

APPENDIX A. POST CONSTRUCTION PERMIT ACTIVITIES – CONSTRUCTION PERMIT CONDITIONS AND FINAL SAFETY ANALYSIS REPORT COMMITMENTS

A.1 Construction Permit Conditions

The U.S. Nuclear Regulatory Commission (NRC) staff (the staff) has determined that additional information is needed to address certain matters related to nuclear criticality safety in the Northwest Medical Isotopes, LLC (NWMI or the applicant) construction permit application. The staff has also determined that a construction permit needs to be conditioned to require that NWMI will implement its quality assurance program during construction. Therefore, the staff recommends that, should the application be granted, the construction permit include the conditions set forth below. Conditions 1 and 2 related to nuclear criticality safety are confirmatory in nature, and must be satisfied prior to the completion of construction. Additional details on the basis for each condition appear in Chapter 6.0, “Engineered Safety Features,” and Chapter 12.0, “Conduct of Operations,” of the NWMI construction permit safety evaluation report (SER).

Proposed Permit Condition	SER Section	Description
1	6.4.5	Prior to the completion of construction, NWMI shall ensure that all nuclear processes are evaluated to be subcritical under all normal and credible abnormal conditions. This determination shall be done for each area as described in Section 6.3.1.1 of the Preliminary Safety Analysis Report (PSAR) prior to each area being completed, and shall be done consistent with the Upper Subcritical Limit (USL) established in Revision 2 of NWMI’s Validation Report. NWMI shall submit periodic reports to the NRC, at intervals not to exceed 6 months from the date of the construction permit, summarizing any changes or indicate no change to the criticality safety evaluations as a result of the revised USL. This condition terminates once NWMI submits its Final Safety Analysis Report (FSAR).
2	6.4.5	Prior to the completion of construction, NWMI shall submit periodic reports to the NRC, at intervals not to exceed 6 months from the date of the construction permit. These reports shall provide the technical basis for the design of the Criticality Accident Alarm System (CAAS) or notify the NRC of no change. Prior to the completion of construction, the reports shall demonstrate detector coverage as defined in the requirements of Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) 70.24(a). This condition terminates once NWMI submits its FSAR.

Proposed Permit Condition	SER Section	Description
3	12.4.9	<p>NWMI shall implement the quality assurance program described, pursuant to 10 CFR 50.34(a)(7), in revision 3 of the NWMI preliminary safety analysis report, including revisions to the quality assurance program in accordance with the provisions below.</p> <p>NWMI may make a change to its previously accepted quality assurance program description initially included in revision 3 of the NWMI preliminary safety analysis report, provided the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the quality assurance program description that do not reduce the commitments must be submitted to the NRC within 90 days. Changes to the quality assurance program description that do reduce the commitments must be submitted to the NRC and receive NRC approval before implementation, as follows:</p> <ul style="list-style-type: none"> • Changes made to the previously accepted quality assurance program description must be submitted as specified in 10 CFR 50.4. • The submittal of a change to the quality assurance program description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the quality assurance program description commitments previously accepted by the NRC. The letter need not provide the basis for changes that correct spelling, punctuation, or editorial items. • A copy of the forwarding letter identifying the changes must be maintained as a facility record for three years. • Changes to the quality assurance program description included in the NWMI preliminary safety analysis report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.

A.2 Regulatory Commitments Identified in Responses to Requests for Additional Information

In responses to requests for additional information, the applicant identified elements of design, analysis, and administration that require additional research and development or correction. The staff determined that resolution of these items is not necessary for the issuance of a construction permit, but the applicant should ensure that these items are fully addressed in the final safety analysis report (FSAR) supporting an NWMI operating license application. The staff is tracking these items as regulatory commitments and will verify their implementation during the review of an NWMI operating license application.

The following regulatory commitments, as identified in NWMI's responses to requests for additional information (RAIs), are the responsibility of the applicant, and have not yet been fulfilled:

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
3.1-1A	April 25, 2016 ML16123A119	The specific Radioisotope Production Facility (RPF) design codes, standards, and other referenced documents, including exceptions or exemptions to the identified requirements, will be finalized in the RPF final design and provided to the U.S. Nuclear Regulatory Commission (NRC) in late 2016. In addition, the codes, standards, and referenced documents for the RPF safety structures, systems, and components (SSCs) that are needed to demonstrate compliance with regulatory requirements will be identified and committed to in the Operating License Application.
3.1-1B	April 25, 2016 ML16123A119	The codes, standards, and referenced documents for the RPF SSCs that are needed to demonstrate compliance with regulatory requirements will be identified and committed to in the Operating License Application. If there are specific exceptions to code requirements, NWMI will identify the exceptions as part of the Operating License Application submittal.
6.3-1	April 25, 2016 ML16123A119	The intent of Section 6.3 of the Construction Permit Application (CPA) (NWMI-2013-021) is to demonstrate an understanding of a nuclear criticality safety (NCS) program by describing aspects of the program. The discussion was not meant to imply that the program would be implemented in its entirety for the CPA. The program will be fully developed as part of the Operating License Application activities.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
6.3-5	April 25, 2016 ML16123A119	To ensure the criticality accident alarm system (CAAS) coverage is adequate for the facility final design, NWMI will conduct a coverage analysis using the minimum accident of concern that produces a detector response when the dose rate at the detector is equivalent to 20 rad/minute (min) at 2 meters (m) from the reacting material. Using the source from the minimum accident of concern, NWMI will conduct one-dimensional deterministic computations, when practical, to evaluate CAAS coverage. For areas of the facility where the use of one-dimensional deterministic computations is not practical, NWMI will use 3D Monte Carlo analysis to determine adequate CAAS coverage. NWMI is designing the CAAS in accordance with American National Standards Institute/American Nuclear Society (ANSI/ANS)-8.3, <i>Criticality Accident Alarm System</i> .
13.1-1	April 25, 2016 ML16123A119	NWMI intends to prevent the occurrence of a criticality accident regardless of whether it results in a high radiation dose. In the Operating License Application, NWMI will clearly state our intent to prevent the occurrence of a criticality accident regardless of whether the event results in a high radiation dose.
G-3	November 28, 2016 ML16344A053	The accident analyses in the final safety analysis report (FSAR), as part of the Operating License Application, will be consistent with the requirements of 10 CFR 70.61.
2.5-1b	November 28, 2016 ML16344A053	A site-specific geotechnical investigation of the RPF will be conducted to ensure that the area does not have the potential for sinkholes. If the investigation does identify the potential for sinkholes, the design would incorporate one of the following alternatives: (1) excavate site both vertically and horizontally to remove that potential and backfill with structural fill, or (2) install piers to bedrock to support the substructure if a sinkhole was to occur. If one of these alternatives needs to be implemented, it will be determined after the geotechnical investigation is complete, incorporated in the final RPF design, and presented in the FSAR as part of the Operating License Application.
2.5-2	November 28, 2016 ML16344A053	A site-specific geotechnical investigation of the RPF site will be conducted to identify the site-specific soil characteristics. If highly plastic clays are identified at the site, the design will include excavation of the clays and then backfill with structural fill. The structural details will be developed in the final RPF design and presented in the FSAR as part of the Operating License Application.
2.5-3	November 28, 2016 ML16344A053	A site-specific geotechnical investigation of the RPF site will be conducted to identify the site-specific soil characteristics. If highly plastic clays are identified at the site, the design will include excavation of the clays and then backfill with structural fill. The structural details will be developed in the final RPF design and presented in the FSAR as part of the Operating License Application.
2.5-6b	November 28, 2016 ML16344A053	Additional information on the seismic requirements and evaluations of the RPF and associated items relied on for safety (IROFS) will be provided in the FSAR as part of the Operating License Application
2.5-9	November 28, 2016 ML16344A053	Additional geotechnical analysis will be conducted on the liquefaction potential of the soils on site.

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3.2-1	November 28, 2016 ML16344A053	During the structural analysis, unknown loads will have a conservative value assumed and marked with "(HOLD)." As the design matures, the actual values will be inserted in the analysis and the HOLDS removed. Final design media cannot be issued if there are HOLDS identified. The facility live loads will be established during the completion of the final facility design and provided in the FSAR as part of the Operating License Application.
3.2-3	November 28, 2016 ML16344A053	The density of all interconnections (e.g., heating, ventilation, and air conditioning (HVAC) ductwork, conduits, cable trays, and piping) between equipment will be conservatively estimated and included in the final design for dead load for fixtures attached to ceilings or anchored to floors in the RPF. This information will be provided in the FSAR as part of the Operating License Application.
3.3-2	November 28, 2016 ML16344A053	Selection of specific fire suppression systems for facility locations will be guided by the recommendations offered in relevant industry standards (e.g., National Fire Protection Association (NFPA) 801, <i>Standard for Fire Protection for Facilities Handling Radioactive Materials</i>) and will depend on the level of fire hazards at those locations, as determined from the final facility and process systems designs. These final detailed designs will include any facility design elements and sensitive equipment protection measures deemed necessary for addressing the maximum inadvertent rate and duration of water discharges from the fire protection systems. The final comprehensive facility design, along with commitments to design codes, standards, and other referenced documents (including any exceptions or exemptions to the identified requirements), will be identified and provided in the FSAR as part of the Operating License Application
3.4-2a	November 28, 2016 ML16344A053	The composition of soil in which the RPF is embedded will be included in the soil-structure-interaction analysis as part of the building response analysis. This information will be provided in the FSAR as part of Operating License Application.
3.4-4a	November 28, 2016 ML16344A053	Design of IROFS will consider seismic loads in all three directions using a combination of square-root-of-the-sum-of-squared or [100]/40/40 methodologies. The [100]/40/40 methodology will be used in the development of the final RPF design and in the FSAR as part of the Operating License Application.
3.4-4b	November 28, 2016 ML16344A053	Design of IROFS will consider seismic loads in all three directions using a combination of square-root-of-the-sum-of-squared or [100]/40/40 methodologies. The [100]/40/40 methodology will be used in the development of the final RPF design and in the FSAR as part of the Operating License Application.
3.4-8a	November 28, 2016 ML16344A053	The capacity of the standard support design for overhead fixtures mounted above RPF IROFS will be checked to ensure that the supports can withstand the seismic loads derived from the floor spectra (e.g., remain stable during and after postulated earthquake effects) of the attachment floor slab. This information will be provided in the FSAR as part of the Operating License Application.

