section 3.4, “Seismic Damage,” states, in part, that the applicant should specify and describe structures, systems and components that are required to maintain the necessary safety function if a seismic event should occur. The reactor facility seismic design should provide reasonable assurance that the reactor could be shut down and maintained in a safe condition. To verify that seismic design functions are met, the applicant should give the bases for technical specifications necessary to ensure operability, testing, and inspection of associated systems, including instrumentation and control portions, as applicable.

NUREG-1537, Part 2, Section 3.4, “Seismic Damage,” states that the review should include the designs and design bases of structures, systems, and components that are required to maintain function in case of a seismic event at the facility site. The finding required is that the facility design should provide reasonable assurance that the RPF can be shut down and maintained in a safe condition.

NUREG-1537, Part 2, Section 2.5, "Geology, Seismology and Geotechnical Engineering," states, in part, that the information has been obtained from sources of adequate credibility and is consistent with other available data, such as data from the USGS or in the FSAR of a nearby nuclear power plant.

NWMI PSAR Section 3.4.1.1, "Design Response Spectra Safe-Shutdown Earthquake," states that:

> The safe-shutdown earthquake … for the RFP facility is specified as risk-targeted maximum considered earthquake (MCE_R), as determined in accordance with ASCE 7 and the Federal Emergency Management Agency (FEMA) P-753, *NEHRP Recommended Seismic Provisions for new Buildings and Other Structures*. The MCE_R for this site is governed by the by the probabilistic maximum-considered earthquake ground shaking, which has an annual frequency of exceedance of $4x10^{-4}$.

MURR and Callaway Nuclear Plant which is in the proximity of the RPF site, adapted the seismic response spectra provided by NRC Regulatory Guide 1.60, "Design Response Spectra for Seismic Design of Nuclear Power Plants," and adjusted to reflect the ground acceleration response of 0.2 g.

Provide justification for not using Regulatory Guide 1.60 spectra adjusted to reflect maximum ground acceleration of 0.2 g for the safe-shutdown earthquake.

(Applies to RAIs 3.4-2 through 3.4-9)

NUREG-1537, Part 2, Section 2.5, "Geology, Seismology and Geotechnical Engineering," states, in part, that "the information on potential seismic effects should be in a form suitable for developing design bases in Chapter 3 for structures, systems and components."

RAI 3.4-2 NWMI PSAR Section 2.5.6, "Vibratory Ground Motion," states that "The Boone County site is a soil site Class D. When modified for a Class D site…the site coefficients Fa and Fv, Sms, and Sml values of 0.341 and 0.223 respectively (Fa=1.6 and Fv=2.4) are obtained."

PSAR Section 3.4.1.1, "Design Response Spectra," in Table 3-22, "Safe-Shutdown Earthquake Criteria," contains different parameters based on soil site Class C.

a. Resolve the inconsistency and update Table 3-22 for site Class D properties, and demonstrate that a correct value was used in the evaluations.

b. Provide justification for the statement that, "This safe-shutdown earthquake spectrum is 5% damped which, per ASCE 43 is appropriate

for the design of the structural systems to be used for the Radioisotope Production Facility (RPF)."

RAI 3.4-3 NWMI PSAR Section 3.4.1.1, "Design Response Spectra Safe-Shutdown Earthquake," Figure 3.1, "Safe-Shutdown Earthquake Response Spectrum," presents the suggested spectrum at five-percent damping.

Provide a discussion that justifies that the identified response spectrum after the adjustments made for Class D site (as discussed in RAI 3.4-2) is adequately representing the ground response accelerations for an Intensity VII earthquake, established in PSAR Section 2.5.5, Table 2-29, "Projected Earthquake Hazards for Boone County," for the RPF site.

RAI 3.4-4 NWMI PSAR Section 3.4.1.2.1, "Equivalent-Static Seismic Analysis," under "Direction of Seismic Loading," states that "the seismic forces are applied independently in two orthogonal horizontal directions and the effects combined using the 100/30 rule. Vertical seismic effects will be accounted for by the use of seismic load combinations set forth in ASCE 7, Sections 12.4.2.3 and 12.4.3.2."

a. Provide a discussion that justifies why the simultaneous application of three directional earthquake effects are not considered.

b. Provide a discussion that justifies why the effects are not combined per Regulatory Guide 1.92, "Combining Modal Responses and Spatial Components in Seismic Response Analysis," using either the square-root-of-sum-of-the squares, or 100-40-40 methodology.

RAI 3.4-5 NWMI PSAR Section 3.4.1.1, "Design Response Spectra – Soil-Structure Interaction and Dynamic Soil Pressures," states that a fixed base model is expected to give conservative results in comparison to accounting for the effects of soil-structure interaction.

However, for a relatively short RPF structure with large plan dimensions, a fixed base model may not accurately represent the dynamic characteristics and the structural response, where the rocking mode may be predominant and significant.

Provide additional justification for the use of fixed base mathematical model for this relatively short facility with a relatively large foot print, where the rocking mode may be predominant in facility response.

RAI 3.4-6 NWMI PSAR Section 3.4.2, "Seismic Qualification of Subsystems and Equipment," describes various qualification methods in PSAR Sections 3.4.2.1, "Qualification by Analysis," and 3.4.2.2, "Qualification by Testing."

Many components whose continued operability/functionality during and after the postulated seismic events cannot be demonstrated by analytical means, require actual shake-table (or other dynamic) testing to be seismically qualified.

Clarify if NWMI's purchase specifications will specify the qualification method to be used, or will it be left to the vendor's discretion.

RAI 3.4-7 NWMI PSAR Section 3.4.2.1.2, "Dynamic Analysis," describes various methods for seismic qualification of subsystems and equipment and cites ASCE 4, "Seismic Analysis of Safety-Related Nuclear Structures and Commentary, 2000" and the NRC Regulatory Guide 1.122, "Development of Floor Design Response Spectra for Seismic Design of Floor Supported Equipment or Components."

ASCE 4 discusses Time History Method and Direct-Spectra-to-Spectra method for the development of in-structure response spectra, while Regulatory Guide 1.122 only covers Time History method.

Clarify which method of in-structure response development is used for the RPF, and if it is the Time History Method which option of ASCE 4 will be used.

RAI 3.4-8 NWMI PSAR Section 3.4.2.2, "Qualification by Testing," states that subsystems and equipment not relied on for nuclear safety but designed as a component of a seismic system per IBC 2012, Chapter 17, will be required to be seismically qualified in accordance with ICC-ES- ACI 156, "Acceptance Criteria for Seismic Certification by Shake-Table Testing of None-structural Components.

However, it is not stated what measures are to be taken to preclude gross failure of the Seismic Category II or Non-Seismic SSCs during postulated seismic events from damaging the safety-related SSCs (generally referred to as Seismic II/I considerations), or detrimental "banging" effects on safety-related SSCs due to the excessive displacements caused by the postulated earthquake.

a. Confirm that the Seismic II/I systems and components whose gross failure may impact the functionality of safety systems and components, are designed to remain stable during and after the postulated earthquake effects.

b. Confirm that a rattle space is established to ensure that the Seismic II/I systems and components cannot damage the safety-related items due to their potentially excessive deformations during the seismic event.

RAI 3.4-9 NWMI PSAR Section 3.4.3, "Seismic Instrumentation," provides a description of the seismic instrumentation provided for the RPF.

However, it does not specify if the seismic instrumentation is considered to be safety-related Seismic Category I, and is purchased as Seismically Qualified system to be able to fulfill the purpose.

Clarify whether the seismic instrumentation will be a safety-related Seismic Category I installation.

Section 3.5 – Systems and Components

(Applies to RAIs 3.5-2 and 3.5-3)

The definition for IROFS is provided in 10 CFR 70.4. The definition states:

> *Items relied on for safety* mean structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at a facility that could exceed the performance requirements in § 70.61 or to mitigate their potential consequences. This does not limit the licensee from identifying additional structures, systems, equipment, components, or activities of personnel (i.e., beyond those in the minimum set necessary for compliance with the performance requirements) as items relied on for safety.

RAI 3.5-2 NWMI PSAR Section 3.5.1.3.1, states that a safety-related SSCs must meet at least one of the following criteria. If they do not, they are considered non-safety-related (NSR). The safety-related criteria are:

- Ensure and safeguard the integrity of the primary system (RPF) boundary
- Provide the capability to prevent or mitigate the consequences of accidents that could result in exposures to workers, the public, or environment that exceed 10 CFR 20 guidelines
- Ensure the potential for an inadvertent criticality accident is not credible
- Ensure that acute chemical exposures to an individual produced from licensed materials or hazardous chemicals will not lead to (1) Irreversible or other serious, long-lasting health effects to workers (2) Mild transient health effects to individuals located outside the RPF RCA
- Prevent intake of 30 milligrams (mg) or more of uranium in soluble form by any individual located outside the RPF RCA

The PSAR proposes a five-part definition of safety-related SSCs, modifies the 10 CFR 50.2 definition of safety-related SSCs to include performance requirements for SSCs important to safety in the RPF. While four of the five parts of this definition are performance-based, the third part of this definition (i.e., “Ensure the

potential for an inadvertent criticality accident is not credible") is not performance-based. The regulations in 10 CFR 70.61 are not a requirement for a production facility, however the NRC staff finds that their use as an accident consequence and likelihood criteria may be found acceptable.

However, 10 CFR 70.61 provides performance requirements for subcriticality. 10 CFR 70.61(d) states:

> In addition to complying with paragraphs (b) and (c) of this section, the risk of nuclear criticality accidents must be limited by assuring that under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of subcriticality for safety. Preventive controls and measures must be the primary means of protection against nuclear criticality accidents.

Provide a performance-based criterion for an inadvertent criticality accident utilizing the criteria of 10 CFR 70.61(d) or explain why the 10 CFR 70.61 performance criteria is not used.

RAI 3.5-3 NWMI PSAR Section 3.5.1.3.3, "Quality Group Classifications for Structures, Systems, and Components," discusses the classification of SSCs. In that discussion, the applicant states that there are three QA Levels.

- QA Level 1 (QL-1) is applied to safety-related SSCs and "implements the full measure of NWMI's QAPP [Quality Assurance Program Plan]."

- QA Level 2 (QL-2) "includes the quality activities performed by NWMI, generally on a continuing basis, that are applied to ensure that the items that are not QA Level 1 are available and reliable to perform their safety functions (when needed). These quality activities include configuration management, maintenance, training and qualifications, procedures, assessments, incident investigations, records management, and other QA elements."

- QA Level 3 (QL-3) is applied to NSR SSCs and is "controlled in accordance with standard commercial practices."

While QL-1 and QL-3 clearly state what SSCs are assigned to these levels and the level of quality assurance applied, this is unclear for QL-2.

From the information provided, it can be inferred that QL-2 does not implement the full measure of NWMI's QAPP and that it is not controlled in accordance with standard commercial practices. Additional information is needed to understand application of QAPP to QL-2.

a. Define and provide the basis for the difference between QL-1 and QL-2.

b. If two SSCs (i.e., pipe, valve, tank, heat exchanger, etc.) must meet the same performance characteristics, but one SSC is governed by QL-1 and the other by QL-2, describe how they will they be physically different.

c. PSAR Table 3-25, “System Safety and Seismic Classification and Associated Quality Level Group,” lists systems that are NSR, Seismic Category II, and QL-2. This infers that only NSR Seismic Category II SSCs are QL-2. If this is the case, state this explicitly, and if this is not the case provide examples of SSCs that are considered QL-2 that are not Seismic Category II.

d. For QL-1 SSCs, clarify whether their associated configuration management, maintenance, training and qualifications, procedures, assessments, incident investigations, records management, etc. are considered QL-1 or QL-2. If considered QL-2, provide justification why they are not controlled under the full measure of NWMI’s QAPP.

RAI 3.5-4 NUREG-1537, Part 2, Section 3.5, “Systems and Components,” Acceptance Criteria, states, in part, that the design criteria should include response to transient and potential accident conditions analyzed in the safety analysis report.

NWMI PSAR Section 3.5.1.3.4 “Seismic Classification for Structures, Systems, and Components,” states that Seismic Category I (C-I) applies to safety-related SSCs, that Seismic Category II (C-II) applies to those NSR SSCs whose structural failure during a safe-shutdown earthquake could degrade the function of safety-related SSCs or impact the main control room, and that SSCs not classified C-I or C-II are classified non-seismic (NS). Since it is not clear what QL-2 encompasses other than the statement that they are not controlled under the "full measure of NWMI’s QAPP," clarification is needed.

a. PSAR Table 3-25, “System Safety and Seismic Classification and Associated Quality Level Group” infers that NSR C-II SSCs are automatically QL-2. Provide the rationale for that QA classification versus the QL-1 classification.

b. Clarify if any NSR C-II SSCs are considered QL-1 or QL-3.

c. Explain the differences in C-I acceptance criteria under QL-1 and the C-II acceptance criteria under QL-2.

d. Since C-II SSCs need only maintain structural integrity, explain if the structural integrity acceptance criteria for C-I SSCs and C-II SSC will be the same or different. If different, provide the basis for the difference.

(Applies to RAIs 3.5-5 and 3.5-6)

In the ISG Augmenting NUREG-1573, Parts 1 and 2, the NRC staff stated, in part, that "addressing the baseline design criteria and defense in depth practices in 10 CFR 70.64 is an acceptable way of demonstrating adequate safety of structures, systems, and components in the design of a radioisotope production facility."

RAI 3.5-5 NWMI PSAR Section 3.5.2.2, "Classification of Systems and Components Important to Safety," discusses SSCs that are considered important to safety. The criteria for important to safety is the five criteria for safety-related SSCs presented in Section 3.5.1.3.1, "Safety-Related Structures, Systems, and Components," and an additional criterion that states:

- Prevent degradation of function and/or performance of any safety-related SSC.

Thus, important to safety encompasses safety-related SSCs and other SSCs that could affect the function/performance of safety-related SSCs. However, NWMI does not provide a classification for important-to-safety SSCs, just the classifications of safety-related and NSR. PSAR, Table 3-25, "System Safety and Seismic Classification and Associated Quality Level Group" associated with PSAR Section 3.5.2.2 delineates systems that are NSR, but also C-II and QL-2. This implies in Section 3.5.2.2 that NSR C-II SSCs are considered important to safety because of their C-II classification. In addition, the term, "important to safety," is not used in Section 3.5.1.3.4, "Seismic Classification for Structures, Systems, and Components," where the C-I, C-II and NS classifications are discussed.

a. Clarify if NSR C-II SSCs are important to safety.

b. Provide examples of NSR NS SSCs that are important to safety.

c. Clarify if all NSR important-to-safety are SSCs QL-2.

d. Provide the basis for not designating NSR SSCs important to safety QL-1.

RAI 3.5-6 NUREG-1537, Part 1, Chapter 9, "Auxiliary Systems," states that the applicant should include the design bases for each auxiliary system.

In cross referencing the design bases in NWMI PSAR Chapter 9.0, "Auxiliary Systems," with those in PSAR Chapter 3.0, "Design of Structures, Systems, and Components," an apparent discrepancy was identified.

PSAR Section 3.5.2, "Radioisotope Production Facility," states that systems and components within the RPF are presented in [PSAR] Section 3.4.1; whereas PSAR Section 3.4.1, "Seismic Input," discusses seismic design considerations.