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3.4-8b	November 28, 2016 ML16344A053	The RPF seismic design will include a check to ensure that pounding or sway impact will not occur between adjacent fixtures (e.g., rattle space). Estimates of the maximum displacement of any fixture can be derived from the appropriate floor response spectrum and an estimate of the fixture's lowest response frequency. This information will be provided in the FSAR as part of the Operating License Operation.
3.4-9	November 28, 2016 ML16344A053	Seismic instrumentation for the RPF site is not an IROFS; it provides no safety related function and is therefore not "safety-related." Although the seismic recorders have no safety function, they must be designed to withstand any credible level of shaking to ensure that the ground motion would be recorded in the highly unlikely event of an earthquake. This capability requires verification of adequate capacity from the manufacturer (e.g., prior shake table tests of their product line), provision of adequate anchorage (e.g. manufacturer-provided anchor specifications to ensure accurate recordings), and a check for seismic interaction hazards such as water spray or falling fixtures. With these design features, the instrumentation would be treated as if it were safety-related Quality Level (QL)-2. Additional information on seismic [instrumentation] will be provided in the FSAR as part of the Operating License Application.
3.5-8	November 28, 2016 ML16344A053	Each of the hot cells will have manipulators that will be used to perform maintenance within the hot cells. Equipment within the hot cells will also be positioned on skids for ease of removal and replacement if necessary. If maintenance cannot be performed by the in-cell manipulators, the cover blocks can be removed and the required equipment replaced. For the tank hot cell, a portable manipulator can be moved to different locations [within] the tank hot cell to perform maintenance. The design philosophy that will be incorporated in the FSAR as part of the Operating License Application will use remote handling for as much maintenance as possible within the hot cells. In [addition], the ventilation and changes in building configuration will be designed to maintain zones and barriers consistent with defense-in-depth, redundancy, and independence to protect workers and the public.
3.5-9e	November 28, 2016 ML16344A053	The quantities or concentrations of fissionable material used in the criticality analyses for all areas or process equipment are provided in each individual criticality calculation or criticality safety evaluation. The single process batch to subcritical limit will be presented in the FSAR as part of the Operating License Application.
5.1-2	November 28, 2016 ML16344A053	The target load per week described in PSAR Section 5.1.1 will be changed to 12 University of Missouri Research Reactor (MURR) targets per week in the FSAR as part of the Operating License Application. The modification will include update of NWMI-2015-CALC-022, <i>Maximum Vessel Heat Load, Temperature, and Pressure Estimates</i> , with a more detailed analysis and revision of PSAR Section 5.1.1, Figure 5-2.

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6.3-9	November 28, 2016 ML16344A053	<p>The validation report NWMI-2014-RPT-006, <i>MCNP 6.1 Validations with Continuous Energy ENDF/B-VII.1 Cross Sections</i>, was generated prior to any calculations being performed for the NWMI RPF process. The intention was to provide as broad a base of coverage within each area of applicability (AoA) parameter range as possible. The H/X range was extended below a value of 8 based on a data trending analysis performed in the validation report. Subsequent to publishing the validation report, analyses have been performed for all NWMI processes show[ing] that the extrapolation is no longer necessary. Therefore, the AoA for H/X will be changed to include values from 8 to 1,400.</p>
6.3-10a	November 28, 2016 ML16344A053	<p>Section 5.1 of the validation report NWMI-2014-RPT-006, including Figures 5, 6, and 7, evaluates trends in important validation parameters. The calculation methodology should have a method bias that has neither dependence on a characteristic nor is a smooth function of a parameter. If a trend in a parameter exists, the bias will vary as a function of that trend over the parameter range. If no trend in the Parameter exists, then the bias will be constant over the parameter range.</p> <p>Figure 5 groups individual experiments into sets that correspond to common moderators that include water, graphite, carbon fluoride (CF₂), hydrogen bound in uranium trihydride (UH₃), and no moderator. When the calculation results for these experiment sets are graphed, some of the experimental results lie below a k_{eff} of 1.0. Figure 5 does not represent a bias calculation; it is an evaluation to determine if a trend exists in the moderator parameter that would suggest the method bias (calculated in Section 5.3 of the validation report) has a dependence on moderation. In the Section 5.1.5 discussion of conclusions regarding the trending evaluation depicted in Figure 5, rather than stating the evaluation demonstrates no significant bias with the various moderators, the statement should read, "the evaluation demonstrates no significant trend with respect to moderation that would influence the method bias."</p> <p>Similarly, for Figure 6, the intent is to determine if a trend exists in the reflector parameter that would suggest the method bias (calculated in Section 5.3) has a dependence on reflection. The Section 5.1.6 discussion will be modified to "the evaluation demonstrates no significant trend with respect to reflection that would influence the method bias."</p> <p>For Figure 7, the intent is to determine if a trend exists with respect to chemical form that would suggest the method bias has a dependence on chemical form. Section 5.1.7 will be modified to "the evaluation demonstrates no significant trend with respect to chemical form that would influence the method bias." The method bias is developed in Section 5.3, and all of the experiment sets included in Figures 5 through 7 are evaluated there for the method bias calculation.</p>

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
6.3-10b	November 28, 2016 ML16344A053	The validation area of applicability in the validation report NWMI-2014-RPT-006 will be changed to include only certain chemical forms.
6.3-11a	November 28, 2016 ML16344A053	Subsequent to publishing the validation report NWMI-2014-RPT-006, analyses have been performed for all RPF processes and it can now be concluded that some of the chemical forms and the moderating, reflecting, and absorbing materials listed in the AoA are not necessary to support the NWMI calculations. Therefore, the AoA will be changed to include only certain chemical forms. The moderating materials will be changed to include no moderator and water. The reflecting materials will be changed to include no reflector, water, concrete, polyethylene, and paraffin, and the absorber materials will be changed to include aluminum, steel, stainless steel, polyethylene, and paraffin.
6.3-11b	November 28, 2016 ML16344A053	For systems that have compounds, elements, or nuclides that fall outside the validation AoA in the validation report NWMI-2014-RPT-006, an increased margin of subcriticality (MoS) may be warranted, depending on the specific problem being analyzed. The analyst will document any extrapolation beyond the validation AoA in the calculation and justify whether an increase to the MoS is or is not required.
6.3-12a	November 28, 2016 ML16344A053	Subsequent to the issue of the validation report NWMI-2014-RPT-006, criticality safety calculations have been performed. Each calculation documentation includes an evaluation of the validation AoA. For systems that are outside the validation AoA, an increased MoS may be warranted, depending on the specific problem being analyzed. The analyst will document any extrapolation beyond the validation AoA in the calculation and justify whether an increase to the MoS is or is not required.
6.3-12b	November 28, 2016 ML16344A053	For systems that are outside the validation AoA, an increased MoS may be warranted, depending on the specific problem being analyzed. The analyst will document any extrapolation beyond the validation AoA in the calculation and justify whether an increase to the MoS is or is not required.
6.3-14b	November 28, 2016 ML16344A053	The current design of the hot cell uranium purification equipment does not include passive backflow design features, as the analyzed controls are considered to be adequate. Consideration will be given to providing passive backflow controls for criticality safety, and will be provided in the FSAR as part of the Operating License Application.
6.3-16	November 28, 2016 ML16344A053	As stated in Section 4.2.4 of NWMI-2015-CSE-008, <i>NWMI Preliminary Criticality Safety Evaluation</i> , criticality in each of these systems will be prevented by incorporation of safe-geometry intermediate day tanks in the liquid systems that are physically isolated from any larger-geometry tanks with an air break, such that backflow of uranium to an unsafe geometry is physically impossible. The current wording of the control CSE-08-PDF12 in NWMI-2015-CSE-008 does not reflect the actual design and will be revised to clarify that the control consists of a safe-geometry intermediate day tank that is physically isolated from any larger geometry tank with an air break.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
7.1-1	November 28, 2016 ML16344A053	The instrument and control (I&C) systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, preliminary design of the RPF I&C systems (e.g., details regarding the design bases, technical aspects, safety, philosophy, and objective for all I&C components that monitor and control RPF processes or systems) was not developed to constitute approval of the safety of any design feature or specification. Such approval is anticipated to be made following the evaluation of the final design of the RPF I&C system, and described in the final safety analysis report (FSAR) as part of the Operating License Application.
7.1-2	November 28, 2016 ML16344A053	The I&C systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the preliminary design of the RPF I&C subsystems (including types of parameters monitored, number of channels designed to monitor each parameter, and actuation logic) was not developed to constitute approval of the safety of any design feature or specification. Such approval is anticipated to be made following the evaluation of the final design of the RPF I&C system, and described in the FSAR as part of the Operating License Application.
7.1-3	November 28, 2016 ML16344A053	The I&C systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the preliminary design of the RPF I&C subsystems, including specific details on human-machine interface (HMI), was not developed to constitute approval of the safety of any design feature or specification. Such approval is anticipated to be made following evaluation of the final design of the RPF I&C system, and described in the FSAR as part of the Operating License Application.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
7.2-1a	November 28, 2016 ML16344A053	The I&C systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the preliminary design of the RPF I&C systems describing all of the equipment and major RPF I&C components (e.g., block, logic and schematic diagrams, software flow diagram, and description of how system operational and support requirements and operator interface requirements are met) was not developed to constitute approval of the safety of any design feature or specification. Such approval is anticipated to be made following evaluation of the final design of the RPF I&C system, and described in the FSAR as part of the Operating License Application.
7.2-1b	November 28, 2016 ML16344A053	The I&C systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the preliminary design of the RPF I&C systems describing the detailed methodology and acceptance criteria used to establish trip or actuation setpoints or interlock functions was not developed to constitute approval of the safety of any design feature or specification. Such approval is anticipated to be made following the evaluation of the final design of the RPF I&C system, and described in the FSAR as part of the Operating License Application.
7.2-2	November 28, 2016 ML16344A053	The I&C systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the preliminary design of the RPF I&C systems describing the detailed methodology and operation of the integrated facility process control (FPC) system as it relates to engineered safety features (ESF) managing, monitoring, and actuation was not developed to constitute approval of the safety of any design feature or specification. Such approval is anticipated to be made following the evaluation of the final design of the RPF I&C system, and described in the FSAR as part of the Operating License Application.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
7.2-3	November 28, 2016 ML16344A053	<p>The I&C systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the preliminary design of the RPF I&C systems describing the detailed methodology and operation of the integrated I&C systems was not developed to constitute approval of the safety of any design feature or specification. Such approval is anticipated to be made following the evaluation of the final design of the RPF I&C system, and described in the FSAR as part of the Operating License Application.</p> <p>When the final RPF design is complete, PSAR Chapter 7.0, Table 7-2, will be expanded to provide a cross-reference to the specific section of each I&C section and how the system is suitable for performing the functions stated for each design basis applicability item.</p>
7.3-1	November 28, 2016 ML16344A053	<p>The I&C systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the preliminary design of the RPF I&C systems describing how the key parameters are monitored to ensure adequate criticality control (e.g., instruments to detect deviations from nominal concentrations and quantities, status of software development procedures) was not developed to constitute approval of the safety of any design feature or specification. Such approval is anticipated to be made following the evaluation of the final design of the RPF I&C system, and described in the FSAR as part of the Operating License Application.</p>
7.4-1	November 28, 2016 ML16344A053	<p>The I&C systems preliminary design was developed to ensure the sufficiency of the principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the preliminary design of the RPF I&C systems describing the functionality and operation required of the ESFs was not developed to constitute approval of the safety of any design feature or specification. Such approval is anticipated to be made following the evaluation of the final design of the RPF I&C system, and described in the FSAR as part of the Operating License Application.</p>