Since the higher tier PSAR Section 3.5 presents RPF systems and components, this statement is potentially incorrect.

Provide additional information to explain and/or correct this apparent discrepancy in PSAR Section 3.5.2 that states systems and components within the RPF are presented in PSAR Section 3.4.1.

RAI 3.5-7 Subparagraph 50.35(a)(1) of 10 CFR Part 50 requires that the applicant describe the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and identifies major features or components incorporated therein for the protection of the health and safety of the public.

The ISG Augmenting NUREG-1537, Part 2, Section 3.5b, "Radioisotope Production Facility," states that the application should provide the same type of information prescribed in Section 3.5a on the design, construction and operating characteristics of all safety-related systems and components in the radioisotope production facility.

NWMI PSAR Chapter 1, Table 1-12, "Summary of Confinement Engineered Safety Features," identifies several IROFS and/or SSCs associated with the offgas treatment and building ventilation system which play an important role in protecting both the worker and public health and safety. These include the process vessel emergency purge system (IROFS FS-03), the exhaust stack height (IROFS FS-05), and the primary offgas relief system (IROFS RS-09).

The design basis earthquake for the RPF is identified in Section 3.4.1.1 of the PSAR (i.e., earthquake with a 2,500 year return period). The PSAR does not state if this seismic design criteria is also being applied to important components within the structure. The staff needs to understand if these components which NWMI has identified as being important for public health and safety are designed to withstand the same design basis earthquake as the facility structure.

Describe the seismic design criteria for portions of the ventilation and offgas systems that NWMI has identified as IROFS and is relying on to protect workers and the public.

RAI 3.5-8 Subparagraph 50.35(a)(1) of 10 CFR Part 50 requires that the applicant describe the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

The ISG Augmenting NUREG-1537, Part 2, Section 3.5b, states that the application should provide the same type of information prescribed in Section 3.5a on the design, construction and operating characteristics of all safety-related systems and components in the radioisotope production facility.

NWMI PSAR Section 3.1.7, “Codes and Standards, “identifies codes and standards used as guidance for the design of the facility. Included in the list is the American Society for Testing and Materials (ASTM) 1533 Standard Guide for General Design Considerations for Hot Cell Equipment (2008). ASTM 1533 (both the 2008 version and the more recent 2015 version) states in Section 7.13 “The method of hot cell equipment repair should be considered during the design phase.” The application does not discuss design features intended to facilitate maintenance in the remote cells, particularly the tank hot cell.

Describe how NWMI has considered maintenance operations, particularly in the hot cells, when it performed its analysis that identified major features that are incorporated into the design for protection of the health and safety of workers and the public.

RAI 3.5-9 The ISG Augmenting NUREG-1537, Part 1, Section 6b.3, “Nuclear Criticality Safety in the Radiological Production Facility,” states, in part, that the license application must propose equipment, facilities, and procedures to ensure that the design provides for criticality control, including adherence to the double-contingency principle. Furthermore, Section 6b.3 of the ISG Augmenting NUREG-1537, Part 1 states, in part, that:

“The applicant should describe a program that ensures compliance with the double-contingency principle, where practicable. Processes in which there are no credible accident scenarios that lead to criticality meet the double-contingency principle by definition. This principle, as given in American National Standards Institute/American Nuclear Society (ANSI/ANS)-8.1-1998, “Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors,” states that at least two changes in process conditions must occur before criticality is possible. If there are no process changes leading to criticality, then the principle is satisfied.”

The ISG Augmenting NUREG-1537, Part 2, Section 6b.3 states that the applicant should describe a program that ensures compliance with the double-contingency principle. Additional details on double-contingency are provide in NUREG-1520, which contains current industry practices on controlled parameters and acceptance criteria. NUREG-1520, Section 3.4.3.2, “Integrated Safety Analysis Summary and Documentation,” states, in part, that if a process is designed, and an IROFS procedure specified, to ensure critical mass control by double-batching proof, the margin from a single batch to the subcritical limit should be specified. Traditionally, the single batch is 45% of the subcritical limit. NUREG-1520, Section 5.4.3.1.7.3, “Evaluation and Implementation of Controlled Parameters”, Subsection 4c, states that when overbatching of special nuclear material (SNM) is credible, the largest mass resulting from a single failure is shown to be subcritical and overbatching beyond double-batching should be considered unless it requires multiple independent failures or is precluded by equipment capacity, availability of material, or other considerations.

NWMI PSAR Chapters 1, 3, 4, and 6 discuss the results of preliminary criticality safety evaluations and the passive design features, active engineering features, and administrative controls necessary for adherence to the double-contingency principle. PSAR Chapters 6 and 13 identify double-batching as a bounding accident. In response to RAI 3.5-1 (ADAMS Accession No. ML16123A119), NWMI states that SSCs will be used to prevent an inadvertent criticality accident and in response to RAI 6.3-5, NWMI commits to maintaining a rigorous nuclear criticality safety program using the double-contingency principle. The PSAR does not specifically address the margin from a single process batch to the subcritical limit nor does it state if overbatching of SNM is credible and whether overbatching beyond double-batching has been considered in the NWMI RPF design.

Additional information is needed for the NRC staff to understand the technical aspects of the criticality safety evaluation and confirm that the acceptance criteria of the ISG Augmenting NUREG-1537 have been met. Specifically, the NRC staff needs to confirm the margin from a single batch to the subcritical limit and whether the margin meets the traditional value of 45%. The NRC staff also needs to understand whether overbatching is credible for the NWMI RPF or is precluded by equipment capacity, availability of material, or other consideration. It is not clear whether the information provided in the PSAR is complete and comprehensive regarding the quantities of fissionable material contained in the process equipment during normal operations.

a. Provide additional detail on the margin from a single process batch to the subcritical limit in all production process equipment and provide an evaluation of overbatching or a reference to such an evaluation.

b. Provide a listing of all areas and process equipment that are expected to contain fissionable material.

c. Provide the maximum quantities (kgs) or concentrations (g/l) of fissionable material possible in all areas or process equipment during normal operations.

d. Provide the bases for the above maximum quantities (numbers and types of targets or SNM in storage or being processed).

e. Provide the quantities (kgs) or concentrations (g/l) of fissionable material used in criticality analyses for all areas or process equipment.

f. Provide a list of references to documents containing criticality analyses for above areas or process equipment.

CHAPTER 5.0 – COOLANT SYSTEMS

The following RAIs are based on the NRC staff review of Chapter 5.0 of the NWMI PSAR (ADAMS Accession No. ML15210A120), using NUREG-1537, Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

Section 5.1 – Summary Description

RAI 5.1-1 The ISG Augmenting NUREG-1537, Part 2, Section 5b, "Radioisotope Production Facility Cooling Systems," states, in part, that "the reviewer should ascertain that the application has provided an adequate analysis to ensure that there is no need for auxiliary cooling during the course of any part of the radioisotope production process." The ISG Augmenting NUREG-1537, Part 1, Section 5b, "Radioisotope Production Facility Cooling Systems," states, in part, that "the license application should consider the decay time allowed after the end of irradiation in the reactor before the separation process progresses."

NWMI PSAR Section 5.1.1, "Irradiated Target Basis," states a minimum decay time for receipt of targets based on the location of the RPF relative to the reactor sites. NWMI, in a public meeting presentation on March 16, 2016 (ADAMS Accession No. ML16153A409), stated that the estimated travel time and distance from the MURR irradiation site and the RPF is 30 minutes and 6 miles. The estimated travel time of 30 minutes is considerably less than the minimum decay time for receipt specified in Section 5.1.1. These targets form the basis of the heat generation rate calculations for evaluating the need for auxiliary cooling.

Additional information is needed for NRC staff to understand the basis of the decay time assumed for MURR targets and that the decay time is conservative for evaluating the need for auxiliary cooling.

Provide additional detail on the minimum decay time allowed after the end of irradiation of MURR targets including how the handling and transportation times have been determined and demonstrate why the minimum decay time for target receipt from MURR is conservative for evaluating the need for auxiliary cooling.

RAI 5.1-2 The ISG Augmenting NUREG-1537, Part 2, Section 5b, "Radioisotope Production Facility Cooling Systems," states, in part, that the reviewer should ascertain that the application has provided an adequate analysis to ensure that there is no need for auxiliary cooling during the course of any part of the radioisotope production process.

NWMI PSAR Section 5.1.1, "Irradiated Target Basis," states, in part, that "The MURR operation is based on irradiating eight targets per week…" and "Therefore, heat load from receipt of MURR targets has been used as an upper bound for irradiated target receipts at the RPF." PSAR Section 4.1.2.1, "Process Design Basis," states that, "The RPF is designed to have a nominal operational processing capability of one batch per week of up to 12 targets from University of

Missouri Research Reactor (MURR)." The nominal operational processing capability of 12 targets per week from MURR as stated in PSAR Section 4.1.2.1 is greater than the 8 targets per week from MURR as stated in PSAR Section 5.1.1 for evaluating the need for auxiliary cooling.

Additional information is needed for NRC staff to understand the upper bound for irradiated target receipts at the RPF as used in the analysis to determine the need for auxiliary cooling.

Resolve the inconsistency between the number of MURR targets (i.e., 8 per week) used for assessing the thermal characteristics of the processing equipment and the number of MURR targets (i.e., 12 per week) used in the RPF facility design basis and demonstrate that 8 targets per week is a conservative design basis for the cooling system evaluation considering that the RPF is designed to have a nominal operational processing capability of up to 12 MURR targets per week.

CHAPTER 6.0 – ENGINEERED SAFETY FEATURES

The following RAIs are based on the NRC staff review of Chapter 6 of the NWMI PSAR (ADAMS Accession No. ML15210A120) using NUREG-1537, Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

Section 6.3 – Nuclear Criticality Safety in the Radioisotope Production Facility

RAI 6.3-8 Section 6.b.3 of the ISG Augmenting NUREG-1537, Part 2, states that the applicant should include a summary description of a documented, reviewed, and approved validation report (by 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) 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, (b) determine the bias and uncertainty in the bias, and (c) determine the upper subcritical limit.

Table 3 and Section 5.1.1 of the Validation Report (NWMI-2014-RPT-006, "MCNP 6.1 Validations with Continuous Energy ENDF/B-VII.1 Cross-Sections," Rev. 0) shows the majority of benchmark experiments to be in the range of 0.005 to 0.1 MeV, which is stated as being in the thermal range. The minimum value of the average neutron energy causing fission (ANECF) for any benchmark is given as 0.0043 MeV, which is considered significantly above the thermal range.

a. Provide the Validation Report (NWMI-2014-RPT-006, "MCNP 6.1 Validations with Continuous Energy ENDF/B-VII.1 Cross-Sections," Rev. 0)

b. Clarify if the units on the ANECF values given in MeV are correct in the validation report.

RAI 6.3-9 Section 6.b.3 of the ISG Augmenting NUREG-1537, Part 2, states that the applicant should include a summary description of a documented, reviewed, and approved validation report (by NCS [nuclear criticality safety] 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) 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, (b) determine the bias and uncertainty in the bias, and (c) determine the upper subcritical limit.

The Validation Report (NWMI-2014-RPT-006, "MCNP 6.1 Validations with Continuous Energy ENDF/B-VII.1 Cross-Sections," Rev. 0) states that the low-enriched uranium (LEU) and intermediate-enriched uranium (IEU) benchmarks only cover the range of 8 – 1611 in H/X, but the Area of Applicability (Table 13) states that the range is covered from 0 – 1400. (The high-enriched uranium

[HEU] cases extend down to H/X of 3, but they are not used in determining the upper subcritical limit and applicability has not been demonstrated.) Since the neutron spectrum is very sensitive to changes in H/X in the low H/X limit, additional information is needed for including the range from 0 – 8 for enrichments occurring at the facility.

Justify including the range of H/X from 0 – 8 in Table 13. If HEU cases are used in making this justification, demonstrate their applicability to your operations

RAI 6.3-10 Section 6.b.3 of the ISG Augmenting NUREG-1537, Part 2, states that the applicant should include a summary description of a documented, reviewed, and approved validation report (by 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) 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, (b) determine the bias and uncertainty in the bias, and (c) determine the upper subcritical limit.

The Validation Report (NWMI-2014-RPT-006, “MCNP 6.1 Validations with Continuous Energy ENDF/B-VII.1 Cross-Sections,” Rev. 0) includes an evaluation of bias in for the criticality evaluation. More information is needed to determine the adequacy of the evaluation.

a. Address the larger negative bias for moderators including hydrogen, reflectors including depleted uranium and labeled “miscellaneous,” and forms including metal and labeled “miscellaneous” (Figures 5, 6, and 7).

b. Justify their inclusion in the area of applicability (Table 13) without additional margin, and clarify what is meant by hydrogen moderator and by miscellaneous reflectors and forms.

RAI 6.3-11 Section 6.b.3 of the ISG Augmenting NUREG-1537, Part 2, states that the applicant should include a summary description of a documented, reviewed, and approved validation report (by 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) 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, (b) determine the bias and uncertainty in the bias, and (c) determine the upper subcritical limit.

The Validation Report (NWMI-2014-RPT-006, “MCNP 6.1 Validations with Continuous Energy ENDF/B-VII.1 Cross-Sections,” Rev. 0) includes a discussion of materials in the area of applicability.

The validation evaluated the bias for certain forms, moderators, and reflectors, but not absorbers. Some of these materials are only present in a small number of cases (e.g., U-ZrH and UO_2SO_4 forms; graphite, concrete, U-238, and BeO reflectors; Cu absorbers), and may not be present across the neutron energy spectrum. Therefore additional information is needed determine whether they should be included in the area of applicability (AOA).

a. Justify inclusion of the various chemical forms and moderating, reflecting, and absorbing materials in the AOA (Table 13).

b. For compounds, elements, and nuclides for which there are few benchmarks available or they do not adequately cover the range in H/X or ANECF, justify their inclusion without additional margin.

RAI 6.3-12 Section 6.b.3 of the ISG Augmenting NUREG-1537, Part 2, states that the applicant should include a summary description of a documented, reviewed, and approved validation report (by 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) 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, (b) determine the bias and uncertainty in the bias, and (c) determine the upper subcritical limit.

The Validation Report (NWMI-2014-RPT-006, "MCNP 6.1 Validations with Continuous Energy ENDF/B-VII.1 Cross-Sections," Rev. 0) includes a discussion of physical parameters in the AOA. Additional information is needed to determine if the range of parameters to be modeled to support the facility design are within the AOA.

a. Describe the physical parameters associated with the anticipated facility design, and compare that to the area of applicability (Table 13).

b. Justify the minimum margin of subcriticality of 0.05.

RAI 6.3-13 Section 6.b.3 of the ISG Augmenting NUREG-1537, Part 2, states that criticality accident evaluations should include accident analyses involving licensed materials and an interpretation of the sequence of events. It is presumed that all criticality accident analyses would assume high consequences; therefore, the applicant should include every credible event that could result in an uncontrolled criticality event.