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
9.1-5	November 28, 2016 ML16344A053	The need for heating, ventilation, and air conditioning (HVAC) space temperature control in Zone I will be evaluated and determined during the final design phase by performing a heat balance on the Zone I ventilation system. The maximum heat load on the ventilation system is anticipated to be dominated by heat losses from equipment in the Zone I ventilated areas (rather than decay heat) when operating at the maximum uranium throughput. Temperature control will also be evaluated for a loss of ventilation scenario. Results of the evaluation (including space temperature control systems that may be identified by the heat balance) will be described in the FSAR as part of the Operating License Application.
9.3-1	November 28, 2016 ML16344A053	<p>Hot cell fire suppression systems have been commercially available for years and include product designs compliant with NFPA and other relevant industry standards. Selection of the specific hot cell enclosure fire suppression system will be finalized during the final RFP design, along with commitments to design codes, standards, and other referenced documents, including any exceptions or exemptions to the identified requirements. These final designs and commitments will be identified and provided in the FSAR as part of the Operating License Application.</p> <p>Selection of the specific hot cell enclosure fire suppression system and its discharged fire suppressant handling systems will be finalized in the RPF and hot cell final detailed designs, along with commitments to relevant design codes and standards. These final designs and commitments will be identified and provided in the FSAR as part of the Operating License Application.</p>
9.3-2	November 28, 2016 ML16344A053	Commitments to specific building and/or fire codes (e.g., NFPA 801) will be finalized and identified in the RPF final detailed design, both for facility construction and for fire protection program maintenance. This final detailed facility design and the relevant commitments to codes and standards will be identified and provided in the FSAR as part of the Operating License Application.
9.3-3	November 28, 2016 ML16344A053	The fire detection systems selected for the RPF's fire-protected areas, and the corresponding test and maintenance programs, will be included in the final RPF detailed designs, along with commitments to design codes, standards, and other referenced documents, including any exceptions or exemptions to the identified requirements. The final designs, test and maintenance programs, and standards commitments will be identified and provided in the FSAR as part of the Operating License Application.
9.3-4	November 28, 2016 ML16344A053	High efficiency particulate air (HEPA) filter fire protection will be included in the final RPF detailed designs, along with commitments to the relevant design codes, standards, and other referenced documents, including any exceptions or exemptions to the identified requirements. The final fire protection system designs, test and maintenance programs, and standards commitments will be identified and provided in the FSAR as part of the Operating License Application.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
9.3-5a	November 28, 2016 ML16344A053	Once finalized, the detailed design of the facility and its systems (including the final designs for fire protection and the final list of key safety systems and components to address severe accidents), along with the management programs to maintain their reliability, will be identified and provided in the FSAR as part of the Operating License Application.
9.3-5b	November 28, 2016 ML16344A053	Once finalized, the detailed design of the facility and its systems (including the final designs for fire protection and the final list of key safety systems and components to address severe accidents), along with the management programs to maintain their reliability, will be identified and provided in the FSAR as part of the Operating License Application.
9.3-6	November 28, 2016 ML16344A053	The combustible loading analysis results and the administrative program to control combustibles within the RPF will be finalized and provided along with the final detailed design information in the FSAR as part of the Operating License Application.
11.1-1a	November 28, 2016 ML16344A053	The calculations of airborne release in PSAR Section 11.1.1.1.2, "Release of Airborne Radionuclides," are based on the processing of eight targets at MURR. This section will be updated in the FSAR as part of the Operating License Application. NWMI stated during the August 23, 2017, Advisory Committee on Reactor Safeguards (ACRS) subcommittee meeting that routine radioactive release calculations for the maximum amount of targets their license allows them to process would be performed for the operating license application.
11.1-1b	November 28, 2016 ML16344A053	PSAR Section 11.1.1.1.2 operating conditions were slightly more conservative than those described in PSAR Section 4.1.2.1. PSAR Sections 4.1.2.1 and 11.1.1.1.2 operating conditions will be aligned in the FSAR as part of the Operating License Application.
11.1-2a	November 28, 2016 ML16344A053	The dose rates in PSAR Chapter 11.0, Table 11-5, were either based on actual shielding calculations or were the goals/endpoints of the shielding analysis. This table will be updated in the FSAR as part of the Operating License Application when the final shielding design and calculations are completed. Areas identified as controlled access areas, restricted areas, radiation areas, and high radiation areas will be designated based definitions provided in 10 CFR 20, "Standards for Protection Against Radiation," and the predicted doses rates presented by the shielding analysis. Although the Radiation Protection Plan has not yet been developed (i.e., this plan will be supplied with the Operating License Application), dosimetry is anticipated to be required in any restricted area.
11.1-3a	November 28, 2016 ML16344A053	Portal survey monitoring will be in-place at the exit from the restricted area into the administrative area. The specifics on the type and instrument used will be described in the FSAR as part of the Operating License Application and will either be a control that allows standing passive detection or hand and foot monitors.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
11.1-6	November 28, 2016 ML16344A053	PSAR Section 11.1.2, Table 11-5, provides estimated dose rates based on the RPF design. Although a dose rate of zero may not be achievable in the controlled areas, this is the goal. As stated in PSAR Section 11.1.5.5.2, an area monitoring program will be established in the controlled area to demonstrate compliance with public exposure limits in the FSAR as part of the Operating License Application.
11.1-7	November 28, 2016 ML16344A053	Details on the area monitoring program will be provided in the FSAR as part of the Operating License Application. Area monitoring is anticipated to comprise a combination of passive (e.g., thermo-luminescent dosimeter (TLD) or optically-stimulated luminescence (OSL) monitors changed out monthly or quarterly) and active (e.g., energy-compensated Geiger-Mueller (G-M) detector systems with local and remote monitoring capability) monitoring systems located at points in the controlled area that would provide reasonable assurance that radiation areas are not present in the controlled area. The selection of specific instrumentation, range of detection, and alert/alarm setpoints will be consistent with the intent to detect radiation areas where they should not be and alert personnel to this changing condition.
11.2-1b	November 28, 2016 ML16344A053	An official charter describing the authority, duties, and responsibilities of personnel in the waste management organization will be described in the FSAR as part of the Operating License Application.
11.2-5a	November 28, 2016 ML16344A053	The estimates for the laboratory facilities or facility support waste volume projections in PSAR Chapter 19.0, Table 19-13, have no definitive basis and will be further defined in the NWMI Operating License Application.
11.3-1a	November 28, 2016 ML16344A053	Details of how the Irradiated Target Receipt Area will transition between ventilation Zones II and III during operating/maintenance activities will be provided in the FSAR as part of the Operating License Application.
11.3-2a	November 28, 2016 ML16344A053	The RPF preliminary design of ventilation and containment systems was developed to ensure the sufficiency of the principal design criteria, design bases, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. The final facility design of the ventilation and confinement system will be described in the FSAR as part of the Operating License Application.
11.3-2b	November 28, 2016 ML16344A053	The RPF preliminary design of ventilation and containment systems was developed to ensure the sufficiency of the principal design criteria, design bases, general arrangement, and approximate dimensions sufficient to provide reasonable assurance that the final design will conform to the design basis. The final facility design of the ventilation and confinement system will be described in the FSAR as part of the Operating License Application.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
11.3-3	November 28, 2016 ML16344A053	The detailed ventilation system criteria, including minimum flow velocity at openings in each zone, maximum differential pressure across filters, and types of filters to be used (e.g. HEPA, high-efficiency gas adsorption (HEGA)), will be provided in the FSAR as part of the Operating License Application.
13.2-4	November 28, 2016 ML16344A053	The third accident scenario in PSAR Section 13.2.2 is a spill of molybdenum-99 (⁹⁹ Mo) product during container loading operations. This scenario will be reevaluated in the Operating [License] Application. The current scenario assumes three to four times the curie content of a shipping cask and does not take in to account the inner container that would also reduce or eliminate the spill. Operating staff dose estimates and worker stay time (if needed) for accident scenarios will be provided in the FSAR as part of the Operating [License] Application.
13.2-5	November 28, 2016 ML16344A053	Loss of power was identified as an initiating event in numerous RPF accident sequences. NWMI concluded that no additional radiological accidents were present beyond what was identified in the hazard analysis and the quantitative risk analysis. No additional IROFS were identified from loss of power. The summary of radiological consequences from the analysis of other accidents where loss of power was an initiator will be provided in the FSAR as part of the Operating License Application.
13.2-6	November 28, 2016 ML16344A053	Dose consequences were not determined for the RPF natural phenomena events. Using integrated safety analysis (ISA) methodology and since the IROFS and RPF processing areas are designed to withstand design-basis events (DBEs) (highly unlikely events), off-site dose calculation[s] were not completed for the Construction Permit Application. The worker dose estimates for a seismic event during target cask unloading will be developed and provided in the FSAR as part of the Operating License Application.
13.2-8b	November 28, 2016 ML16344A053	The process hazard analysis (PHA) tables for the RPF molybdenum system and waste handling will be updated for hazards associated with the molybdenum resin as part of the ongoing ISA process and will be reflected in the [Operating License Application]. Hazards/accidents will include changing temperature, flow and acid conditions, and their impacts on the anion resin.
13.2-9a	November 28, 2016 ML16344A053	The technical specification[s] will define modes and limiting conditions for operation (and maintenance). As suggested in the RAI, maintenance activities (e.g., removing a cover block to replace a piece of failed equipment) could change the configuration of the facility. For these situations, limits on operations activities or acceptable inventories will be defined and implemented.
13.2-9b	November 28, 2016 ML16344A053	The technical specification[s] will define modes and limiting conditions for operation (and maintenance). As suggested in the RAI, maintenance activities (e.g., removing a cover block to replace a piece of failed equipment) could change the configuration of the facility. For these situations, limits on operations activities or acceptable inventories will be defined and implemented.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
13.2-10	November 28, 2016 ML16344A053	General RPF design features intended to prevent/mitigate a nitric acid fume release include RPF building containment and nitric acid storage tank construction and venting. Specific features will be addressed in the FSAR as part of the Operating License Application.
13.3-1b	November 28, 2016 ML16344A053	Detailed RPF accident scenarios for chemical hazards will be developed, analyzed, and documented in the FSAR as part of the Operating License Application
13.3-2	November 28, 2016 ML16344A053	Specific chemical safety accidents will be developed, analyzed, and documented in the FSAR as part of the Operating License Application, along with identification of relevant technical specifications.
14.0-1	November 28, 2016 ML16344A053	Technical specifications on items involved with preventing release of radioactive materials routinely or in the event of an accident are planned for inclusion in sections that address limiting conditions of operation and surveillance/maintenance in the FSAR as part of the Operating License Application.
12A-3	April 28, 2017 ML17128A065	The individuals who fill the 24-hour on-shift staff positions designated and trained to perform the initial responsibilities of the Emergency Director, Emergency Coordinator, Radiation Safety Officer, and Radiological Assessment Team, until these positions are filled by responding emergency personnel, will be developed and submitted as part of the NWMI Operating License Application.
12A-8	April 28, 2017 ML17128A065	Effluent monitors used to project dose rates and radiological effluent releases and any associated setpoints for such systems will be identified in the NWMI Operating License Application. The manufacturer, detection methodology, and (therefore) instrument setpoints will also be identified in the Operating License Application.
12A-9b	April 28, 2017 ML17128A065	PSAR Chapter 12.0, Appendix A, Table A-1, will be amended such that the emergency action levels (EALs) for each emergency class are consistent with that found in ANSI/ANS 15.16.
12A-9b	April 28, 2017 ML17128A065	PSAR Chapter 12.0, Appendix A, Table A-1, will be amended such that the EALs for each emergency class are consistent with that found in ANSI/ANS 15.16.
6.3-17a	April 28, 2017 ML17128A067	For systems that are outside the validation AoA, an increased MoS may be warranted, depending on the specific problem being analyzed. The analyst will document any extrapolation beyond the validation AoA in the calculation and justify whether an increase to the MoS is or is not required.
6.3-17b	April 28, 2017 ML17128A067	NWMI will continue to develop its computer code validation described in NWMI-2014-RPT-006 prior to the facility final design phase and submission of the Operating License Application.
9.7-4a	April 28, 2017 ML17128A067	The PSAR, Table 3-3, calls out Regulatory Guide 3.10, <i>Liquid Waste Treatment System Design Guide for Plutonium Processing and Fuel Fabrication Plants</i> , as an appropriate design guide. As part of final design, NWMI will evaluate the need for use of Regulatory Guide 1.143, <i>Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants</i> .