As part of the evaluation of NWMI application the staff reviewed NWMI-2015-CSE-008, "NWMI Preliminary Criticality Safety Evaluation: Hot Cell Uranium Purification," Revision A. This document provided an evaluation of criticality safety scenarios in the hot cell purification unit. More information is needed to ensure subcriticality under normal and credible abnormal conditions.

a. Provide NWMI-2015-CSE-008, “NWMI Preliminary Criticality Safety Evaluation: Hot Cell Uranium Purification,” Revision A.

b. Justify the determination in Scenario C1 that the volume that could be spilled from the tanks and/or associated equipment and piping would be insufficient to exceed the single parameter limit on slab thickness.

c. Explain why the analysis was limited to a 1cm slab of solution on the hot cell floor.

RAI 6.3-14 Section 6.b.3 of the ISG Augmenting NUREG-1537, Part 2, states that criticality accident evaluations should include accident analyses involving licensed materials and an interpretation of the sequence of events. It is presumed that all criticality accident analyses would assume high consequences; therefore, the applicant should include every credible event that could result in an uncontrolled criticality event.

As part of the evaluation of NWMI application the staff reviewed NWMI-2015-CSE-008, “NWMI Preliminary Criticality Safety Evaluation: Hot Cell Uranium Purification,” Rev. A. This document provided an evaluation of criticality safety scenarios in the hot cell purification unit. Additional information is needed to determine if this analysis ensures that the process is subcritical under normal and abnormal conditions and adequately satisfies the double contingency principle

a. Justify that the measures preventing solution backflow to the fresh resin supply system in Scenario C7 are sufficiently reliable to ensure criticality is “highly unlikely,” specifically the double block-and-bleed valve and the paddle blank.

b. Whereas both of these controls are considered administrative, in that they rely on proper valve alignment or equipment installation, justify their use in lieu of more traditional passive backflow prevention (e.g., overflow drains, siphon breaks), in accordance with NWMI preferred design hierarchy.

RAI 6.3-15 Section 6.b.3 of the ISG Augmenting NUREG-1537, Part 2, states that criticality accident evaluations should include accident analyses involving licensed materials and an interpretation of the sequence of events. It is presumed that all criticality accident analyses would assume high consequences; therefore, the applicant should include every credible event that could result in an uncontrolled criticality event.

As part of the evaluation of NWMI application the staff reviewed NWMI-2015-CSE-008, “NWMI Preliminary Criticality Safety Evaluation: Hot Cell Uranium Purification,” Revision A. This document provided an evaluation of

criticality safety scenarios in the hot cell purification unit. Additional information is needed to determine if this analysis ensures that the process is subcritical under normal and abnormal conditions and adequately satisfies the double contingency principle.

a. Explain the nature and operation of tank venting and the overloop seal system described in Scenario C8, including whether they are passive or active, and justify that they are sufficiently reliable to ensure criticality is "highly unlikely."

b. Clarify whether the overloop seal system is passive, as stated in Section 4.1.4.4 of the NWMI-2015-CSE-008, or active, as stated in NWMI PSAR, Section 13.2.4.8.6.

RAI 6.3-16 Section 6.b.3 of the ISG Augmenting NUREG-1537, Part 2, states that criticality accident evaluations should include accident analyses involving licensed materials and an interpretation of the sequence of events. It is presumed that all criticality accident analyses would assume high consequences; therefore, the applicant should include every credible event that could result in an uncontrolled criticality event.

As part of the evaluation of NWMI application the staff reviewed NWMI-2015-CSE-008, "NWMI Preliminary Criticality Safety Evaluation: Hot Cell Uranium Purification," Rev. A. This document provided an evaluation of criticality safety scenarios in the hot cell purification unit. Section 4.2.4 states that Scenario C6 is prevented by the use of favorable-geometry intermediate day tanks isolated from unfavorable chemical reagent or water supply systems with air breaks. However, Section 6.1 describes CSE-08-PDF12 as requiring either a day tank or an air break. Insufficient information is provided on how the day tank or air break will be used to prevent criticality.

Clarify whether both day tanks and air breaks will be used on these unfavorable geometry supply systems, or only one or the other.

CHAPTER 7.0 – INSTRUMENTATION AND CONTROL SYSTEMS

The following RAIs are based on the NRC staff review of Chapter 7.0 of the NWMI PSAR (ADAMS Accession No. ML15210A120) using NUREG-1537, Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

Section 7.1 – Summary Description

RAI 7.1-1 NUREG-1537, Part 1, Section 7.1, "Summary Description," states, in part, that the applicant should summarize the technical aspects, safety, philosophy, and objectives of the instrument and control (I&C) design and discuss such factors as redundancy, diversity, and isolation of functions. The ISG Augmenting NUREG-1537, Parts 1 and 2, Section 7b, "Radioisotope Production Facility Instrumentation and Control Systems," Section 7b.1, "Summary Description," states, in part, that the applicant should provide a summary description of the I&C systems including the design bases; the safety, considerations, and objectives; and the operational characteristics of the production facility that determine or limit the I&C design. NUREG-1537, Part 2, Section 7.1, "Summary Description," states, in part, that the acceptance of the summary description should be based on its completeness in addressing the factors listed in Part 1.

NWMI PSAR Section 7.1, "Summary Description," discusses the I&C design in terms of RPF processes and systems including SNM preparation and handling processes, radioisotope extraction and purification processes, process utility and support systems, criticality accident alarm system, radiation monitoring system, facility ventilation system, and mechanical utility systems. PSAR Section 7.1 states that the facility process control (FPC) and the building management system (BMS) provide monitoring and control functions. PSAR Section 7.1 identifies how and where the processes or systems are monitored and controlled. However, it does not identify any specific I&C technical aspects, philosophy, or objectives of the instrumentation. The discussion does not address redundancy, diversity, or isolation of functions except for the engineering safety features which are stated to be independent, hard-wired analog controls. The discussion does not state the design basis or operational characteristics of the I&C.

Additional information is needed for the NRC staff to understand the design basis, technical aspects, safety, philosophy, and objectives of the I&C design and confirm that the I&C design meets the acceptance criteria of NUREG-1537, Part 2, Section 7.1.

Provide additional detail regarding the design bases, technical aspects, safety, philosophy, and objectives for all I&C components that monitor and control RPF processes or systems.

RAI 7.1-2 NUREG-1537, Part 1, Section 7.1, "Summary Description," states, in part, that the general description of each category of I&C subsystems should include the types of parameters monitored, the number of channels designed to monitor

each parameter, and the actuating logic. NUREG-1537, Part 2, Section 7.1, "Summary Description," states, in part, that the acceptance of the summary description should be based on its completeness in addressing the factors listed in Part 1.

NWMI PSAR Section 7.1, "Summary Description," discusses the I&C design in terms of RPF processes and systems. Section 7.1 states that the FPC and the BMS provide monitoring and control functions, but it does not discuss I&C subsystems that are part of the overall FPC system and BMS. PSAR Section 7.1 identifies how and where the processes or systems are monitored and controlled without identifying the types of parameters monitored, the number of channels monitoring each parameter or the actuation logic.

Additional information is needed for the NRC staff to understand the types and numbers of parameters monitored and the actuation logic and confirm that the I&C design meets the acceptance criteria of NUREG-1537, Part 2, Section 7.1.

Provide additional detail for each category of I&C subsystems that includes the types of parameters monitored, the number of channels designed to monitor each parameter, and the actuating logic.

RAI 7.1-3 NUREG-1537, Part 1, Section 7.1, "Summary Description," states, in part, that the general description of each category of I&C subsystems should include a summary of the human-machine interface principles used in the location of instrumentation and controls. NUREG-1537, Part 2, Section 7.1, "Summary Description," states, in part, that the acceptance of the summary description should be based on its completeness in addressing the factors listed in Part 1.

NWMI PSAR Section 7.1, "Summary Description," discusses the I&C design in terms of RPF processes and systems. PSAR Section 7.1 states that the target fabrication process, target receipt and disassembly process, target dissolution process, molybdenum recover and purification process, and low-dose liquid waste handling will be controlled by operators at local human-machine interfaces (HMI). PSAR Section 7.1 also identifies that operators at local HMIs will control the plant air system, gas supply system, process chilled water chillers, process steam boilers, demineralized water system, chemical supply system, and standby electric power system. PSAR Section 7.1 uses several different terms (i.e., operator interface displays, operator interface terminals, and HMIs) when referring to operator-controlled equipment. PSAR Section 7.1 does not include a summary of the HMI principles used in the location of I&C and does not define the different terms used to describe operator-controlled equipment.

Additional information is needed for the staff to understand the various HMIs being discussed and to confirm that the I&C design meets the acceptance criteria of NUREG-1537, Part 2, Section 7.1.

Provide additional information for each category of I&C subsystems that includes a summary of the HMI principles used in the location of I&C and define the difference in functionality and design between operator interface displays, operator interface terminals, and HMIs.

Section 7.2 – Design of Instrumentation and Control Systems

RAI 7.2-1 NUREG-1537, Part 1, Section 7.2.3, "System Description," states, in part, that:

> the system description in the SAR should include equipment and major components as well as block, logic, and schematic diagrams … the applicant should submit hardware and software descriptions and software flow diagrams for digital computer systems [and that] the applicant should describe how the system operational and support requirements will be met, how the operator interface requirements will be met, [and] should address the methodology and acceptance criteria used to establish and calibrate the trip or actuation setpoints, or interlock functions.

NWMI PSAR Section 7.2.3, "System Description," describes the RPF I&C system basic components as including the FPC system, engineering safety feature (ESF) actuation systems, control console and display instruments, and the BMS. PSAR Sections 7.2.3.1 through 7.2.3.5 do not include a description of the ESF actuation systems or the BMS. Instead, PSAR Sections 7.2.3.1 through 7.2.3.5 provide high-level functional descriptions of the FPC system, control room/operator interface, fire protection system, facility communication systems, and analytical laboratory system. PSAR Section 7.2.3 also does not contain block, logic, or schematic diagrams of these subsystems nor does it address the methodology and acceptance criteria used to establish and calibrate the trip or actuation setpoints, or interlock functions.

Additional information is necessary for the NRC staff to understand the relationship among all of the major I&C components.

a. Provide additional information describing all of the equipment and major RPF I&C components including block, logic, and schematic diagrams to show the relationship between the various I&C subsystems; software flow diagrams for the digital computer systems; a description of how the system operational and support requirements and operator interface requirements are met.

b. Provide a description of the methodology and acceptance criteria used to establish the trip or actuation setpoints or interlock functions.

RAI 7.2-2 NUREG-1537, Part 1, Section 7.2.4, "System Performance Analysis," states, in part, that the applicant should conduct a performance analysis of the proposed system to ensure the design criteria and design bases are met and licensing

requirements for the performance of the system are specified. The analysis should describe the operation of the I&C system and present the analysis of how the system design meets the design criteria and design bases.

NWMI PSAR Section 7.2.4, "System Performance Analysis," states that IROFS will be managed by the FPC system. PSAR Section 7.2.4.2.2 states that the FPC system will initiate and control ESF activation and isolation. PSAR Section 7.2.4.2.6 states that the FPC system will have the ability to perform a manual activation of the ESF. However, PSAR Section 7.1 states that ESF systems will operate independently from the FPC system or BMS; will use hard-wired analog controls/interlocks to protect workers, the public, and environment; and ESF parameters and alarm functions will be integrated into and monitored by the FPC system or BMS. The different descriptions of the FPC system functionality in different sections of the PSAR appear to be inconsistent.

Additional information is necessary for the NRC staff to fully understand the operation of the integrated RPF I&C system.

Provide additional information in the I&C system description and performance analysis of the FPC system as it relates to ESF managing, monitoring, and actuation. Resolve the apparent inconsistency between the description in PSAR Section 7.1 that states "ESF systems are only monitored by the FPC," and the descriptions in PSAR Sections 7.2.4.2.2 and 7.2.4.2.6 that state "ESF system activation and isolation is initiated and controlled by the FPC and the FPC system has the ability to manually activate ESF."

RAI 7.2-3 NUREG-1537, Part 1, Section 7.2.5, "Conclusion," states that the applicant should summarize why the system design is sufficient and suitable for performing the functions stated in the design basis.

NWMI PSAR Section 7.2.4.3, "Conclusion," states, in part, that the RPF I&C systems will meet the stated design criteria and design basis requirements outlined in NUREG-1537. PSAR Table 7-2, "Instrumentation and Control Criteria Crosswalk with Design Basis Applicability and Function Means," presents a crosswalk of the I&C subsystems and attempts to cross-reference the different I&C subsystems to specific design criteria. The table lacks the cross-referencing information necessary to locate the specific PSAR Chapter 7 section that provides a detailed description of how the design basis is satisfied. The omission of the cross-referencing information prevents evaluating that the system design is sufficient and suitable for performing the functions stated in the design basis.

Additional information is necessary to fully understand the operation of the integrated RPF I&C systems.

Provide additional information in Table 7-2 that provides a cross-reference to the specific section of PSAR Chapter 7 that discusses how the system is suitable for performing the functions stated for each design basis applicability item.

Section 7.3 – Process Control Systems

RAI 7.3-1 The ISG Augmenting NUREG-1537, Part 2, Section 7b.3, "Process Control Systems," Acceptance Criteria, states, in part, that the system should be designed with sufficient control of reactivity for all required production and SNM fuel reconditioning process operations.

NWMI PSAR Section 7.3, "Process Control Systems," states, in part, that the RPF process control will be administered by the FPC system and, for specific transfers identified by the operator, the FPC system will provide a permissive to allow for the active pump in that circuit to be energized once the operator has manually configured the routing. For transport requiring a pump, the FPC system will control the ability of the pump to be energized. For specific transfers, the FPC system will provide controlled fluid flow transfers based on a closed-loop control. The operator will initialize the transfer of fluids. The applicant must control quantities of fissionable materials and assure the quality of both software and operating procedures to preclude the possibility of criticality accidents.

Additional information is necessary to understand how the key parameters are monitored to ensure adequate criticality control.

Provide additional information regarding the adequacy of the facility's instrumentation to detect deviations from nominal concentrations and quantities, should they occur or provide a status of the development of the software and/or procedures, stating why this is not necessary for a CP.

Section 7.4 – Engineered Safety Features Actuation Systems

RAI 7.4-1 The ISG Augmenting NUREG-1537, Part 2, Section 7b.4, "Engineered Safety Features Actuation Systems," states, in part, that this section of the PSAR should describe the actuation systems for any ESFs discussed in PSAR Chapters 6 or 13. NUREG-1537, Part 1, Section 7.5, "Engineered Safety Features Actuation Systems," states, in part, that the "applicant should describe the ESF actuation system in sufficient detail to describe the functions required of the ESF and the operation of the system."

NWMI PSAR Section 7.4, "Engineered Safety Features Actuation Systems," Section 7.4.1, "System Description," states that the PSAR Table 7-13, "Engineered Safety Feature Actuation or Monitoring Systems," lists the ESFs that will require actuation by the I&C system. PSAR Section 7.4 does not describe the actuation systems for any ESFs.

Additional information is necessary to understand the functionality required of the ESF and operation of the system to meet the acceptance criteria of NUREG-1537, Part 2, and the ISG Augmenting NUREG-1537, Part 2.

Provide additional information in sufficient detail describing the required functions and operation of the ESF actuation system.

CHAPTER 8.0 – ELECTRICAL POWER SYSTEMS

The following RAIs are based on the NRC staff review of Chapter 8.0 of the NWMI PSAR (ADAMS Accession No. ML15210A117) using NUREG-1537, Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

Section 8.2 – Emergency Electric Power Systems

RAI 8.2-1 Section 50.9, "Completeness and accuracy of information," of 10 CFR Part 50 requires that information maintained by the applicant be complete and accurate in all material respects.

NUREG-1537, Part 1, Section 8.2, "Emergency Electric Power Systems," states that the design bases should provide voltage power requirements for emergency electric power systems.

NUREG-1537, Part 2, Section 8.2, Acceptance Criteria, states, in part:

> The functional characteristics of the emergency power system should be commensurate with the design bases, which are derived from analyses presented in other chapters of the SAR. …The source of electrical power (generator, batteries, etc.) should be capable of supplying power for the duration required by the SAR analysis.

NWMI PSAR Section 8.1.2, "Design for Safe Shutdown," states that the uninterruptable power supplies (UPSs) will be designed to operate up to 90 minutes, except the UPS for the fire protection system will operate for up to 24 hours. However, PSAR Section 3.5.2.7.9, "Standby Electrical Power," states that the design basis value for the UPSs is to "…maintain power availability for a minimum of 120 min [minutes] post-accident."

Provide additional information to resolve or explain this apparent discrepancy in power availability times.

RAI 8.2-2 Section 50.9, "Completeness and accuracy of information," of 10 CFR Part 50 requires that information maintained by the applicant be complete and accurate in all material respects.

NUREG-1537, Part 1, Section 8.2, "Emergency Electric Power Systems," states that the design bases should provide voltage power requirements for emergency electric power systems.

NUREG-1537, Part 2, Section 8.2, Acceptance Criteria, states, in part:

> The functional characteristics of the emergency power system should be commensurate with the design bases, which are

> derived from analyses presented in other chapters of the SAR. …The source of electrical power (generator, batteries, etc.) should be capable of supplying power for the duration required by the SAR analysis.

NWMI PSAR Section 8.2 states that a 1000-kilowatt (kW) (1341 horsepower [hp]) diesel generator will provide standby electrical power (SEP). However, PSAR Section 8.2.2, "Ranges of Emergency Electrical Power Required," states, in part, that: "The total peak SEP required for the RPF is 1,140 kW (1,528 hp)." Further, PSAR Table 8-1, "Summary of Radioisotope Production Facility and Ancillary Facilities Electrical Loads," lists the RPF electrical loads and shows that the total SEP required is 1,173.6 kW (1,585 hp). PSAR, Chapter 19.0, "Environmental Review," Table 19-60, "Emissions for Standby Emergency Diesel Generator" cites 2,600 kW as the basis for design diesel generator emissions.

Provide additional information to resolve or explain these apparent discrepancies in SEP requirements.

CHAPTER 9.0 – AUXILIARY SYSTEMS

The following RAIs on this chapter are based on the NRC staff review of Chapter 9.0 of the NWMI PSAR (ADAMS Accession No. ML15210A118) using NUREG-1537, Parts 1 and 2, in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

Section 9.1 – Heating, Ventilation and Air Conditioning (HVAC) Systems

(Applies to RAIs 9.1-1 through 9.1-3)

NUREG-1537, Part 1, Chapter 9, "Auxiliary Systems," states that the applicant should include the design bases for each auxiliary system.

NUREG-1537, Part 1, Chapter 3, "Design of Structures, Systems and Components," states, in part, that: "The bases for the design criteria for some of the systems discussed in this chapter may be developed in other chapters and should be appropriately cross referenced."

NUREG-1537, Part 2, Section 9.1, "Heating, Ventilation, and Air Conditioning Systems," Review Procedures, states, in part, that: "The design bases should be compared with requirements from other chapters of the SAR …"

RAI 9.1-1 NWMI PSAR Section 9.1.1, "Design Basis," states:

> The ventilation system is designed to provide confinement of hazardous chemical fumes and airborne radiological materials and conditioning of the RPF environment for facility personnel and equipment. The design basis of the ventilation system includes:
>
> - Confining hazardous chemical fumes
> - Preventing release and dispersal of airborne radioactive materials to protect health and minimize danger to life or property
> - Maintaining dose uptake through ingestion to levels ALARA [as low as reasonably achievable]
> - Providing ventilation air and conditioning the RPF environment for workers or occupants
> - Providing makeup air and condition the RPF environment for process and electrical equipment

Whereas, PSAR Section 3.5.2.7.12, "Facility Ventilation System," which appears to refer to what PSAR Section 9.1.1 calls the "Ventilation System," states that the "facility ventilation system" design basis "functions" are as follows:

- Provide confinement of hazardous chemical fumes and airborne radiological materials and conditioning of RPF environment for facility personnel and equipment

- Prevent release and dispersal of airborne radioactive materials (e.g., maintain pressure gradients to ensure proper flow of air from least potentially contaminated areas to most potentially contaminated areas) to protect health and minimize danger to life or property

- Maintain dose uptake through ingestion to levels as low as reasonably achievable (ALARA)

- Provide makeup air and condition the RPF environment for process and electrical equipment

- Process exhaust flow from the process vessel ventilation system

- Provide confinement of airborne radioactive materials by providing for the rapid, automatic closure of isolation dampers within confinement zones for various accident conditions

- Provide conditioned air to ensure suitable environmental conditions for personnel and equipment in RPF

Thus, PSAR Section 9.1.1 appears to be inconsistent with PSAR Section 3.5.2.7.12 in that PSAR, Section 3.5.2.7.12 refers to the “facility ventilation system,” which is called the “ventilation system” in PSAR Section 9.1.1. PSAR Section 3.5.2.7.12 also lists two design basis functions for the facility ventilation system that are not listed in PSAR Section 9.1.1 for the “ventilation system,” specifically:

- Process exhaust flow from the process vessel ventilation system

- Provide confinement of airborne radioactive materials by providing for the rapid, automatic closure of isolation dampers within confinement zones for various accident conditions

Additionally, PSAR Section 3.5.2.7.12 lists five design basis “values” that are not included among the design bases in PSAR Section 9.1.1; specifically:

- Maintain primary fission product boundary during and after normal operations, shutdown conditions, and DBEs

- Provide an integrated leak rate for confinement boundaries that meets the requirements of accident analyses that complies with 10 CFR 20 dose limits

- 30-year design life
- Maintain occupied space at 24 degrees Celsius (°C) (75 degrees Fahrenheit [°F]) (summer) and 22°C (72°F) (winter), with active ventilation to support workers and equipment
- Maintain air quality that complies with 10 CFR 20 dose limits for normal operations and shutdown

It is not clear whether what is called the "facility ventilation system" in PSAR, Section 3.5.2.7.12 is exactly the same as what is called the "ventilation system" in PSAR, Section 9.1.1, or if the terms are not interchangeable, whether one of the systems, or which parts thereof, are parts of the other system.

Additional information is needed to clarify the use of inconsistent terminology for systems and subsystems. Inconsistent design basis functions/values make it difficult to identify system boundaries and to determine the adequacy of the design basis.

Provide additional information to resolve and explain these apparent discrepancies in the description of the ventilation system. Explain how NWMI will correct the apparent discrepancies, as necessary, in the PSAR, and explain how NWMI will ensure the PSAR uses consistent terminology in these and other sections.

RAI 9.1-2 NWMI PSAR, Section 9.1.1 states, in part:

> The offgas treatment system will provide primary system functions to protect on-site and off-site personnel from radiological and other industrial related hazards by:
>
> - Collecting the air in-leakage sweep from each of the numerous vessels and other components in the main processes
> - Segregating the numerous vessel vents into subsystems
> - Directing the vessel vent subsystem that may contain iodine to abatement equipment to reduce any iodine levels in the offgas stream
> - Collecting a special high-volume humid vessel vent stream from the waste handling system

- Merging the collected vent subsystems into the main facility ventilation system for further treatment or filtration to remove entrained radionuclides

- Removing radionuclide particulate to comply with facility emission limits

- Providing airflow and negative pressure to the fission product offgas system and to ventilate RPF vessels

Additional information on the design basis is provided in Chapter 3.0, “Design of Structures, Systems, and Components.”

However, PSAR Section 3.5.2.7.11, “Process Vessel Ventilation System,” appears to refer to what PSAR Section 9.1.1 calls the “offgas treatment system,” and states that the “process vessel ventilation system” design basis “functions” are as follows:

- Provide primary system functions to protect on-site and off-site personnel from radiological and other industrial related hazards

- Collect air in-leakage sweep from each of the numerous vessels and other components in main RPF processes and maintain hydrogen concentration process tanks and piping below lower flammability limit

- Minimize reliance on administrative or complex active engineering controls to provide a confinement system as simple and fail-safe as reasonably possible

PSAR Section 3.5.2.7.11 then lists design basis “values” as follows:

- Prevent inadvertent criticality and maintain primary fission product boundary during and after normal operations, shutdown conditions, and DBEs

- 30-year design life

- Contain and store noble gases generated in the RPF for at least 60 days

Thus, PSAR Section 9.1.1 appears to be inconsistent with PSAR Section 3.5.2.7.11 in that PSAR Section 3.5.2.7.11:

- refers to the “process vessel ventilation system,” which is apparently called the “offgas treatment system” in PSAR Section 9.1.1

- lists three design basis functions for the process vessel ventilation system that are not listed in PSAR Section 9.1.1 for the "offgas treatment system"

- omits six of the seven design bases given in PSAR, Section 9.1.1 for the offgas ventilation system (the exception being the design basis/function of "Collect air in-leakage sweep from each of the numerous vessels and other components in main RPF processes")

- lists three design basis "values" that are not included among the design bases given in PSAR Section 9.1.1

Additional information is need to clarify whether the "process vessel ventilation system" in PSAR Section 3.5.2.7.11 is the same as the "offgas treatment system" in PSAR Section 9.1.1, or if the terms are not interchangeable, whether one of the systems, or which parts thereof, are parts of the other system. The use of inconsistent terminology for systems and subsystems and inconsistent design basis functions/values make it difficult to identify system boundaries and to determine the adequacy of the design basis.

Provide additional information to resolve or explain these apparent discrepancies in the descriptions of the ventilation system to offgas system. Explain how NWMI will correct the apparent discrepancies, as necessary, in the PSAR.

RAI 9.1-3 NWMI PSAR Section 9.1.1, states, in part, that:

> The design basis of the ventilation system includes the following:
>
> - Providing ventilation air and conditioning the RPF environment for workers or occupants
>
> - Providing makeup air and condition the RPF environment for process and electrical equipment

PSAR, Section 3.5.2.7.12, "Facility Ventilation System," appears to refer to what PSAR Section 9.1.1 calls the "Ventilation System," and states that the facility ventilation system "design basis functions" include the following:

- Provide makeup air and condition the RPF environment for process and electrical equipment

- Provide conditioned air to ensure suitable environmental conditions for personnel and equipment in RPF

PSAR Section 3.5.2.7.23, “Supply Air System,” states that the design basis functions of the supply air system include the following:

- Providing conditioned (e.g., filtered) air for facility workers and equipment and supply makeup air for exhaust air systems
- Drawing outside air into the RPF air supply system through air handling units
- Providing makeup air and condition the RPF environment for process and electrical equipment
- Providing conditioned air to ensure suitable environmental conditions for personnel and equipment

PSAR, Section 3.5.2.7.23 further lists supply air system “design basis values” as follows:

- 30-year design life with the exception of common replaceable parts (e.g., pumps)
- Maintain occupied space at 24°C (75°F) (summer) and 22°C (72°F) (winter), with active ventilation to support workers and equipment
- Maintain air quality that complies with 10 CFR 20 dose limits for normal operations and shutdown

PSAR Section 3.5.2.7.23 introduces another system designation (i.e., “supply air system”), which has design basis elements (functions and values) that appear to correspond to two of the design basis elements (functions/values) of the ventilation/facility ventilation system, further described in PSAR Section 9.7.2.2, “Supply Air System.”

Thus, it appears, that the “supply air system” in PSAR, Section 3.5.2.7.23 is a subsystem of the “facility ventilation system” in PSAR Section 3.5.2.7.12, and the “ventilation system” in PSAR, Section 9.1.1. Additional information is needed to clarify relationship among the supply air system, facility ventilation system, and ventilation system. The use of inconsistent terminology for systems and subsystems and inconsistent design basis functions/values make it difficult to identify system boundaries and determine the adequacy of the design basis.

Provide additional information to clarify the relationship among the supply air, facility ventilation, and ventilation systems. Explain how NWMI will correct the apparent discrepancies, as necessary, in the PSAR.

RAI 9.1-4 NUREG-1537, Part 1, Chapter 9 states that the applicant should include the design bases for each auxiliary system.

NWMI PSAR Section 9.1.2, "System Description," states, in part: "abatement technologies, primarily high-efficiency particulate air (HEPA) filtration and activated carbon, will be used to ensure that air exhausted to the atmosphere meets 40 CFR 61, 'National Emission Standards for Hazardous Air Pollutants' (NESHAP), and applicable State law."

The meeting of 40 CFR Part 61 and applicable state law constitutes a regulatory/legal requirement that should form part of the system design basis such that the system design will meet the performance requirements. However, the design requirement that exhaust air meet the stated regulatory/legal requirements it is not listed among the design basis elements in PSAR Section 9.1.1 and is not listed among the design basis functions or values in PSAR Section 3.5.2.7.12, as are certain other applicable regulatory requirements.

Provide additional information to clarify whether this regulatory/legal requirement is a design basis element, function, or value. If so, include it in the lists in PSAR Sections 9.1.1 and/or 3.5.2.7.12 as appropriate.

RAI 9.1-5 NUREG-1537, Part 1, Chapter 9 states that the applicant should include the design bases for each auxiliary system.

NUREG-1537, Part 1, Section 9.1 states that all used spaces in a facility may require HVAC systems to provide acceptable environments for personnel and equipment."

NUREG-1537, Part 2, Section 9.1, states that areas of review should include features of the HVAC system that affect habitability and the working environment in the reactor facility for personnel and equipment.

NWMI PSAR Section 9.1.2.3.1, "Zone I Exhaust System," states that the space temperature control will not be provided for Zone I spaces unless thermal loads are expected to cause temperatures to exceed equipment operating ranges without additional cooling. However, it is not explained what circumstances would result in temperatures exceeding operating ranges. Therefore, additional information is needed to determine whether HVAC systems can properly provide an acceptable environment.

Provide additional information to explain when (i.e., design phase, construction, facility/systems testing, or operation) and how, (e.g., as an operational sensing, calculation and control function), NWMI will determine whether HVAC space temperature control in Zone I will need to be provided.

Section 9.3 – Fire Protection Systems and Programs

(Applies to RAIs 9.3-1 through 9.3-4)

NUREG-1537, Part 2, Section 9.3, "Fire Protection Systems and Programs," Acceptance Criteria, states, in part, that "[m]ethods to detect, control, and extinguish fires should be stated in the plan."

RAI 9.3-1 NWMI PSAR Section 9.3.3.1.1, "Hot Cell, Waste Handling, and Shipping Areas," discusses the hot cell fire area. However, no information on fire suppression inside the hot cell enclosure was provided. Additional information is needed on the hot cell fire protection to determine if methods to detect, control, and extinguish fires are adequate.