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description
6.3-19	September 28, 2017	<p>Prior to end of construction and with the submittal of the Operating License Application, NWMI will ensure that all processes containing SNM within the RPF are evaluated to be subcritical under all normal and credible abnormal conditions. The evaluation will be done consistent with the upper subcritical limit (USL) as established in NWMI-2014-RPT-006, <i>MCNP 6.1 Validations with Continuous Energy ENDF/B-VII.1 Cross-Sections</i> (Rev. 2).</p> <p>Parameters available for nuclear criticality safety (NCS) controls include mass, geometry, density, enrichment, reflection, moderation, concentration, interaction, absorption, volume, heterogeneity, physicochemical form, and process variables. Of these parameters, NWMI will use controls for mass, geometry, moderation, volume, and interaction.</p> <p>NWMI commits to evaluate controlled parameters at the associated safety limits (or more conservatively) and to evaluate parameters that are not controlled at the most reactive credible values. In addition, NWMI acknowledges that the use of a single NCS control to maintain the values of two or more controlled parameters constitutes only one component necessary to meet the double-contingency principle.</p> <p>NWMI will make every effort to use passive engineered controls, in particular, passive engineered geometry control. In addition, NWMI will strive to use NCS controls over reliance on the natural and credible course of events and will use control of two or more parameters over multiple controls on a single parameter, where possible. If the RPF operations rely on two or more controls on a single parameter, NWMI commits to using diverse over-redundant means of control.</p>

A.3 Fulfilled Regulatory Commitments Identified in Responses to Requests for Additional Information

NWMI has fulfilled the following regulatory commitments initially identified in responses to RAIs, as verified by the staff:

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
3.5-1	April 25, 2016 ML16123A119	The Chapter 3.0 bullet in question, located in both referenced sections, Sections 3.5.1.3.1 and 3.5.2.2: <ul style="list-style-type: none"> • Ensure the potential for an inadvertent criticality accident is not credible will be changed to delete the “not credible” language.	Incorporated into PSAR Chapter 3, Revision 2 (ML17221A370).
6.3-6A	April 25, 2016 ML16123A119	NWMI will provide analysis for CAAS coverage in all areas where special nuclear material (SNM) is handled, processed, or stored. PSAR Section 3.5.2.7.7 will be revised to be consistent with this approach.	Incorporated into PSAR Chapter 3, Revision 2 (ML17221A370).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
6.4-1	April 25, 2016 ML16123A119	<p>NWMI commits to the following standards and guides:</p> <ul style="list-style-type: none"> • ANSI/ANS-8.1, <i>Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors</i> - NCS practices, including administrative practices, technical practices, and validation of a calculational method • ANSI/ANS-8.3, <i>Criticality Accident Alarm System</i> - CAAS placement analysis and procedure development; the standard is used as modified by NRC Regulatory Guide 3.71, <i>Nuclear Criticality Safety Standards for Fuels and Material Facilities</i> • ANSI/ANS-8.19, <i>Administrative Practices for Nuclear Criticality Safety</i> - NWMI NCS program development as it applies to organization, administration, roles, and responsibilities • ANSI/ANS-8.20, <i>Nuclear Criticality Safety Training</i> - NCS staff and contractor qualification and training procedure development • ANSI/ANS-8.24, <i>Validation of Neutron Transport Methods for Nuclear Criticality Safety Calculations</i> - Validation of a calculational method • NUREG-1520, <i>Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility</i> - Guidance for meeting 10 CFR 70.61, "Performance Requirements" • NUREG/CR-4604, <i>Statistical Methods for Nuclear Material Management</i> - Guidance for normality testing of the data from critical experiment calculations • NUREG/CR-6698, <i>Guide for Validation of Nuclear Criticality Safety Calculational Methodology</i> - Guidance for validation of a calculational method <p>Chapters 3.0 and 6.0 of the CPA (NWMI-2013-021) will be verified and/or modified to reflect these commitments.</p>	Incorporated into PSAR Chapter 3, Revision 2, and Chapter 6, Revision 2 (ML17221A370).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
G-3	November 28, 2016 ML16344A053	Based on the response to RAI G-3, PSAR Section 13.2, "Analysis of Accidents with Radiological and Criticality Safety Consequences" will be revised to be consistent with the requirements of 10 CFR 70.61, and the maximum hypothetical accident (MHA) discussion in PSAR Section 13.2.1 will be deleted.	Incorporated into PSAR Chapter 13, Revision 2 (ML17221A370).
G-4	November 28, 2016 ML16344A053	SSCs will be designed to protect against both high and [intermediate] consequences. PSAR Section 3.5.1.3.1 described both the high and the [intermediate] consequence performance requirements from 10 CFR 70.61. To eliminate confusion and ensure completeness, these bullets were removed from PSAR Section 3.5.1.3, and the 10 CFR 70.61 performance requirements are referenced.	Incorporated into PSAR Chapter 3, Revision 2 (ML17221A370).
2.2-1a	November 28, 2016 ML16344A053	Information related to aircraft crash impact frequencies will be added to PSAR Section 2.2.2.	Incorporated into PSAR Chapter 2, Revision 2 (ML17221A370).
2.2-1b	November 28, 2016 ML16344A053	PSAR Section 2.2.2.1 had a typographical error. 10.4 km (6.5 mi) is the correct distance from the Columbia Regional Airport to the RPF site, based on Google Earth measurements, and 10.4 km (6.5 mi) is the distance used in the associated calculations. The stated distance of 10.5 km will be changed to 10.4 km (6.5 mi) in PSAR Section 2.2.2.1.	Incorporated into PSAR Chapter 2, Revision 2 (ML17221A370).
2.3-1	November 28, 2016 ML16344A053	The boundary of the "controlled area" described in PSAR Chapters 11.0 and 13.0 is the same as the "exclusion area boundary." PSAR Chapters 2.0, 11.0, and 13.0 will be updated to use the same terminology when referring to the "exclusion area boundary."	Partially incorporated into PSAR Chapter 2, Revision 2, Chapter 11, Revision 1, and Chapter 13, Revision 2 (ML17221A370). PSAR Chapter 13, page 13-52, uses "controlled area or exclusion area boundary," without being clear that these are the same thing.
2.3-2a	November 28, 2016 ML16344A053	The seasonal and annual frequencies of tornadoes, thunderstorms, [lightning], and hail will be added to PSAR Section 2.3.1.7.	Incorporated into PSAR Chapter 2, Revision 2 (ML17221A370).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
2.3-2b	November 28, 2016 ML16344A053	A table of winter weather events since 1996 in Boone County, Missouri will be added to PSAR Section 3.2.5.	Incorporated into PSAR Chapter 2, Revision 2 (ML17221A370). NWMI added the information to PSAR Section 2.3.1.7 instead of PSAR Section 3.2.5.
2.5-4	November 28, 2016 ML16344A053	PSAR Chapter 2.0, Table 2-28, will be revised to incorporate earthquakes since 2002 with a magnitude over 3.0.	Incorporated into PSAR Chapter 2, Revision 2 (ML17221A370). Table 2-28 was renumbered to Table 2-41.
2.5-5	November 28, 2016 ML16344A053	The 2009 International Building Code (IBC) reference callouts in PSAR Chapter 2.0 will be changed to 2012.	Incorporated into PSAR Chapter 2, Revision 2 (ML17221A370).
2.5-8	November 28, 2016 ML16344A053	Reference to the Boone County site as being soil Class D in PSAR Chapter 2.0, Section 2.5.6 will be changed to Class C.	Incorporated into PSAR Chapter 2, Revision 2 (ML17221A370).
3.2-2	November 28, 2016 ML16344A053	The PSAR, including Section 3.2.4.2 and all appropriate supporting documentation, will be modified to state that Regulatory Guide 1.76, <i>Design Basis Tornado and Tornado Missiles for Nuclear Power Plants</i> , will be the basis for tornado wind loads and wind-generated missiles.	Incorporated into PSAR Chapter 3, Revision 2 (ML17221A370).
3.3-1	November 28, 2016 ML16344A053	PSAR Sections 3.3.1 and 3.3.1.1 will be modified to point to PSAR Section 2.4.3 (instead of PSAR section 2.5.3) for flood information.	Incorporated into PSAR Chapter 3, Revision 2 (ML17221A370).
3.4-2a	November 28, 2016 ML16344A053	Table 3-22 will be deleted from PSAR Section [3.4.1.1]. In addition, Regulatory Guide 1.60 will be added to PSAR Section 3.4.1.1 for the determination of the RPF design response spectra. The seismic soil classification for the RPF site is Class C. Thus, the reference to the Boone County site as being soil Class D in PSAR Section 2.5.6 will be changed to Class C. PSAR Section 2.5.6 will be modified to reflect the above information.	Incorporated into PSAR Chapter 2, Revision 2, and Chapter 3, Revision 2 (ML17221A370).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
3.4-3	November 28, 2016 ML16344A053	Table 3-22 will be deleted from PSAR Section [3.4.1.1]. In addition, Regulatory Guide 1.60 will be added to PSAR Section 3.4.1.1 for the determination of the RPF design response spectra. The seismic soil classification for the RPF site is Class C. Thus, the reference to the Boone County site as being soil Class D in PSAR Section 2.5.6 will be changed to Class C. PSAR Section 2.5.6 will be modified to reflect the above information.	Incorporated into PSAR Chapter 2, Revision 2, and Chapter 3, Revision 2 (ML17221A370).
3.5-2	November 28, 2016 ML16344A053	NWMI is using the 10 CFR 70.61 performance requirement for subcriticality. PSAR Section 3.5.1.3 was revised to reflect this, the bullets listing criteria for safety-related SSCs were removed, and 10 CFR 70.61 performance requirements/criteria are referenced.	Incorporated into PSAR Chapter 3, Revision 2 (ML17221A370).
3.5-3a	November 28, 2016 ML16344A053	NWMI has revised its Quality Assurance (QA) Plan to clarify the difference between QL-1 and QL-2. PSAR Section 3.5.1.3 was modified to reflect the changes in the quality level definitions.	Incorporated into PSAR Chapter 3, Revision 2, and Chapter 12, Revision 1 (ML17221A370).
3.5-3b	November 28, 2016 ML16344A053	The QA Plan will be revised to clarify the difference between QL-1 and QL-2.	Incorporated into PSAR Chapter 12, Revision 1 (ML17221A370).
3.5-3c	November 28, 2016 ML16344A053	PSAR Chapter 3.0, Table 3-25, has been modified to match the changes in the NWMI QA Plan.	Incorporated into PSAR Chapter 3, Revision 2 (ML17221A370). Table 3-25 has been renumbered to Table 3-24.
3.5-3d	November 28, 2016 ML16344A053	The QA Plan will be revised to clarify the difference between QL-1 and QL-2. PSAR Section 3.5.1.3 was modified to reflect the changes in the quality level definitions.	Incorporated into PSAR Chapter 3, Revision 2, and Chapter 12, Revision 1 (ML17221A370).
3.5-4a	November 28, 2016 ML16344A053	The QA Plan will be revised to clarify the difference between QL-1 and QL-2. PSAR Chapter 3.0, Table 3-25, was updated to reflect the changes in the quality level definitions.	Incorporated into PSAR Chapter 3, Revision 2, and Chapter 12, Revision 1 (ML17221A370). Table 3-25 has been renumbered to Table 3-24.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
3.5-4b	November 28, 2016 ML16344A053	The QA Plan will be revised to clarify the difference between QL-1 and QL-2. PSAR Section 3.5.1.3 was revised to change the definition of nonsafety-related SSCs, and PSAR Chapter 3.0, Table 3-25, was modified to match the changes in the NWMI QA Plan.	Partially incorporated into PSAR Chapter 3, Revision 2, and Chapter 12, Revision 1 (ML17221A370). No change in the definition of nonsafety-related SSCs in Section 3.5.1.3. Table 3-25 has been renumbered to Table 3-24.
3.5-4c	November 28, 2016 ML16344A053	The QA Plan will be revised to clarify the difference between QL-1 and QL-2. PSAR Section 3.5.1.3 was revised to change the definitions and Table 3-25 was modified to match the changes in the NWMI QA Plan.	Incorporated into PSAR Chapter 3, Revision 2, and Chapter 12, Revision 1 (ML17221A370). Table 3-25 has been renumbered to Table 3-24.
3.5-5a	November 28, 2016 ML16344A053	The QA Plan will be revised to clarify the difference between QL-1 and QL-2. PSAR Section 3.5.1.3 has been revised to change the definition of nonsafety-related SSCs, and Table 3-25 was modified to match the changes in the NWMI QA Plan.	Partially incorporated into PSAR Chapter 3, Revision 2, and Chapter 12, Revision 1 (ML17221A370). No change in the definition of nonsafety-related SSCs in Section 3.5.1.3. Table 3-25 has been renumbered to Table 3-24.
3.5-5b	November 28, 2016 ML16344A053	The QA Plan will be revised to clarify the difference between QL-1 and QL-2. PSAR Section 3.5.1.3 has been revised to change the definition of nonsafety-related SSCs, and Table 3-25 was modified to match the changes in the NWMI QA Plan.	Partially incorporated into PSAR Chapter 3, Revision 2, and Chapter 12, Revision 1 (ML17221A370). No change in the definition of nonsafety-related SSCs in Section 3.5.1.3. Table 3-25 has been renumbered to Table 3-24.
3.5-5c	November 28, 2016 ML16344A053	The QA Plan will be revised to clarify the difference between QL-1 and QL-2. PSAR Section 3.5.1.3 has been revised to change the definition of nonsafety-related SSCs, and Table 3-25 was modified to match the changes in the NWMI QA Plan.	Partially incorporated into PSAR Chapter 3, Revision 2, and Chapter 12, Revision 1 (ML17221A370). No change in the definition of nonsafety-related SSCs in Section 3.5.1.3. Table 3-25 has been renumbered to Table 3-24.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
3.5-5d	November 28, 2016 ML16344A053	The QA Plan will be revised to clarify the difference between QL-1 and QL-2. PSAR Section 3.5.1.3 has been revised to change the definition of nonsafety-related SSCs, and Table 3-25 was modified to match the changes in the NWMI QA Plan.	Partially incorporated into PSAR Chapter 3, Revision 2, and Chapter 12, Revision 1 (ML17221A370). No change in the definition of nonsafety-related SSCs in Section 3.5.1.3. Table 3-25 has been renumbered to Table 3-24.
3.5-6	November 28, 2016 ML16344A053	The first sentence in PSAR section 3.5.2, which pointed to PSAR Section 3.4.1 will be changed to PSAR Section 3.5.1.	Incorporated into PSAR Chapter 3, Revision 2 (ML17221A370).
7.1-3	November 28, 2016 ML16344A053	To be consistent in the PSAR, terms like "operator interface displays" and "operator interface terminals" will be replaced with the single term, HMI (e.g., pages 7-i, 7-iv, 7-4, 7-15, 7-17, 7-18, 7-20, and 7-21).	Partially incorporated into PSAR Chapter 7, Revision 2 (ML17221A370). "Operator interface workstations" used 4 times in Table 7-2 (pages 7-18 and 7-21). "Two or three operator interface stations or HMIs" used on page 7-46 without making clear that these are the same thing.
7.2-2	November 28, 2016 ML16344A053	PSAR Section 7.1 states, "Engineered safety feature (ESF) systems will operate independently from the FPC system or BMS [building management system]." This sentence will be amended in future versions of the PSAR to say, "Engineered safety feature (ESF) systems will operate upon actuation of an alarm setpoint reached for a specific monitoring instrument/device. For redundancy, this will be in addition to the FPC system or BMS ability actuate ESF as needed." By amending this sentence, the descriptions in PSAR Sections 7.2.4.2.2 and 7.2.4.2.6 will be consistent with Section 7.1.	Incorporated into PSAR Chapter 7, Revision 2 (ML17221A370).
8.2-1	November 28, 2016 ML16344A053	PSAR Section 8.1.2 and 8.2 values for uninterruptable power supply (UPS) operation time were changed to 120 minutes to reflect the design basis in PSAR Section 3.5.2.7.9.	Incorporated into PSAR Chapter 8, Revision 2 (ML17221A370).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
8.2-2	November 28, 2016 ML16344A053	The column headings in Table 8-1 of PSAR Chapter 8.0 were changed from "... power requirement" to "...peak power load" to be consistent with the description preceding the table. PSAR Section 8.2.2 will be modified to reflect the peak power of 1,178.6 kW (1,585 hp), as determined from Table 8-1.	Partially incorporated into PSAR Chapter 8, Revision 2 (ML17221A370). Section 8.2.2 was updated, however, Section 8.2 still reflects previous value of 1,000 kW.
9.1-1	November 28, 2016 ML16344A053	PSAR Section 9.1 will be modified to clarify terminology and to correct the apparent discrepancies noted in RAI 9.1-1. The bulleted items in PSAR Section 9.1 will be deleted, and the design basis description in Section 9.1.1 will be modified to cross-reference to PSAR Section 3.5.2.7.12 and to PSAR Chapter 6.0. References to "ventilation system" in PSAR Section 9.1 will be amended to read "facility ventilation system."	Partially incorporated into PSAR Chapter 9, Revision 1 (ML17193A418). Section 9.1.1 references PSAR Section 3.5.7.2, not 3.5.2.7.12 (there is no 3.5.7.2). Not all references to "ventilation system" corrected.
9.1-2	November 28, 2016 ML16344A053	PSAR Section 9.1 will be modified to clarify terminology and to correct the apparent discrepancies noted in RAI 9.1-2. The bulleted items in PSAR Section 9.1 will be deleted. The design basis description in PSAR Section 9.1.1 will be modified to cross-reference to PSAR Section 3.5.2.7.11 and to PSAR Chapter 6.0. References to "offgas treatment system" in PSAR Section 9.1 will be amended to read "process vessel ventilation system."	Partially incorporated into PSAR Chapter 9, Revision 1 (ML17193A418). Section 9.1.1 references PSAR Section 3.5.7.2, not 3.5.2.7.11 (there is no 3.5.7.2). Not all references to "offgas treatment system" corrected.
9.1-3	November 28, 2016 ML16344A053	PSAR Section 9.1 will be modified to clarify terminology and to correct the apparent discrepancies noted in RAI 9.1-3. The bulleted items in PSAR Section 9.1 will be deleted, and the design basis description in PSAR Section 9.1.1 will be modified to cross-reference to PSAR Section 3.5.2.5.12 and to PSAR Chapter 6.0. References to "ventilation system" in PSAR Section 9.1 will be amended to read "facility ventilation system." The supply air is a subsystem of the facility ventilation system. PSAR Section 3.5.2.7.23, "Supply Air System," will be eliminated and appropriate design basis values moved to PSAR Section 3.5.2.7.12, "Facility Ventilation."	Partially incorporated into PSAR Chapter 3, Revision 2, and Chapter 9, Revision 1 (ML17221A370 and ML17193A418). Section 9.1.1 references PSAR Section 3.5.7.2, not 3.5.2.7.12 (there is no 3.5.7.2). Not all references to "ventilation system" corrected.