Provide information on the type of fire suppression system that will be used in the hot cell enclosure, including a discussion of any life safety concerns that could arise from use of the suppression system.

RAI 9.3-2 NWMI PSAR Section 9.3, "Fire Protection Systems and Programs," discusses the fire protection program for the NWMI facility, including the fire detection and suppression systems, as well as alarm systems and life safety concerns, however it does not address which building or fire codes the facility will be built to. Additional information is needed to determine if methods to detect, control, and extinguish fire are adequate.

Identify the building and fire codes that NWMI is committing to follow with regards to the fire protection program, both for construction and maintenance of systems.

RAI 9.3.3 While NWMI PSAR, Section 9.3, provides information on fire protection system design, it does not describe how high radiation areas may affect the performance of ionization detectors, while photoelectric detectors can be affected by the presence of dust or particulates. Additional information is needed to determine the fire detection capabilities of the facility.

Provide the basis for how detectors will be chosen, as well as for the maintenance program that will be put in place to ensure their functionality.

RAI 9.3-4 NWMI PSAR Section 9.3.2.1, "Fire Suppression Subsystem" and Section 9.3.2.2, "Fire Detection and Alarm Subsystem," states that HEPA filter plenum deluge systems and heat detectors will be used to detect and suppress fires involving the HEPA filter system.

Provide a description of the testing and maintenance of these systems, including information about any codes or standards that NWMI is committing to.

RAI 9.3-5 NUREG-1537, Part 1, Section 9.3, "Fire Protection Systems and Programs," states that the application should discuss passive design features required by the facility design characteristics to, in part, limit fire consequences. The facility should be designed and protective systems should exist to prevent the uncontrolled release of radioactive material if a fire should occur.

NWMI PSAR Section 9.3.3.1, "Radioisotope Production Facility Fire Area," discusses fire hazards and ignition sources that were considered for the RPF, but does not describe which fire safety systems or management measures are necessary to prevent or mitigate high or intermediate consequence accidents. Additional information is required to determine if the plan for the prevention of fires is adequate.

a. Identify which fire detection and suppression systems are necessary to prevent or mitigate high or intermediate consequence accidents in the RPF (i.e., IROFS).

b. Describe any management measures that will assure that these systems and components are constructed, procured, installed, and tested to ensure that they will be available and reliable to perform their intended functions when needed.

RAI 9.3.6 NUREG-1537, Part 2, Section 9.3, "Fire Protection Systems and Programs," states that the fire protection plan should discuss the prevention of fires, including limiting the types and quantities of combustible materials. However the application did not provide any information of the combustibles in each fire area. Additional information is needed to determine if the facilities plan to limit the types of quantities of combustible materials is adequate.

Provide additional information on the types of combustibles found in each fire area and how the combustible materials will be controlled, including any administrative controls and management measures.

Section 9.4 – Communication System

RAI 9.4-1 Section 50.9, "Completeness and accuracy of information," of 10 CFR Part 50 requires that information maintained by the applicant be complete and accurate in all material respects.

NUREG-1537, Part 1, Chapter 9, "Auxiliary Systems," states that the applicant should include the design bases for each auxiliary system.

NWMI PSAR Section 9.4.1, "Design Basis," states that:

> The communications system design basis is to provide communications during normal and emergency conditions between vital areas of the RPF and the Administration Building.

> This communications capability will include the ability of operators or other designated staff members to announce an emergency in all areas of the RPF and provide two-way communications between all operational areas and the control room. Design of the telecommunication system also complies with Electronic Industries Alliance and Telecommunications Industry Association requirements. Additional information on the communications system design basis is provided in Chapter 3.0.
> .

However, PSAR Chapter 3.0, "Design of Structures, Systems, and Components," does not appear to provide any additional information on the communication system.

Provide additional information to clarify this apparent gap in information.

Section 9.6 – Cover Gas Control in Closed Primary Coolant Systems

RAI 9.6-1 Section 50.9, "Completeness and accuracy of information," of 10 CFR Part 50 requires that information maintained by the applicant be complete and accurate in all material respects.

NUREG-1537, Part 1, Chapter 9, "Auxiliary Systems," states that the applicant should include the design bases for each auxiliary system.

NWMI PSAR Section 9.6.1, "Design Basis" states that:

> The [cover gas control] system design basis is to ensure that the hydrogen concentration in the coolant system is less than 25 percent of the lower flammability limit of 5-percent H_2; so that no uncontrolled release of radioactive material can occur, and that gases within the system do not reach explosive levels. Additional information on the design basis of cover gas control in the closed primary coolant system is provided in Chapter 3.0 ['Design of Structures, Systems, and Components']."

However, the only additional information on the cover gas control function or its design basis in PSAR Chapter 3.0 is in PSAR Section 3.5.2.7.17, "Process Chilled Water System," which lists one of the design basis functions of the process chilled water system as providing cover gas to prevent flammable conditions.

Provide additional information clarify this apparent gap in information.

Section 9.7 – Other Auxiliary Systems

RAI 9.7-1 NUREG-1537, Part 1, Chapter 9, "Auxiliary Systems," states that the applicant should include the design bases for each auxiliary system.

NWMI PSAR Section 9.7.1, “Utility Systems,” states, in part:

> The utility systems will provide heating, cooling, process water, compressed gases, instrument, motive force, and other functions to support uranium processing, waste handling, and ventilation. The utility systems will include the following subsystems:
>
> - Process steam
> - Process chilled water
> - Demineralized water
> - Plant and instrument air
> - Gas supply, which supplies nitrogen, helium, hydrogen, and oxygen
> - Purge/sweep gas
>
> The PSAR further states the utility systems are designed to ensure that any potential malfunctions do not cause accidents in the RPF or an uncontrolled release of radioactivity. The systems are designed to ensure that in the event radioactive material is released by the operation of one of these systems, potential radiation exposures would not exceed the limits of 10 CFR 20 and are consistent with the NWMI ALARA program. No function or malfunction of the auxiliary systems will interfere with or prevent safe shutdown of the RPF.

PSAR Section 9.7.1.1, “Design Basis,” states that:

> The utility systems design basis is to provide:
>
> - Saturated steam at 1.7 kilograms (kg)/square centimeter (cm2) (25 pounds [lb]/square inch [in^2]) and 4.2 kg/cm^2 (60 lb/in^2) gauge to various process equipment
>
> - Chilled water to various process equipment at no greater than 10 °C (50 °F) during normal operations
>
> - Demineralized water to the process steam and cooling water systems
>
> - Plant air for instrument air, air-diaphragm pump power, mechanical tools, and grouting material conveyor
>
> - Instrument air for bubblers and valve actuation

- Gas supply, including nitrogen, helium, and hydrogen to the reduction furnace, and nitrogen and oxygen to the dissolvers

- Purge/sweep gases provide adequate flow such that the accumulation of combustible gases is below hazardous concentrations and reduces radiological hazards due to accumulation of gaseous fission products

Additional information on the utility systems design basis is provided in Chapter 3.0.

PSAR Section 3.5.2.7.14, “Plant and Instrument Air System,” states that the design basis functions of the plant and instrument air system are as follows:

- Provide small, advective flows of plant air for several RPF activities (e.g., tool operation, pump power, purge gas in tanks, valve actuation, and bubbler tank level measurement)

- Provide plant air receiver buffer capacity to make up difference between peak demand and compressor capacity

- Provide plant air to instrument air subsystem for bubblers and valve actuation

- Provide instrument air receiver buffer capacity to make up difference between peak demand and compressor capacity

PSAR Section 3.5.2.7.14 lists the following design basis values of the plant and instrument air systems as:

- 30-year design life with the exception of common replaceable parts (e.g., pumps)

- Provide instrument air dried in regenerable desiccant beds to a dew point of no greater than -40°C (-40°F) and filtered to a maximum 40 micron (μ) particle size

Thus, PSAR, Section 9.7.1.1 appears inconsistent or not clearly correlated with PSAR Section 3.5.2.7.14 in that PSAR Section 3.5.2.7.14 lists three design basis functions for the plant and instruments air systems that are not listed among the two plant-and-instrument-air-system-related design basis elements in PSAR Section 9.7.1.1, specifically:

- Provide small, advective flows of plant air for several RPF activities (e.g., tool operation, pump power, purge gas in tanks, valve actuation, and bubbler tank level measurement)

- Provide plant air receiver buffer capacity to make up difference between peak demand and compressor capacity

- Provide instrument air receiver buffer capacity to make up difference between peak demand and compressor capacity

Additionally, PSAR Section 3.5.2.7.14, does not include two of the design bases given in PSAR Section 9.7.1.1 for the plant and instrument air systems. Also, PSAR, Section 3.5.2.7.14 lists two design basis "values" that are not included among the design basis elements given in PSAR Section 9.7.1.1

While, PSAR Section 9.7.1.1 does indicate that PSAR Chapter 3.0 provides additional information on the utility systems design bases, it is not clear how each of the design basis functions and values in PSAR Section 3.5.2.7.14 supports or correlates with the design basis elements in PSAR Section 9.7.1.1.

Additional information is needed to resolve inconsistent and incomplete design basis elements, functions, and values; inconsistent level of detail; unclear correlation of design basis functions and values with design basis elements. Lack of clarity in identifying which design basis elements belong to which system or subsystem make it difficult to identify system functional boundaries and to determine adequacy of the design basis.

a. Provide additional information to resolve or explain these apparent discrepancies in the design basis of utility systems.

b. Explain how NWMI will correct or clarify the apparent discrepancies in the PSAR.

RAI 9.7-2 NUREG-1537, Part 1, Chapter 9, states that the applicant should include the design bases for each auxiliary system.

NWMI PSAR Section 9.7.1, "Utility Systems," states that the utility systems comprise the following subsystems:

- Process steam
- Process chilled water
- Demineralized water
- Plant and instrument air
- Gas supply, which supplies nitrogen, helium, hydrogen, and oxygen
- Purge/sweep gas

PSAR Section 9.7.1.1 states, in part that one of the utility systems design bases is to provide chilled water to various process equipment at no greater than 10 °C (50 °F) during normal operations.

PSAR Section 3.5.2.7.17, “Process Chilled Water System,” lists the process chilled water system design basis functions as follows:

- Provide process chilled water loop for three secondary loops through plate-and-frame heat exchangers
  - One large geometry secondary loop in hot cell
  - One criticality-safe geometry secondary loop in hot cell
  - One criticality-safe geometry secondary loop in target fabrication area

- Provide monitoring of chilled water loops for loss of primary containment

- Provide cover gas to prevent flammable conditions

PSAR Section 3.5.2.7.17 lists the process chilled water system design basis values as follows:

- 30-year design life with the exception of common replaceable parts (e.g., pumps)

- Chilled water to various process equipment at no greater than 10°C (50°F) during normal operations

PSAR Section 3.5.2.7.18, “Facility Chilled Water System,” lists the facility chilled water system design basis functions as follows:

- Provide cooling media to heating, ventilation, and air conditioning (HVAC) system

- Supply HVAC system with cooling water that is circulated through the chilled water coils in air handling units

PSAR Section 3.5.2.7.18 lists facility chilled water system design basis values as follows:

- Provide cooling water at a temperature of 9°C (48°F) to the HVAC air-handling unit cooling coils

- 30-year design life with the exception of common replaceable parts (e.g., pumps)

PSAR Section 3.5.2.7.19, “Facility Heated Water System,” lists facility heated water system design basis functions as follows:

- Provide heated media to HVAC system
- Supply the HVAC system with heated water that is circulated through the heated water coils in the air-handling units

PSAR Section 3.5.2.7.19 lists facility heated water system design basis values as follows:

- Provide heated water at a temperature of 82°C (180°F) to HVAC air-handling unit heating coils and reheat coil
- 30-year design life with the exception of common replaceable parts (e.g., pumps)

PSAR Section 3.5.2.7, “Radioisotope Production Facility Specific System Design Basis Functions and Values,” discusses the facility chilled water system (3.5.2.7.18) and the facility heated water system (3.5.2.7.19). However, neither of these systems is included among the utility systems listed in PSAR Section 9.7.1, or for which the design bases are given in PSAR Section 9.7.1.1. These systems are described briefly in PSAR Section 9.7.1.2.2, “Chilled Water.” Additional information is needed to determine the relationship among these systems.

Provide additional information to correct, explain or clarify this apparent discrepancy in discussions of the process and facility chilled water system and the facility heated water system.

CHAPTER 11.0 – RADIATION PROTECTION AND WASTE MANAGEMENT

The following RAIs are based on the NRC staff review of Chapter 11.0 of the NWMI PSAR (ADAMS Accession No. ML15210A118) using NUREG-1537, Parts 1 and 2, in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

Section 11.1 – Radiation Protection

(Applies to 11.1-1 through 2)

Paragraph 20.1101(d) of 10 CFR Part 20 states that a constraint on emissions of radioactive material shall be established by licensees such that individual members of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent (TEDE) in excess of 10 millirem (mrem) per year from these emissions.

RAI 11.1-1 NUREG 1537, Part 2, Section 11.1.1, "Radiation Sources," states the applicant should identify models and assumptions that are used for predicting and calculating the dose rates and accumulative doses from such radionuclides as Argon-41, Nitrogen-16 and airborne radioactive particulates in both restricted, controlled, and unrestricted areas. The analysis should contain conservative best estimates of the predicted annual total doses to at least the following in the unrestricted areas: (1) the maximum exposed individual, (2) the nearest permanent residence, and (3) any location of special interest.

NWMI PSAR Section 11.1.1.1.2, "Release of Airborne Radionuclides," provides Table 11-2, "Radionuclide Stack Release Source Term Input to COMPLY" to determine the constraint on release of airborne radionuclides to the environment.

PSAR Section 1.2.2, "Consequences from the Operation and Use of the Facility," states the anticipated radionuclide inventory in the RPF is based on a weekly throughput of eight MURR targets processed a specified time after end of irradiation (EOI). Section 4.1.2.1 states the RPF is designed to have a nominal operational processing capability of one batch per week of up to 12 targets from MURR for up to 52 weeks per year and approximately 30 targets from the Oregon State University (OSU) TRIGA Reactor (OSTR) or a third university reactor for 8 weeks per year per reactor. It is not clear whether the calculation of airborne release of radionuclides is based on 8 or 12 MURR targets per week.

a. Clarify the basis of the calculation of airborne release of radionuclides, i.e. which target processing throughput is the basis of the computation for maximum dose to the public described in the section.

b. If the nominal processing capability cited in PSAR Section 4.1.2.1 was not used for the computation, re-evaluate the maximum dose to the public.

RAI 11.1-2 NUREG-1537, Part 2, Section 11.1.1, "Radiation Sources," states the applicant should present the best estimates of the maximum annual dose and the collective doses for major radiological activities during the full range of normal operations for facility staff and members of the public. The doses shall be shown to be within the applicable limits of 10 CFR Part 20.

NWMI PSAR Section 11.1.2, "Radiation Protection Program," states NWMI management is committed to protecting RPF workers, the public, and environment from unacceptable exposure to radiation sources. The NWMI RPF administrative exposure limits have been set below the limits specified in 10 CFR Part 20 to ensure that regulatory radiation exposure limits are not exceeded and to emphasize ALARA principles. Table 11-5, "Estimated Radioisotope Production Facility Controlled and Restricted Area Dose Rates," provides dose rates for a variety of work areas to include the administrative spaces. However, a basis was not provided for does rates, designation of radiation areas, and assignment of dosimetry. This information is needed to determine ALARA and compliance with does limits in 10 CFR 20

a. Provide the basis of the dose rates established in Table 11-5 of the PSAR.

b. Describe if there are any areas within the RPF that would be designated radiation areas or high radiation areas.

c. Describe the NWMI basis for assigning personnel dosimetry to staff.

d. Explain what is meant by "dose investigation level of 5 mSv/yr" in Section 11.1.2 of the PSAR.

RAI 11.1-3 Subparagraph 20.2001(a)(2) of 10 CFR Part 20 states that one of the methods that a licensee shall dispose of licensed material is decay-in-storage.

NUREG 1537, Part 2, Section 11.1.5, "Radiation Exposure Control and Dosimetry," states the design bases of radiation shielding, ventilation, and remote handling and decontamination equipment should be planned so radiation doses are maintained ALARA and should be within the regulatory limits.

NWMI PSAR Section 4.2.1.1, "Biological Shield Function," provides a general description of the biological shield and the intent to reduce radiation dose rates and accumulated doses to not exceed the limits of 10 CFR Part 20. It is not clear on the access controls for entering the RPF from the administrative support area. This information is need to ensure that radiation doses are maintained ALARA and within applicable limits of 10 CFR Part 20.

a. Describe the requirements (dosimetry, personal protection equipment, etc.) and access controls for entering the RPF from the administrative support area.

b. Describe the anticipated radiation levels and occupancy status of the corridor separating from the tank hot cell.

RAI 11.1-4 Subparagraph 20.1501(a)(2) of 10 CFR Part 20 states that each licensee shall make or cause to be made, surveys of areas, that are reasonable under the circumstances to evaluate the potential radiological hazards of the radiation levels and residual radioactivity detected.

NUREG 1537, Part 2, Section 11.1.1, "Radiation Sources," states the applicant should present the best estimates of the maximum annual dose and the collective doses for major radiological activities during the full range of normal operations for facility staff and members of the public. The doses shall be shown to be within the applicable limits of 10 CFR Part 20.

NWMI PSAR Section 4.3.2.2.6, "Radiological Hazards," describes the anticipated radionuclide inventory to be managed following irradiated target receipt, which excludes trace and decayed products of the irradiation process. The basis of this inventory is a weekly throughput of 8 MURR targets processed at a specified time following end of irradiation.

PSAR Section 4.3.2.2.5, "Special Nuclear Material Description," describes processing a potential 30 irradiated targets per week from the OSTR. It is not clear how these additional irradiated targets impact the radiation dose to the public.

Explain how these additional 30 irradiated targets impact the inventory and the maximum dose to the public described in Section 11.1.1.1.2 of the PSAR.

(Applies to RAI 11.1-5 through 11.1-9)

Paragraph 20.1101(a) of 10 CFR Part 20 states that each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part.

RAI 11.1-5 NUREG 1537, Part 2, Section 11.1.1, "Radiation Sources," states the applicant should identify models and assumptions that are used for conservative best estimates of the predicted annual total doses to the maximum exposed individual.

NWMI PSAR Section 13.2.1, "Maximum Hypothetical Accident," shows in Tables 13-18, Table 13-19, and Table 13-20, the distance-dependent inhalation, exposure, and total receptor MHA doses, respectively, versus distance from the RPF stack for an assumed bounding 2-hr exposure. NWMI provides the TEDE due to the MHA for the maximally exposed individual but does not provide the Committed Dose Equivalent (CDE) to the thyroid.

Provide the CDE to the thyroid from the presented scenario and the impact to the public.

RAI 11.1-6 NUREG-1537, Part 1, Section 11.1.3, "ALARA Program," states the facility's ALARA program should require that radiation dose received by facility staff and the public are maintained ALARA, economic factors having been taken into account.

NWMI PSAR Section 11.1.2, "Radiation Protection Program," states the NWMI administrative exposure limits have been set below the limits specified in 10 CFR Part 20 to ensure that regulatory radiation exposure limits are not exceeded and to emphasize ALARA principles. Table 11-5, "Estimated Radioisotope Production Facility Controlled and Restricted Area Dose Rates," states the dose rate in the administration and support area and utility area will be 0 mrem/hr. It is not clear how NWMI will demonstrate these areas will be maintained at 0 mrem/hr (unrestricted area).

Describe how NWMI will demonstrate that the administration and utility areas are no different than unrestricted areas.

RAI 11.1-7 NUREG-1537, Part 1, Section 11.1.4, "Radiation Monitoring and Surveying," states that a complete range of radiation monitoring and sampling equipment, appropriate to the facility, should be employed throughout the facility, including equipment employed by experimental and operations support personnel, including remote area monitors.

NWMI PSAR Section 11.1.5.5.2, "Controlled Area," states that area monitoring will demonstrate compliance with public exposure limits for visitors. Area monitoring equipment is not described in Section 11.1.4 of the PSAR.

Provide a description of the area monitoring equipment NWMI intends to use to demonstrate compliance with public exposure limits for visitors.

RAI 11.1-8 NUREG-1537, Part 1, Section 11.1.7, "Environmental Monitoring," states the methods and techniques to sample analyze the radiological effect of facility operation should be complete, applicable, and of sufficient validity that the environmental impact can be unambiguously assessed.

NWMI PSAR Section, 4.1.3.6.1, "Waste Handling System Process Overview," states that a portion of the low-dose liquid fraction is expected to be suitable for recycle to selected hot cell systems as processed water. Water that is not recycled will be adjusted and then mixed with an adsorbent material in 55-gallon drums. Further, waste streams will be containerized, stabilized as appropriate, and shipped offsite for treatment and disposal. Figure 4-23, "Low-Dose Liquid Waste Disposition Process," and Figure 4-25, "Low Dose Liquid Waste Evaporation Facility Location," describes an evaporation system and facility.

It is not clear how the evaporation effluent is controlled from the low-dose wastewater tanks.

Describe the endpoint of the evaporation effluent from this facility and clarify whether any evaporate will be exhausted to the environment. Explain, if NWMI's intends to exhaust to the environment, what type of effluent sampling and documentation of results will be performed.

RAI 11.1-9 NWMI PSAR Section 4.3.2.2.5, "Special Nuclear Material Description," states weekly cask shipments from the OSTR will consist of two transport casks, not to exceed a total of 30 targets. Weekly cask shipments from the MURR will consist of two transport casks containing four targets. PSAR Section 4.2.3.1, "Initial Source Term," states the photon source strength for the NWMI shielding analysis was determined based on the activity associated with eight MURR irradiated targets. Additional information is required to understand the process of target receipt and processing and the impact to the shielding analysis.

Clarify the anticipated target receipt inventory and explain how the additional irradiated targets from OSTR will bear on the shielding analysis.

RAI 11.1-10 Paragraph 20.1101(d) of 10 CFR Part 20 states that a constraint on emissions of radioactive material shall be established by licensees such that individual members of the public likely to receive the highest dose will not be expected to receive a TEDE in excess of 10 millirem (mrem) per year from these emissions.

NUREG-1537, Part 2, Section 11.1.1, "Radiation Sources," Acceptance Criteria, states, in part, that all sources of radiation should be discussed by the applicant. This discussion should include the physical and chemical form, type (e.g., neutron, gamma), curie strength or exposure rates, energy level, encapsulation (sealed or unsealed), use, storage conditions and locations, and planned program for disposal of all radioactive material subject to the reactor license.

NWMI PSAR Section 4.4.1, "Processing of Irradiated Special Nuclear Material," provides an overview of the uranium recovery system and states it is sized to purify approximately 22 kg/week for recycle to the target fabrication system. Section 4.4.1 also states the 22 kg/week is based on processing 30 targets.

PSAR Section 1.2.2, "Consequences from the Operation and Use of the Facility," states the anticipated radionuclide inventory in the RPF is based on a weekly throughput of eight MURR targets processed at a specified time after the end of irradiation. PSAR Section 4.1.2.1 states the RPF is designed to have a nominal operational processing capability of one batch per week of up to 12 targets from MURR for up to 52 weeks per year and approximately 30 targets from the OSTR or a third university reactor for 8 weeks per year per reactor.

a. Identify whether or not this recyclable material is a part of the inventory described in Table 1.1.

b. Clarify the radionuclide inventory, maximum dose to the public, and other radiological hazards based on planned processing capabilities.

Section 11.2 – Radioactive Waste Management

RAI 11.2-1 NUREG-1537, Part 1, Section 11.2, "Radioactive Waste Management," introduces the expectations for the content of the PSAR. It includes the statement, "The magnitude and nature of the effort required should depend upon the size and complexity of both the reactor facility and its utilization programs. Therefore, the nature and details of the radioactive waste management program should also be commensurate with those factors." Based on the annual generation rate of high-dose Class C waste presented in PSAR Table 11-6, "Waste Produced in the Radioisotope Production Facility," and the capacity of the container proposed for Class C waste presented in PSAR Table 4-17, "Waste Container Geometric Data," there will be one or more Class C shipments for disposal every week. The complexity of waste processing is indicated by both the number of chemical operations and adjustments required, as discussed in PSAR Sections 4.1.3.6, "Waste Handling," and 9.7.2, "Control and Storage of Radioactive Waste," and by the number of potential accidents involving waste operations, as identified in NWMI PSAR Chapter 13, "Accident Analysis Methodology and Preliminary Hazards Analysis." Given the amount of waste and the complexity of waste management operations, the "…nature and details of the radioactive waste management program…" should be well explained.

NUREG-1537, Section 11.2.1, "Radioactive Waste Management Program," delineates specific expectations for the description of the radioactive waste management program. NUREG-1537, Part 2, Section 11.2.1, "Radioactive Waste Management Program," states that factors addressed by the applicant should include organization of the management function, program staffing and position descriptions, and program personnel responsibilities and qualifications as discussed in the format and content guide.

PSAR Section 11.2.1.3.2, "Waste Management Lead," identifies the individual responsible to the Plant Manager for waste management activities, including self-assessments. PSAR Chapter 12, "Conduct of Operations," does not include the position "Waste Management Lead," nor is it on any of the management figures. PSAR Section 11.1.2.1.3, "Radiation Protection Manager," states that the Radiation Protection Manager will be responsible for overseeing handling and disposal of radioactive wastes. This PSAR inconsistency results in uncertainty regarding the management function, program staffing and position descriptions, and program personnel responsibilities.

a. Provide a more complete and comprehensive description of the radioactive waste management organization and responsibilities within the NWMI management structure.

b. Clarify the line of authority for radioactive waste management.

RAI 11.2-2 Section 50.9, "Completeness and accuracy of information," of 10 CFR Part 50 requires that information maintained by the applicant be complete and accurate in all material respects.

NUREG-1537, Part 1, Section 11.2.2, "Radioactive Waste Controls," states that the applicant should identify and discuss the plans for management of all forms of radioactive waste.

NWMI PSAR Section 11.2.3, "Release of Radioactive Waste," Table 11-6 presents estimates of the annual generation rates of specific waste streams, but without adequate specificity to ascertain what these generation rates include and whether all potential waste streams have been considered.

PSAR Section 9.7.2.2.1 states that caustic solution is added, as needed, to the high-dose liquid stream.

a. Clarify if the values presented in PSAR Table 11-6 include this added volume of caustic solution.

b. Confirm if mixing ratios of waste liquid to solidification agent have been included in PSAR Table 11-6 values for solidified waste volume.

PSAR Section 4.4.1.4, "Special Nuclear Material Description," contains references to drains to geometrically safe locations. There appears to be no discussion of how these streams are controlled after collection and whether they will be treated as waste.

c. Provide a discussion of how these streams are controlled after collection, whether they are treated as waste, and if so, whether that volume is included in PSAR Table 11-6.

PSAR Section 4.1.2.1, "Process Design Basis," states that the RPF is designed to have a nominal operational processing capability of one batch per week of up to 12 targets from MURR for up to 52 weeks per year and approximately 30 targets from the OSTR or a third university reactor for 8 weeks per year per reactor." Therefore, the nominal operational processing capability of the RPF is 1,104 targets per year. This section also states that the overall process functional requirement for the handle waste function is, "Providing the capability to handle waste generated from processing up to 120 irradiated targets per month." PSAR Table 11-6, Waste Produced in the Radioisotope Production Facility, is based on processing only 8 MURR targets per week, or about 38% of the RFP nominal operational processing capability.

d. Given these statements, justify that, the data presented in PSAR Table 11-6, which is based on processing only 8 MURR targets per week is reasonable basis for waste production in the RPF.

RAI 11.2-3 Paragraph 20.1101(d) of 10 CFR Part 20 states that a constraint on emissions of radioactive material shall be established by licensees such that individual members of the public likely to receive the highest dose will not be expected to receive a TEDE in excess of 10 millirem (mrem) per year from these emissions.

NUREG-1537, Part 2, Section 11.2.1, "Radioactive Waste Management Program," states the program should be designed to address all technical and administrative functions necessary to limit radiation hazards related to radioactive waste.

PSAR Section 4.3.4.1, "Process Description," states that the overall process concept for radioactive noble gases is to delay gas release so that decay will reduce the radioisotope content sufficiently to allow the decayed noble gases to be safely discharged to the stack. The PSAR states that a 60 day period will effect that delay, driven by Xenon-133. The PSAR does not address how longer-lived radioactive isotopes are limited to reduce radiation hazards related to radioactive waste.

Describe how NWMI intends to address longer-lived radioisotopes that generate hundreds or thousands of curies of activity in this process, identified in Table 4-33, "Target Disassembly In-Process Radionuclide Inventory," such as Promethium-143 and 145, Cesium-137, Cerium-144, etc.

RAI 11.2-4 Section 50.9, "Completeness and accuracy of information," of 10 CFR Part 50 require that information submitted, or information required to be maintained by the applicant be complete and accurate in all material respects.

NWMI PSAR Section 11.2.2.1, "Waste Designation," states that the RPF will generate class A, B, and C low-level radioactive waste. Table 11-6, "Waste Produced in the Radioisotope Production Facility," identifies several items as Class C waste. High-dose and other types of waste are identified as Class C, and annual generation volumes are provided.

In its November 2, 2015, response to environmental RAI WM-R-1, (ADAMS Accession number ML15328A071) NWMI stated that high-dose and encapsulated waste are projected to be Class B waste, and provided bounding annual generation rates (in kilograms per year). Additionally, in the response to RAI WM-R-1, NWMI stated that volume reduction has the potential to change the disposed waste classification from Class B to class C as a result of optimization activities, and results will be described in the Operating Permit Application, but did not identify any specific generation rates of Class C waste. Additional information is needed to resolve this apparent discrepancy between Table 11-6 and NWMI's response to RAI WM-R-1.

Provide additional information to resolve the apparent discrepancy of whether Class C waste will be produced, or may potentially be produced, in Table 11-6 and NWMI's response to RAI WM-R-1.