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
9.1-4	November 28, 2016 ML16344A053	The bulleted items in PSAR Section 9.1 will be deleted, and the design basis description in PSAR Section 9.1.1 will be modified to cross-reference to PSAR Section 3.5.2.7.12 and Chapter 6.0.	Partially incorporated into PSAR Chapter 9, Revision 1 (ML17193A418). Section 9.1.1 references PSAR Section 3.5.7.2, not 3.5.2.7.12 (there is no 3.5.7.2).
9.4-1	November 28, 2016 ML16344A053	PSAR Section 9.4.1 will be modified, and the sentence, "Additional information on the communications system design basis is provided in PSAR Chapter 3.0.," will be deleted, in order to address the information gap regarding the communication system design basis.	Incorporated into PSAR Chapter 9, Revision 1 (ML17193A418).
9.7-1a	November 28, 2016 ML16344A053	PSAR Sections 3.5.2.7 and 9.7 will be aligned with each other to enhance clarity and resolve discrepancies. The design basis bullets in PSAR Section 9.7.1.1 will be deleted, and the design basis description in PSAR Section 9.7.1 will be modified to cross-reference to the appropriate subsection of PSAR Section 3.5.2.7. Subsequent information in PSAR Section 9.7 will focus on the description of systems and components that satisfy the design basis functions.	Partially incorporated into PSAR Chapter 3, Revision 2, and Chapter 9, Revision 1 (ML17221A370 and ML17193A418). Section 9.7.1 references PSAR Section 3.5.2.7, not a subsection of 3.5.2.7, and it is not clear which subsection(s) are applicable.
9.7-1b	November 28, 2016 ML16344A053	The design basis description in PSAR Section 9.7.1 will be modified to cross-reference to the appropriate subsection of PSAR Section 3.5. Subsequent information in PSAR Section 9.7 will focus on the description of systems and components that satisfy the design basis functions.	Partially incorporated into PSAR Chapter 9, Revision 1 (ML17193A418). Section 9.7.1 references PSAR Section 3.5.2.7, not a subsection of 3.5.2.7, and it is not clear which subsection(s) are applicable.
9.7-2	November 28, 2016 ML16344A053	PSAR Sections 3.5.2.7 and 9.7 will be revised to enhance clarity and resolve discrepancies. The RPF system and subsystem designations will be used to align the utility systems. The design basis bullets in PSAR Section 9.7.1.1 will be deleted.	Incorporated into PSAR Chapter 3, Revision 2, and Chapter 9, Revision 1 (ML17221A370 and ML17193A418).
11.1-5	November 28, 2016 ML16344A053	The MHA is being deleted from the PSAR, consistent with the response to RAI G-3.	Incorporated into PSAR Chapter 13, Revision 2 (ML17221A370).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
11.2-1a	November 28, 2016 ML16344A053	<p>The Waste Management Lead (not the Radiation Protection Manager) has responsibility for oversight, handling, and disposal of radioactive wastes. PSAR Section 11.1.2.1.3 will be modified to delete “overseeing handling and disposal of radioactive wastes” from the description of the responsibilities of the Radiation Protection Manager; this information will be added to PSAR Section 11.2.1.3.2.</p> <p>Radioactive waste management responsibilities within the NWMI management structure include:</p> <ul style="list-style-type: none"> • Implements waste management policy • Develops waste management procedures for the processing, packaging, and shipment of radioactive waste from the facility • Processes, packages, and ships radioactive waste from the facility • Provides technical input to the design of equipment and processes • Provides technical input to the waste management training program • Establishes and maintains contractual relationships with waste disposal sites and radioactive waste carriers • Maintains working knowledge of the waste acceptance criteria, standards, guides, and codes with respect to waste disposal • Conducts self-assessments of waste management practices and compliance with procedures in accordance with the waste management self-assessment program <p>These responsibilities will be added to PSAR Section 11.2.1.3.2.</p>	Incorporated into PSAR Chapter 11, Revision 1 (ML17221A370).
11.2-5a	November 28, 2016 ML16344A053	The estimated facility support waste values in Table 19-13 will be added to PSAR Chapter 11.0, Table 11-6.	Incorporated into PSAR Chapter 11, Revision 1 (ML17221A370).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
C.2.2-1	November 28, 2016 ML16344A053	The QA Plan will be revised to clarify the difference between QL-1 and QL-2. PSAR Section 3.5.1.3 was modified to reflect the changes in quality level definitions.	Incorporated into PSAR Chapter 3, Revision 2, and Chapter 12, Revision 1 (ML17221A370).
13.2-2	November 28, 2016 ML16344A053	The MHA discussion in PSAR Section 13.2.1 will be removed from the PSAR, consistent with the response to RAI G-3.	Incorporated into PSAR Chapter 13, Revision 2 (ML17221A370).
13.2-3	November 28, 2016 ML16344A053	The data in Figure 13-2 of PSAR Section 13.2.1 is in units of total effective dose equivalent (TEDE). The labels on the figure will be corrected.	Incorporated into PSAR Chapter 13, Revision 2 (ML17221A370).
13.2-4	November 28, 2016 ML16344A053	In the Construction Permit Application, NWMI originally used both the Radiological Assessment System for Consequence Analysis (RASCAL) and Radiological Safety Analysis Code (RSAC) to model off-site accident consequences. Since the submission of the application, NWMI has selected RSAC for off-site accident consequence modeling. For the liquid spills and spray accident in PSAR Section 13.2.2, NWMI has rerun the off-site dose calculations using RSAC. The nearest permanent resident (432 m [0.27 mi] away) unmitigated dose estimate is 300 mrem, while the maximum receptor location (1,100 m [0.68 mi] away) has a TEDE of 1.8 rem.	Incorporated into PSAR Chapter 13, Revision 2 (ML17221A370).
13.2-7	November 28, 2016 ML16344A053	RSAC has been selected as the model platform for all accident release and dose calculations for the RPF. The accidents described in PSAR Section 13.2.2.2 have been reevaluated using RSAC (instead of RASCAL). The maximum dose to the public occurs at a distance of 1,100 m (0.68 mi).	Partially incorporated into PSAR Chapter 13, Revision 2 (ML17221A370). The uranium separations feed spray release accident is still only evaluated using RASCAL, not RSAC. NWMI states in PSAR Section 13.2.2.7.2 that the uranium feed modeling will be rerun using RSAC as part of the operating license application.