RAI 11.2-5 NUREG-1537, Part 1, Section 11.2.2, "Radioactive Waste Controls," states that the applicant should describe the plans and procedures for managing solid radioactive wastes generated during operations, research, and utilization of the reactor. This description should include how solid radioactive materials are generated and where they enter the waste control and treatment systems. Additionally, NUREG-1537, Part 1, Section 11.2.3, "Release of Radioactive Waste," states that the applicant should identify all radioactive materials for which transfer to other parties for disposal is planned.

NWMI PSAR Table 19-13, "Solid Waste Produced at the Radioisotope Production Facility," includes an estimate of 40,000 L of potentially contaminated waste (e.g., decontamination materials, PPE). PSAR Section 11.2 does not identify personal protective clothing and dry active waste from decontamination and maintenance activities as a waste stream and does not provide information regarding the estimated amount or handling of dry active wastes generated at the RPF. It is not clear whether this waste stream is included in PSAR Table 11-6, "Waste Produced in the Radioisotope Production Facility." PSAR Chapters 4 and 9 do not contain information regarding the proposed collection, volume reduction, packaging or storage of this waste steam. PSAR Section 9.7.2.2.8, "Waste Staging and Storage Building," provides the volume of the Waste Staging and Shipping Building but provides no details regarding the processes occurring within that building.

More information is needed to provide reasonable assurance that radioactive wastes will be controlled at all times in a manner that protects the environment and the health and safety of the facility staff and the public.

a. Provide the basis for the estimate of the generation rate and discuss the processes used to minimize the volume stored prior to disposal, and include the waste stream in PSAR Table 11-6.

b. Clarify which waste processing steps are accomplished in the RPF and which are accomplished in the Waste Staging and Shipping Building.

Section 11.3 – Respiratory Protection Program

RAI 11.3-1 Subparagraph 20.2001(a)(1) of 10 CFR Part 20 states that a licensee shall dispose of licensed material by transfer to an authorized recipient, as provided in 10 CFR 20.2006.

The ISG Augmenting NUREG-1537, Part 2, Section 11.3, "Respiratory Protection Program," states that the applicant shall describe surveillance requirements,

including preventive and corrective maintenance and performance testing, to ensure that the ventilation and containment systems operate when required and are within their design specifications.

NWMI PSAR Section 4.1.4.5, “Irradiated Target Receipt Area,” states that the irradiated target receipt bay will be designed to operate as a Zone II airspace during fuel element unloading procedures and when the hot cell cover block is removed for maintenance. Table 4-5, “Facility Areas and Respective Confinement Zones," in Section 4.1.4.3 states the bay will operate as a Zone IV area. More information is needed to understand zone management to determine the adequacy of confinement and radioactive material contamination control.

a. Describe how these zonal differences are managed, how the changes will be evaluated, and posted.

b. Describe the occupancy status when operating as a Zone II area.

RAI 11.3-2 Section 20.1902 of 10 CFR Part 20 establishes posting requirements for radiation areas, airborne radioactivity areas and areas or rooms in which licensed material is used or stored.

The ISG Augmenting NUREG-1537, Part 2, Section 11.3, states that the applicant will install appropriately sized ventilation and containment systems in areas of the plant identified as having potential airborne concentrations of radionuclides that could exceed the occupational derived air concentration values specified in 10 CFR Part 20, “Standards for Protection against Radiation,” Appendix B, “Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage.”

NWMI PSAR Section 9.1.2, “System Description,” states that the facility ventilation system will maintain a series of cascading pressure zones to draw air from the cleanest areas of the facility to the most contaminated areas. Zone IV will be a clean zone that is independent of the other ventilation zones. Zone III will be the cleanest of the potentially contaminated areas, with each subsequent zone being more contaminated and having lower pressures. More information is needed to determine the adequacy of the confinement and radioactive material contamination control.

a. Describe the process whereby NWMI will maintain these ventilation zones in regards to contamination.

b. Describe the gradients of potential contamination separating each zone.

RAI 11.3-3 Section 20.1701 of 10 CFR Part 20 states that the applicant shall use, to the extent practical, process or other engineering controls to control radioactive material in air.

The ISG Augmenting NUREG-1537, Part 2, Section 11.3, states that the applicant will describe the criteria for the ventilation and containment systems, including minimum flow velocity at openings in these systems, maximum differential pressure across filters, and types of filters to be used.

NWMI PSAR Section 9.1, “Heating, Ventilation, and Air Conditioning Systems,” states that the RPF design features ensure that airflow and relative pressure will prevent inadvertent diffusion or other uncontrolled release of airborne radioactive material from the RPF. The facility is also designed and operated to ensure that no uncontrolled release of airborne radioactive material to the unrestricted environment can occur. More information is needed to determine the adequacy of the confinement and radioactive material contamination control.

Describe the criteria for the ventilation and containment systems, including minimum flow velocity at openings in these systems, maximum differential pressure across filters, and types of filters to be used.

CHAPTER 12.0 – CONDUCT OF OPERATIONS

The following RAIs are based on the NRC staff review of Chapter 12.0 of the NWMI PSAR. Specifically, the staff focused its review on Appendix C, "Quality Assurance Program Plan for the Design, Construction, and Operation of the Radioisotope Production Facility" and guidance in Regulatory Guide 2.5, "Quality Assurance Program Requirements for Research and Test Reactors." The quality assurance program was reviewed against the guidance provided in ANSI/ANS-15.8, "Quality Assurance Program Requirements for Research Reactors."

Appendix 12C, Section 2.2 – Quality Control Program

RAI C.2.2-1 Subparagraph 50.34(a)(7) of 10 CFR Part 50 requires a description of the quality assurance (QA) program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility.

Section 70.4 of 10 CFR Part 70 defines IROFS as "structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at a facility that could exceed the performance requirements in §70.61 or to mitigate their potential consequences." The ISG augmenting NUREG-1537, Part 1, states that meeting the performance requirements in 10 CFR 70.61 are not required by regulation, but that their use as accident consequence and likelihood criteria could be found acceptable by the NRC staff.

NWMI's QA program defines QA Level 1 items as including those items in which failure or malfunction could indirectly result in a condition that adversely affects workers, the public, and/or environment as described in 10 CFR 70.61. The failure of a QA Level 2 item, in conjunction with the failure of an additional item, could result in a high or intermediate consequence. All building and structure IROFS associated with credible external events are QA Level 1. QA Level 1 items also include those attributes of items that could interact with IROFS due to a seismic event, and result in high or intermediate consequences as described in 10 CFR 70.61.

NWMI PSAR description of QA Level 1 IROFS appears to only include structures. Additional information is needed to understand the applicability of the QA plan to other IROFS besides structures.

Clarify the scope of IROFS addressed by the applicant's QA program and describe the applicability of different QA levels to IROFS to factors including systems, equipment, components and activities.

Appendix 12C, Section 2.3 – Design Control

RAI C.2.3-1 ANS 15.8 states that the need for or the use of qualification tests shall be defined in a formal test plan that shall include appropriate acceptance criteria and shall demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions. Test results shall be documented and

evaluated by the responsible design organization to assure that test requirements have been met. NWMI's PSAR did not provide how this criteria will be met and how it is incorporated on the QA program.

Clarify whether NWMI intends to perform qualification testing or the need to demonstrate the adequacy of performance of systems, structures or components under conditions that simulate the most adverse design conditions. For example, if it is required for any type of qualification testing for an identified IROFS during the construction period, how will this be stated in the QA program.

RAI C.2.3-2 ANS 15.8 states that where a significant design change is necessary because of an incorrect design, the design process and verification procedure should be reviewed and modified as necessary.

NWMI's QA program does not provide details on how design changes are captured, documented, and monitor during the construction period and how this will transition to the operation period.

Clarify whether NWMI intends to provide that when a significant design change is necessary because of an incorrect design, the design process and verification procedure should be reviewed and modified as necessary. For example how will any design change be documented or tracked during the construction period, and how will this be documented thru the QA program.

Appendix 12C, Section 2.11 – Test Control

RAI C.2.11-1 ANS 15.8 states, in part, that testing shall include prototype qualification tests, proof tests prior to installation, and functional tests.

NWMI's QA program does not provide the extent or applicability of the QA program to prototype testing pre and post installation.

Clarify the scope of testing activities (e.g., prototype qualification tests, proof tests prior to installation, functional tests) the applicant intends to conduct under the QA program.

RAI C2.11-2 NWMI PSAR, Chapter 12, Section C2.11.2.4, "Computer Software," states, in part, that "Testing shall include verification tests, hardware integration tests, in-use tests, or other tests as specified by the *customer*, as appropriate."

NWMI's QA program does not provide the extent or applicability of the QA program to software applicability on these tests or the authority responsible for such verification.

Clarify whether the computer software testing is to be done by another entity other than NWMI and whether these software testing controls are applicable to NWMI.

Appendix 12C, Section 2.15 – Control of Nonconforming Items

RAI C2.15-1 Part 21, "Reporting of Defects and Noncompliance," of 10 CFR states that this part applies, except as specifically provided other in Parts 31, 34, 35, 39, 40, 60, 61, 63, 70, or Part 72 of this chapter.

NWMI PSAR, Chapter 12, Section C2.15.2.4, "Nonconforming Condition," states, "When required by contract or specification, the nonconforming conditions shall be transmitted to the *customer* for evaluation as a potentially reportable condition under 10 CFR 21."

a. Clarify the applicability of 10 CFR Part 21 to the applicant. In the statement above from the PSAR, it appears the applicability of 10 CFR Part 21 requirements apply to another entity.

b. Clarify the circumstances in which 10 CFR Part 21 and 50.55(e) will be applicable to another entity.

Appendix 12C, Section 2.17 – Quality Records

RAI C2.17-1 ANS 15.8 states that the [quality] records shall include as a minimum: inspection and test results, results of quality assurance reviews, quality assurance procedures, and engineering.

NWMI PSAR, Chapter 12, Section C2.17.2, "Requirements," states that what is considered a quality record will be provided in implementing procedures. PSAR, Section 12.6 "Records," states that the records management program will define process for managing records and will be consistent with the requirement of applicable regulations. It also states that the identification, generation and authentication, maintenance, and disposition of records will be provide in the Operating License Application. There were no additional details on how the records for the construction, installation and other documentation are going to be maintained. Furthermore, there is no clarification on the retention of period of the documents listed above.

Clarify if the implementing procedures, at a minimum, address the above listed quality records and retention time for such records.

RAI C2.17-2 ANS 15.8 states that some records shall be maintained by or for the plant owner for the life of the particular item while it is installed in the plant or stored for future use. Such records shall be classified in accordance with the following criteria: (a) those which would be of value in demonstrating capability for safe operation; (b) those which would of value in maintaining, reworking, repairing, replacing, or modifying an item; (c) those which would be of value in determining the cause of results of an accident or malfunction of a safety-related item; (d) those which provide required baseline data for in-service inspections; or (e) those which would be of value in planning for facility decommissioning.

NWMI PSAR, Chapter 12, Section C2.17.2.2, “Classifications,” states in part, that what is considered lifetime records will be delineated within implementing procedures. However, it does not state if NWMI will be following ANS 15.8 guidance regarding lifetime records.

Clarify whether the lifetime records, at a minimum, will be classified in accordance with ANS 15.8 criteria.

Appendix 12C, Section 2.19 – Experimental Equipment

RAI C2.19-1 ANS 15.8 states that the QA program shall provide controls over the design, fabrication, installation, and modification of experimental equipment to the extent that these impact safety-related items.

The NWMI PSAR does not appear to state whether the QA program will provide controls over the design, fabrication, installation, and modification of experimental equipment to the extent that these impact safety-related items.

Clarify whether the applicant intends to provide controls over the design, fabrication, installation, and modification of experimental equipment to the extent that these impact safety-related items or where this information is stated in the PSAR.

CHAPTER 13.0 – ACCIDENT ANALYSIS

The following RAIs are based on the NRC staff's review of Chapter 13 of the NWMI PSAR (ADAMS Accession No. ML15210A122 and ML15210A124) using the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

Section 13.1 – Accident Analysis Methodology and Preliminary Hazards Analysis

RAI 13.1-2 Subparagraph 50.35 (a)(2) of 10 CFR Part 50 requires that further technical or design information as may be required to complete the safety analysis and which can be left for later consideration, will be supplied in the final safety analysis report.

NWMI PSAR, Section 13.1, page 13-28, "Uranium Recovery Open Item," identifies two potential accident sequences for the uranium recovery operation preliminary hazard analyst items 4.2.4.8 and 4.3.4.8 (tentative accident sequence S.R.14) that involves an interaction between a high temperature nitric acid solution and the uranium purification ion exchange media. The application states that adverse events need to be further researched, but is not clear on the specific nature of this research or when it will be completed.

a. Describe what additional work has occurred or is planned to understand the likelihood and potential consequences of such an accident sequence.

b. Describe how the research and development results might influence the final design of the RPF and the uranium recovery process equipment.

The staff needs to understand NWMI's assessment of the potential for exothermic reactions involving the chemical extractant in the ion exchange columns resin and other process equipment which may handle the resin including the evaporators that are downstream of the ion exchange system. The PSAR states the operating temperature range of the uranium concentrators in Table 4-50, "Uranium Recovery and Recycle Process Equipment" (UR-Z-320 and UR-Z-520) and the nitric acid concentration of the first concentrator (UR-Z-320) in Section 4.4.1.1

c. Explain whether the research and development includes an assessment of the potential for thermal and radiolytic decomposition of the chemical extractant which is the active component of the resin. Information in technical literature discusses exothermic decomposition at temperatures around 100°C conclude that the chemical extractant has resistance to radiation and nitric acid than tributylphosphate.

Section 13.2 – Analysis of Accidents with Radiological and Criticality Safety Consequences

RAI 13.2-2 The ISG Augmenting NUREG-1537, Part 1, Section 13b.2, "Analyses of Accidents with Radiological Consequences," states that the radiation dose

estimates should include estimates for the operating staff throughout the event and during recovery operations and also for the maximally exposed individual in the uncontrolled areas and at the nearest permanent residence.

NWMI PSAR Section 13.2.1, "Maximum Hypothetical Accident," describes the accident scenario and presents the calculated TEDE results in PSAR Table 13-20, "Maximum Hypothetical Accident Total Effective Dose Equivalent," and PSAR Figure 13-2, "Total Effective Dose Equivalent (Inhalation plus External) for 2-Hour Ground Level Exposure from Maximum Hypothetical Accident," for a range of distances from the accident release site. PSAR Table 13-20 identifies the maximum dose as 22.6 rem at a distance of 1,100 m from the accident release site. No results or discussion is provided pertaining to operating staff dose or dose to the public at the nearest permanent residence. The location of the nearest permanent residence is not identified,

Provide results and discussion pertaining to operating staff dose, including worker stay time. Identify the location of the nearest permanent residence and provide results and discussion pertaining to the dose to the public at the nearest permanent residence.

RAI 13.2-3 The ISG Augmenting NUREG-1537, Part 1, Section 13b.2, "Analyses of Accidents with Radiological Consequences," states that the radiological consequences should be in terms of TEDE.

NWMI PSAR Figure 13-2 is titled "Total Effective Dose Equivalent (Inhalation plus External) for 2-Hour Ground Level Exposure from Maximum Hypothetical Accident." However, the title on the top of the graph states, "Total CEDE [committed effective dose equivalent] Dose Results for 25 ft Stack."

Confirm if CEDE or TEDE is actually presented in PSAR Figure 13-2.