14.0-1	November 28, 2016 ML16344A053	<p>The variables or conditions in the table below are probable subjects of technical specifications based on their involvement with preventing release of radioactive materials routinely or in the event of an accident. This table will be added to the PSAR Chapter 14.0.</p> <table border="1"> <thead> <tr> <th data-bbox="583 411 833 443">Item or variable</th> <th data-bbox="839 411 1086 443">Reason</th> </tr> </thead> <tbody> <tr> <td data-bbox="583 451 833 594">Uranium mass limits on batches, samples, and approved containers^a</td> <td data-bbox="839 451 1086 594">Criticality control</td> </tr> <tr> <td data-bbox="583 602 833 745">Spacing requirements on targets and containers with SNM^a</td> <td data-bbox="839 602 1086 745">Criticality control</td> </tr> <tr> <td data-bbox="583 753 833 814">Floor and sump designs^a</td> <td data-bbox="839 753 1086 814">Criticality control</td> </tr> <tr> <td data-bbox="583 823 833 884">Hot cell liquid confinement^a</td> <td data-bbox="839 823 1086 884">Criticality control</td> </tr> <tr> <td data-bbox="583 892 833 953">Process tank size and spacing^a</td> <td data-bbox="839 892 1086 953">Criticality control</td> </tr> <tr> <td data-bbox="583 961 833 1022">Evaporator condensate monitor</td> <td data-bbox="839 961 1086 1022">Criticality control</td> </tr> <tr> <td data-bbox="583 1031 833 1092">Criticality monitoring system</td> <td data-bbox="839 1031 1086 1092">Criticality control</td> </tr> <tr> <td data-bbox="583 1100 833 1161">In-line uranium content monitoring</td> <td data-bbox="839 1100 1086 1161">Criticality control</td> </tr> <tr> <td data-bbox="583 1169 833 1245">Air pressure differential between zones^a</td> <td data-bbox="839 1169 1086 1245">Control of airborne RAM</td> </tr> <tr> <td data-bbox="583 1253 833 1314">Ventilation system filtration^a</td> <td data-bbox="839 1253 1086 1314">Control of airborne RAM</td> </tr> <tr> <td data-bbox="583 1323 833 1383">Process offgas subsystem</td> <td data-bbox="839 1323 1086 1383">Control of airborne RAM</td> </tr> <tr> <td data-bbox="583 1392 833 1453">Primary offgas relief system</td> <td data-bbox="839 1392 1086 1453">Control of airborne RAM</td> </tr> <tr> <td data-bbox="583 1461 833 1537">Hot cell shield thickness and integrity^a</td> <td data-bbox="839 1461 1086 1537">Occupation and general public dose reduction</td> </tr> <tr> <td data-bbox="583 1545 833 1621">Hot cell secondary confinement boundary^a</td> <td data-bbox="839 1545 1086 1621">Control of airborne RAM</td> </tr> <tr> <td data-bbox="583 1629 833 1705">Double-wall piping</td> <td data-bbox="839 1629 1086 1705">Control of liquid RAM/criticality control</td> </tr> <tr> <td data-bbox="583 1713 833 1789">Process closed heating and cooling loops</td> <td data-bbox="839 1713 1086 1789">Control of both airborne and liquid RAM</td> </tr> </tbody> </table>	Item or variable	Reason	Uranium mass limits on batches, samples, and approved containers ^a	Criticality control	Spacing requirements on targets and containers with SNM ^a	Criticality control	Floor and sump designs ^a	Criticality control	Hot cell liquid confinement ^a	Criticality control	Process tank size and spacing ^a	Criticality control	Evaporator condensate monitor	Criticality control	Criticality monitoring system	Criticality control	In-line uranium content monitoring	Criticality control	Air pressure differential between zones ^a	Control of airborne RAM	Ventilation system filtration ^a	Control of airborne RAM	Process offgas subsystem	Control of airborne RAM	Primary offgas relief system	Control of airborne RAM	Hot cell shield thickness and integrity ^a	Occupation and general public dose reduction	Hot cell secondary confinement boundary ^a	Control of airborne RAM	Double-wall piping	Control of liquid RAM/criticality control	Process closed heating and cooling loops	Control of both airborne and liquid RAM	Incorporated into PSAR Chapter 14, Revision 1 (ML17221A370).
Item or variable	Reason																																				
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RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description		Details of Fulfillment and ADAMS Accession Number
		System backflow prevention devices	Control of liquid RAM/criticality control	
		Stack height ^a	Control of airborne RAM	
		Area radiation monitoring system	Occupation and general public dose reduction	
		^a Items that will significantly influence the final design. RAM = radioactive material, SNM = special nuclear material		
12A-1a	April 28, 2017 ML17128A065	A legible figure of the proposed Northwest Medical Isotopes, LLC (NWMI) Radioisotope Production Facility (RPF) will replace Figure A-3 in NWMI-2013-021, <i>Construction Permit Application for Radioisotope Production Facility</i> , Chapter 12.0, "Conduct of Operations," Appendix A, "Emergency Response Plan."		Incorporated into PSAR Chapter 12, Revision 1 (ML17221A370).
12A-2b	April 28, 2017 ML17128A065	The listing of the Missouri Office of Emergency Coordination as the primary contact for radiological emergencies is in error. The Missouri Office of Emergency Coordination will be replaced with the Missouri State Emergency Management Agency in Section A3.1.2 of PSAR Chapter 12.0, Appendix A.		Incorporated into PSAR Chapter 12, Revision 1 (ML17221A370).
12A-2c	April 28, 2017 ML17128A065	The Missouri State Emergency Management Agency has responsibility for the State's formal radiological emergency preparedness program. Sections A3.1.2 and A3.3.3 of PSAR Chapter 12.0, Appendix A, will be updated to include the responsibility of this agency.		Incorporated into PSAR Chapter 12, Revision 1 (ML17221A370).
12A-4	April 28, 2017 ML17128A065	The following sentence will be added to the first paragraphs of PSAR Chapter 12.0, Appendix A, Sections A4.2 and A4.3, "The appropriate off-site agency described in Section A3.1 (depending on the nature of the emergency), should be notified within 15 minutes of the emergency being declared. Notification shall be made to the NRC Operations Center as soon as is reasonably possible, but no later than one hour after the declared emergency."		Incorporated into PSAR Chapter 12, Revision 1 (ML17221A370).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
12A-5	April 28, 2017 ML17128A065	The eighth bullet under the responsibilities of the Emergency Director will be deleted in PSAR Chapter 12.0, Appendix A, Section A3.3.2. Authorization for reentry after an evacuation will rest with the Emergency Coordinator only.	Incorporated into PSAR Chapter 12, Revision 1 (ML17221A370).
12A-6a	April 28, 2017 ML17128A065	<p>In PSAR Chapter 12.0, Appendix A, Section A3.3.1, a second paragraph will be added to read, "The Safety, Security and Emergency Preparedness Manager will have organizational responsibility for maintenance and implementation of an emergency preparedness program, including this plan, for facility equipment and personnel, including the scheduling and performance of equipment maintenance, personnel training, coordination with off-site support organizations, and drills associated with the emergency plan." The last three bullets in Section A3.3.2 under the responsibilities of the Emergency Coordinator will be deleted. The first item in Section A10.1 will be amended to read, "Initial and annual retraining will be conducted for emergency response personnel to maintain the ability to perform their assigned functions during an emergency event."</p> <p>The third item in Section A10.1 will be amended to read, "Training will also include, as appropriate, information on the use of protective equipment, protective clothing, and monitoring devices used in emergency response relevant to the personnel listed above. Initial training on the emergency plan should nominally take two hours and annual retraining should take one hour to perform."</p>	Incorporated into PSAR Chapter 12, Revision 1 (ML17221A370).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
12A-7	April 28, 2017 ML17128A065	<p>Item one of PSAR Chapter 12.0, Appendix A, Section A10.2, will be amended to read, "Annual on-site emergency drills will be conducted as action drills, with each required emergency measure being executed as realistically as is reasonably possible. Drills should be conducted such that:</p> <ul style="list-style-type: none"> • Qualified individuals for each position in the emergency response organization demonstrate task-related knowledge through periodic participation. • Emergency drills demonstrate that resources are effective and used to control the site, mitigate further damage, control radiological releases, perform required on-site activities under simulated radiation or airborne and other emergency conditions, accurately assess the facility's status during an accident, and initiate recovery. • Emergency drills demonstrate personnel protection measures, including controlling and minimizing hazards to individuals during fires, medical emergencies, mitigation activities, search and rescue, and other similar events. • Emergency drills demonstrate that on-site communications effectively support emergency response activities. • Emergency drills demonstrate that the emergency public information organization disseminates accurate, reliable, timely, and understandable information." <p>The following will be added to Section A10.4.2(1.), "The ability to communicat[e] with off-site responding agencies shall be checked quarterly."</p>	Incorporated into PSAR Chapter 12, Revision 1 (ML17221A370).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
12A-9a	April 28, 2017 ML17128A065	The PSAR, Chapter 13.0, as amended, shows that the maximum dose to the general public will not reach the emergency action levels defined for a Site Area Emergency or a General Emergency. Therefore, PSAR Chapter 12.0, Appendix A, Section A4.4 and A4.5, will be amended to read, "This class of emergency is not credible for the [RPF] because the doses predicted in Chapter 13.0 do not exceed the action levels specified for this emergency in ANSI/ANS 15.16, <i>Emergency Planning for Research Reactors</i> ." The references to these two emergency classification[s] will also be removed from PSAR Chapter 12.0, Appendix A, Table A-1.	Incorporated into PSAR Chapter 12, Revision 1 (ML17221A370).
3.5-10d	April 28, 2017 ML17128A067	There is an error in PSAR Table 3-25. Since part of the process steam system, the in-cell secondary steam loops, has criticality controls, the system should be assigned as QL-1, not QL-2.	Incorporated into PSAR Chapter 3, Revision 2 (ML17221A370). Table3-25 has been renumbered to Table 3-24.
9.7-3a	April 28, 2017 ML17128A067	The PSAR, Section 9.7.2, was rewritten to address the items listed in RAI 9.7-3a. The operational processing capabilities align with the PSAR, Section 4.1.2.1, "Process Design Basis."	Incorporated into PSAR Chapter 9, Revision 1 (ML17193A418).
9.7-3b	April 28, 2017 ML17128A067	The PSAR, Section 9.7.2, was rewritten to address key elements of these requests for additional information (RAI). The inputs to the high-dose waste collection tank are batch transfers. The inputs must be sampled before transferring to the non-criticality safe, high-dose waste collection tank. The high-dose collection tank can be "isolated" (i.e., no incoming waste, agitated, and sampled when needed). Similarly, the high-dose concentrate tank is filled in a batch manner from the high-dose waste concentrator, agitated, and sampled prior to transfer to the solidification process.	Incorporated into PSAR Chapter 9, Revision 1 (ML17193A418).