RAI 13.2-4 The ISG Augmenting NUREG-1537, Part 1, Section 13b.2 states that the radiation dose estimates should include estimates for the operating staff throughout the event and during recovery operations and also for the maximally exposed individual in the uncontrolled areas and at the nearest permanent residence.

NWMI PSAR Section 13.2.2, "Liquid Spills and Sprays with Radiological and Criticality Safety Consequences," describes the accident scenario and presents the calculated TEDE dose results in PSAR Table 13-24, "Spray Release Consequence Summary." PSAR Table 13-24 identifies the maximum unmitigated TEDE dose as 12 rem to the public. PSAR Section 13.2.2.7.2, "Confinement Release Consequence," contains a discussion of the mitigated dose consequence value of 0.97 rem to the public. No results or discussion is provided pertaining to operating staff dose or dose to the public at the nearest permanent residence. The location of the nearest permanent residence is not identified.

Provide results and discussion pertaining to operating staff dose, including worker stay time. Identify the location of the nearest permanent residence and provide results and discussion pertaining to the dose to the public at the nearest permanent residence.

RAI 13.2-5 The ISG Augmenting NUREG-1537, Part 1, Section 13b.2 states, "These analyses should include accident scenarios within the operating categories listed in Section 13.b.1.1 and, as a minimum, include accidents caused by those initiating events listed in Section 13b.a.2 within each operating category." The ISG Augmenting NUREG-1537, Part 1, Section 13.b.1.2, "Accident – Initiating Events," states "…should include the following initiating events: Loss of electrical power."

NWMI PSAR Section 13.2.5, "Loss of Power," describes the accident scenario. PSAR Section 13.2.5.7, "Evaluation of Potential Radiological Consequences," does not present any dose consequence results for the loss of power accident scenario and states, in part, that "A detailed evaluation of potential radiological consequences will be developed for the Operating License Application."

The purpose of Chapter 13 of the construction application is to provide adequate accident analysis that results in identifying necessary safety SSCs and IROFs to proceed with design and construction. Since a Loss of Power event would be an anticipated (not unlikely) event, potentially affecting operational processes involving radioactive and fissile materials; a Loss of Power event analysis, results, and identification of derived safety SSCs and IROFs are important to preliminary facility and process design.

Provide an analysis, results, and discussion pertaining to the potential radiological consequences from a postulated loss of power accident.

RAI 13.2-6 The ISG Augmenting NUREG-1537, Part 2, Section 13b.1.2, "Accident-Initiating Events, External Events," states, in part, that "Consequences of natural external events that cause facility damage (e.g., seismic events that damage the confinement or containment) are within the bounds discussed for other accidents in this chapter."

NWMI PSAR Section 13.2.6, "Natural Phenomena Events," states that:

> The RPF is designed to withstand the effects of natural phenomena events. Consequences of natural phenomena accident sequences have been evaluated. Sections 13.2.6.1 through 13.2.6.6 provide event descriptions and identify any additional controls required to protect the health and safety of workers, the public, and environment.

Subsequent PSAR Sections 13.2.6.1 through 13.2.6.6 each provide a brief discussion of the qualitative dose consequence resulting from each specific natural phenomena event, but do not provide any comparison of dose consequences to the dose consequences from the bounding accidents previously analyzed and documented in PSAR Sections 13.2.2 through 13.2.5.

Provide a comparison of PSAR Sections 13.2.6.1 through 13.2.6.6 of the dose consequence values for each natural phenomena event versus the associated bounding event dose consequence analyzed in PSAR Sections 13.2.2 through 13.2.5, supporting why the natural phenomena events dose consequences are bounded by the dose consequences of other analyzed accidents in Chapter 13.

RAI 13.2-7 The ISG Augmenting NUREG-1537, Part 1, Section 13.b.2 states, in part, "Evaluate the potential radiological consequences using realistic methods."

NWMI PSAR Section 13.2.2.7.2, "Confinement Release Consequence," discusses the dose consequence results for the liquid spills and sprays event category and documents the calculated dose consequence results in PSAR Table 13-24. The discussion text section and Table 13-24 demonstrate that the unmitigated dose consequence for the bounding event is 12 rem to the public, and the mitigated dose consequence is 0.97 rem to the public. In this same section, PSAR Table 13-23, "Release Consequence Evaluation RASCAL Code Inputs," documents the analysis inputs and assumptions used to calculate the dose consequences for this bounding event. PSAR Table 13-23 shows that a receptor distance of 100 m is selected in the analysis. The selection of a receptor distance of 100 m for the accident analysis consequences documented in PSAR Section 13.2.2.7.2 is not consistent with the identification of the maximum dose location at 1,100 m in PSAR Table 13-20 and Table 13-26.

Provide additional discussion of why a receptor distance of 100 m would result in the limiting public dose for this event, when other event dose consequence results in PSAR Table 13-20 and Table 13-26, "Target Dissolver Offgas Accident Total Effective Dose Equivalent," demonstrate that the maximum dose to the public occurs at a distance of 1,100 m.

(Applies to RAI 13.2-8 through 13.3-1)

Subparagraph 50.35(a)(1) of 10 CFR Part 50 requires that the applicant has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

RAI 13.2-8 The ISG augmenting NUREG-1537, Part 2, Section 13b.2, states that the application should describe the potential accidents caused by process deviations or other events internal to the facility and credible external events.

NWMI PSAR Section 4.3.5.1, “Process Description,” identifies the ion exchange material in the secondary ion exchange column (MR-IS-225) as an ion exchange resin which will be eluted with nitric acid. Table 4-44 identifies the normal operating temperature but the process uses an active cooler (Chiller MR-Z-230) to maintain a specified temperature.

There is experience of energetic reactions with anion exchange resins in nitric acid media. Most of the accident experience is for nitric acid concentration higher than that proposed for elution, but it is also noted that resin degradation rates vary with resin type, temperature, and acid concentration. There appears to be some potential for anion exchange reactions under upset conditions or off normal conditions at the NWMI facility. The practical guidelines information sheet for ion exchange resins identifies a temperature maximum on the order of 30 to 60^{o}C and nitric acid as a material that can cause explosive reactions.

The accident analysis for the molybdenum recovery system in Table 13-11, “Adverse Event Summary for Molybdenum Recovery and Identification of Accident Sequences Needing Further Evaluation,” of the PSAR does not identify an accident involving overheating and reaction of the anion exchange material and there is no discussion of why this accident is not considered given the presence of decay heat and the use of nitric acid as an eluting agent.

Information is needed on why this type of accident was not or does not need to be considered in the accident analysis for the molybdenum recovery system or the waste management systems that would handle the spent anion exchange resin. The description of waste management systems in Chapter 4 of the PSAR does not describe the handling of spent resin from the molybdenum recovery and purification operations.

a. Describe NWMI’s assessments of accidents involving the anion exchange media used in the molybdenum purification system.

b. Provide a discussion of any potential accidents involving this material that were identified and evaluated and any design features considered reasonable for managing this hazard have been adequately defined.

RAI 13.2-9 The ISG Augmenting NUREG-1537, Part 2, Section 13b, discusses facility accident analysis for the radioisotope production facility. The section states that NUREG-1520, Section 3.4, provides additional criteria for adherence to the safety program and integrated safety analysis (ISA) performance. Section 3.4.3.1.(5)(b) of NUREG-1520 states that process hazard analysis methods (i.e., ISA Methods) are acceptable if the method addresses all modes of operation, including startup, normal operation, shutdown, and maintenance.

The NWMI PSAR has analyzed potential accidents that might occur during normal process operations as part of its process for identifying major features or components incorporated into the design for the protection of the health and

safety of the public. These major features are included in PSAR Tables 1-8, 1-12, 6-1, 6-2 and Table 4-21 of the ISA Summary. These analyses are discussed in Chapter 13 and the ISA Summary of the PSAR and are the basis for design features intended to protect the health and safety of workers and the public for these potential accident conditions (e.g., to protect the plant personnel during normal operations (i.e., manipulator-accessed hot cells and the larger tank hot cell).

PSAR Chapter 13 accident analysis does not address other operating modes (e.g., startup, maintenance, extended shutdown) that can introduce different types of hazards. For example maintenance operations can involve reduced protective barriers between the hazardous materials and workers. Extended shutdown might create a situation where radiolytic hydrogen would be generated over extended periods and could accumulate in unusual locations. Extended shutdown could also result in organic ion exchange resins degradation making it more prone to react exothermically upon process startup.

a. Describe how the accident analysis evaluated non-routine situations to determine if there are additional hazards that have to be accommodated by design features.

b. Describe how NWMI will address an extended RPF shutdown to ensure the protection of health and safety of workers and the public.

RAI 13.2-10 The ISG Augmenting NUREG-1537, Part 2, Section 13b.2, states that the application should describe the potential accidents caused by process deviations or other events internal to the facility and credible external events.

Section 13.3.2, “Nitric Acid Fume Release,” of the NWMI PSAR discusses nitric acid fume release. The NRC staff performed an independent verification of the Areal Locations of Hazardous Atmospheres calculations and confirms that the scenario modeled would exceed the thresholds of high consequence for a worker and for the public. The NRC staff needs to understand any design features that NWMI plans to rely on to protect workers and the public from this high consequence event.

Identify and describe any design features NWMI plans to rely on to prevent or mitigate a nitric acid fume release.

Section 13.3 – Analysis of Accidents with Hazardous Chemicals

RAI 13.3-1 The ISG Augmenting NUREG-1537, Part 2, Section 13b.2, states that the application should provide that the applicant’s facility design, operations, and safety controls for chemical safety provide reasonable assurance that they will function as intended and ensure the safe handling of licensed material at the facility.

NWMI PSAR, Chapter 4, Section 4.3.4.6, “Chemical Hazards,” describes the chemical protection provisions for each process. For processes having the potential of a chemical accident, the PSAR states that those features preventing release of radioactive material and limiting radiation exposure will also protect workers and the public from exposures to hazardous chemicals. The staff needs to understand any design features that NWMI plans to rely on to protect workers and the public from chemical hazards.

a. Identify and describe the specific design features that NWMI plans to rely on to protect workers and public from exposures to hazardous chemicals.

b. Identify and describe the accident scenarios that will discuss these safety features.

RAI 13.3-2 Per 10 CFR 50.35 (a)(2), a construction permit will be issued if the Commission finds that further technical or design information as may be required to complete the safety analysis and which can be left for later consideration, will be supplied in the final safety analysis report.

The ISG Augmenting NUREG-1537, Part 2, Section 13b.2, states that the application should provide that the applicant’s facility design, operations, and safety controls for chemical safety provide reasonable assurance that they will function as intended and ensure the safe handling of licensed material at the facility.

NWMI PSAR Section 9.7.4.3, “Operational Analysis and Safety Function,” discusses operational analysis and safety function and identifies two IROFS that will be implemented CS-18, “Backflow Preventive Device and CS-19, “Safe Geometry Day Tanks” to ensure criticality and chemical safety. The chemical safety roles of these IROFS is not described in PSAR, Section 13.3 or the ISA Summary. The NRC staff needs to understand the chemical safety role NWMI plans for these two IROFS.

Provide additional information that identifies the specific chemical safety accidents these IROFS will be preventing or mitigating.

CHAPTER 14.0 – TECHNICAL SPECIFICATIONS

The following RAIs on this chapter are based on the NRC staff review of Chapter 14.0 of the NWMI PSAR (ADAMS Accession No. ML15210A122) using NUREG-1537, Parts 1 and 2, in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2.

RAI 14.0-1 Paragraph 50.34(a), "Preliminary safety analysis report," of 10 CFR Part 50 states that each application for a construction permit shall include a preliminary safety analysis report. Section 50.34(a)(5) states that the minimum information to be included shall consist of the identification and justification for the selection of those variables, conditions, or other items which are determined as the result of preliminary safety analysis and evaluation to be probable subjects of technical specifications for the facility, with special attention given to those items which may significantly influence the final design.

The ISG Augmenting NUREG-1537, Part 1, Chapter 14, "Technical Specifications," states, in part, that:

> NUREG-1537, Part 1, Chapter 14 of the format and content guide, as augmented by this ISG, is applicable to providing a description of the technical specifications for the licensing of a radioisotope production facility and a non-power reactor facility. Whenever the term 'reactor' appears, it is understood to mean a 'non-power reactor facility,' a 'radioisotope production facility,' or both, as applicable.

NWMI PSAR Section 3.0, "Design of Structures, Systems, and Components," states that the design information for the complete range of normal operating conditions for various facility systems is provided throughout the construction permit application, and includes potential conditions or other items that will be probable subjects of technical specifications associated with the RPF structures and design features are discussed in Chapter 14.0.

PSAR, Chapter 14.0, states, in part, that:

> This chapter describes the process by which the Northwest Medical Isotopes, LLC (NWMI) Radioisotope Production Facility (RPF) technical specifications will be developed and written. For the Construction Permit Application, NWMI has prepared the strategy and content of what will be required for technical specifications during RPF operations.

However, PSAR, Section 3.0 and Chapter 14.0 does not provide the stated design information.

In accordance with 10 CFR 50.34(a)(5), identify and justify the selection of those variables, conditions, or other items which are determined as the result of

preliminary safety analysis and evaluation to be probable subjects of technical specifications for the facility, with special attention given to those items which may significantly influence the final design.

ACRONYM LIST

10 CFR	Title 10 of the *Code of Federal Regulations*
ADAMS	Agencywide Documents Access and Management System
ALARA	as low as reasonable achievable
ANECF	average neutron energy causing fission
ANSI/ANS	American National Standards Institute/American Nuclear Society
ASCE	American Society of Civil Engineers
ASTM	American Society for Testing and Materials
BMS	building management system
CDE	committed dose equivalent
CEDE	committed effective dose equivalent
CP	construction permit
CSE	criticality safety evaluation
DBE	design-basis event
ER	environmental report
EOI	end of irradiation
FEMA	Federal Emergency Management Agency
FPC	facility process control
FSAR	final safety analysis report
HEPA	high-efficiency particulate air
HMI	human-machine interfaces
hp	horsepower
HVAC	heating, ventilation and air conditioning
I&C	instrument and control
IBC	international building code
IROFS	items relied on for safety
ISA	integrated safety analysis
ISG	interim staff guidance
kW	kilowatt
mg	milligram
mRem	millirem
MHA	maximum hypothetical accident
MU	Missouri University
MURR	University of Missouri Research Reactor
NCS	nuclear criticality safety
NESHAP	National Emission Standards for Hazardous Air Pollutants
NWMI	Northwest Medical Isotopes, LLC

NRC	Nuclear Regulatory Commission
NSR	non-safety related
OSU	Oregon State University
OSTR	Oregon State University TRIGA Reactor
PPE	personal protective equipment
PSAR	preliminary safety analysis report
QAPP	Quality Assurance Program Plan
RAI	request for additional information
RAMS	remote area monitors
RCA	radiologically controlled area
RPF	radiological production facility
RWP	radiation work permit
SAR	safety analysis report
SEP	standby electrical power
SNM	special nuclear material
SR	safety-related
SSC	structures, systems and components
TEDE	Total effective dose equivalent
TBD	to be determined
UPS	Uninterruptable power supplies
USGS	U.S. Geological Survey
WMA	waste management area