RAI Number	Date and ADAMS Accession Number for NWMI Response to RAI	Description	Details of Fulfillment and ADAMS Accession Number
9.7-4b	April 28, 2017ML17128A067	The PSAR, Section 9.7.2, was rewritten to address key elements of these requests for additional information (RAI). The inputs to the high-dose waste collection tank are batch transfers. The inputs must be sampled before transferring to the non-criticality safe, high-dose waste collection tank. The high-dose collection tank can be "isolated" (i.e., no incoming waste, agitated, and sampled when needed). Similarly, the high-dose concentrate tank is filled in a batch manner from the high-dose waste concentrator, agitated, and sampled prior to transfer to the solidification process.	Incorporated into PSAR Chapter 9, Revision 1 (ML17193A418).

A.4 Regulatory Commitments Identified Through Meeting with the Advisory Committee on Reactor Safeguards Northwest Medical Isotopes Subcommittee

Following meetings on June 19, July 11, August 22 – 23, and September 21, 2017, with the Advisory Committee on Reactor Safeguards (ACRS) Northwest Medical Isotopes Subcommittee, NWMI identified elements of design, analysis, and administration that require additional information to fully address the comments of the ACRS Northwest Medical Isotopes Subcommittee members. NWMI listed these items in its letters dated September 18, 2017 (Reference 63) and September 28, 2017 (Reference 65). The staff determined that the resolution of these items is not necessary for the issuance of a construction permit, but that the applicant should ensure that these items are fully addressed in the FSAR supporting an NWMI operating license application. The staff is tracking these items as regulatory commitments and will verify their implementation during the review of an NWMI operating license application.

The following regulatory commitments, as identified by NWMI, are the responsibility of the applicant, and have not yet been fulfilled:

Date and ADAMS Accession Number for Correspondence	Description
September 18, 2017 ML17265A048	NWMI will provide an evaluation of the effects of high frequency spectral accelerations (i.e., > 10 hertz) on high-frequency sensitive structures, systems, and components during seismic events (e.g., electrical relays, instrumentation) in its FSAR.
September 18, 2017 ML17265A048	NWMI will provide details on the final grading of site, ensuring that stormwater from localized downpours will be directed around and away from the Radioisotope Production Facility (RPF), in its FSAR.
September 18, 2017 ML17265A048	NWMI will provide a final hazards analysis (FHA) for its facility as part of its FSAR. This FHA will re-examine those accident sequences that were screened out of the preliminary hazards analysis, ensuring that the FHA properly accounts for the accident sequences relevant to the final design of the facility.
September 18, 2017 ML17265A048	NWMI will provide an evaluation of the potential impacts of a uranium fire in the target manufacturing facility licensed under 10 CFR Part 70 on the RPF.
September 18, 2017 ML17265A048	NWMI will provide an evaluation the possible effects of damaged electrical equipment and resulting in possible unexpected effects of interaction between otherwise unrelated, independent, and separate circuits.
September 28, 2017 ML17283A108	NWMI will determine during RPF final design whether facility operations will use an on-site dedicated fire water supply and/or use the City of Columbia fire water supply.
September 28, 2017 ML17283A108	NWMI will resolve the discrepancy in the maximum estimated precipitation for the 24-hour and 48-hour period during the RPF final design and provide the information in the operating license application.

Date and ADAMS Accession Number for Correspondence	Description
September 28, 2017 ML17283A108	NWMI will reexamine and ensure the accuracy of its estimates for aircraft take-offs and landings at the Columbia Regional Airport and for the surrounding heliports.
September 28, 2017 ML17283A108	NWMI will provide its strategy for addressing an extended shutdown of the NWMI production facility.
September 28, 2017 ML17283A108	NWMI will further assess the need for an independent control room as part of our RPF final design.

A.5 Ongoing Research and Development

The provisions of 10 CFR 50.34(a)(8) allow for ongoing research and development to confirm the adequacy of the design of structures, systems, and components (SSCs) to resolve safety questions prior to the completion of construction. In accordance with 10 CFR 50.34(a)(8), and as described in NWMI PSAR Section 1.3.4, "Experimental Facilities and Capabilities," and in NWMI's response to RAI 13.1-2, NWMI has identified ongoing research and development activities, as described below. The staff is tracking these activities and will verify their resolution prior to the completion of construction.

Reference	Date and ADAMS Accession Number for Correspondence	Description
PSAR, Chapter 1	September 8, 2017 ML1717257A022	NWMI will be performing testing to validate the acceptable operating conditions for material and target solution compatibility at MURR and the Department of Energy (DOE) national laboratories. Selected materials will be examined following irradiation testing at fluence levels expected in the operation of the target solution vessel for a 30-year lifetime. The testing will include specific work involving irradiation in a corrosive environment to examine the effects on the properties of selected raw materials and welded samples in an as-received and as-fabricated state.
Response to RAI 13.1-2a	November 28, 2016 ML16344A053	Laboratory resin tests are being completed to determine the interactions between solutions and resin as a function of temperature. The results from these tests will help define necessary hazard and accident controls.
Response to RAI 13.1-2b	November 28, 2016 ML16344A053	Tests are being performed to confirm whether a pressure relief system is feasible to design for an ion exchange column operating at approximately 45 lb/in ² gauge and the uranium separation process approach will continue, or if a design change to the system or implementation of additional controls/process parameters to reduce the likelihood of a reaction or change of separation technology is required.
Response to RAI 13.1-2c	November 28, 2016 ML16344A053	Tests are being performed to evaluate the release of diamylamylphosphonate (DAAP) from the ion exchange column media during operation. Swollen media beads have the potential to release DAAP from the media skeleton to other process vessels. Release of DAAP is considered an issue from both a thermal/radiolytic decomposition perspective (e.g., in concentrators) and represents a potential criticality issue if DAAP were to collect as a separate phase in a non-geometrically favorable vessel.