6.0 ENGINEERED SAFETY FEATURES

Engineered safety features (ESFs) are active or passive features designed to mitigate the consequences of accidents and to keep radiological exposures to the public, the facility staff, and the environment within acceptable values at the Northwest Medical Isotopes, LLC (NWMI or the applicant) proposed production facility. The ESFs associated with confinement of the process radionuclides and hazardous chemicals for the NWMI production facility are summarized in Table 6-1, "Summary of Confinement Engineered Safety Features," of the NWMI preliminary safety analysis report (PSAR).

This chapter of the NWMI construction permit safety evaluation report (SER) describes the U.S. Nuclear Regulatory Commission (NRC) staff (the staff) technical review and evaluation of the preliminary design of the NWMI production facility ESFs, as presented in Chapter 6.0, "Engineered Safety Features," of the NWMI PSAR, Revision 3, as supplemented by the applicant's responses to staff request for additional information (RAI). As explained in SER Section 1.1.1, "Scope of Review," the NWMI construction permit application generally refers to the building that will house all activities, structures, systems, and components (SSCs) related to medical isotope production as its radioisotope production facility (RPF). The RPF consists of the production facility and the target fabrication area as discussed below. In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a license for a Title 10 *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," production facility as "the NWMI production facility" or "the facility." In this SER, the staff refers to the SSCs within the RPF associated with the activities that NWMI states it will conduct under a separate 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," license as "the target fabrication area." The staff reviewed the entire NWMI construction permit application to understand the anticipated interface between and impact on the NWMI production facility from the target fabrication area. However, the staff's findings and conclusions in this SER are limited to whether the NWMI production facility satisfies the 10 CFR Part 50 requirements for the issuance of a construction permit.

6.1 Areas of Review

The staff reviewed NWMI PSAR Chapter 6.0 against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary design and performance of the NWMI production facility ESFs for the purposes of issuance of a construction permit. As part of this review, the staff evaluated descriptions and discussions of the NWMI production facility ESFs, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of ESF systems was evaluated to ensure the sufficiency of principal design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions to provide reasonable assurance that the final design will conform to the design basis. In addition, the staff reviewed NWMI's identification and justification for the selection of those variables, conditions, or other items which are determined to be probable subjects of technical specifications (TSs) for the facility, with special attention given to those items which may significantly influence the final design.

Areas of review for this section included a summary description of the NWMI production facility ESFs, as well as a description of the NWMI production facility confinement and nuclear criticality safety analysis. Within these review areas, the staff assessed, in part, confinement system and components, functional requirements of confinement, management of the nuclear criticality safety program (NCSP), planned responses to criticality accidents, criticality-safety controls, nuclear criticality safety evaluations (CSEs), and the criticality accident alarm system (CAAS).

6.2 Summary of Application

NWMI PSAR Section 6.1, "Summary Description," briefly describes the SSCs that constitute the confinement and criticality safety ESFs in the NWMI production facility design and summarizes the postulated accidents that are mitigated. As described in greater detail in NWMI PSAR Chapter 13.0, "Accident Analysis," specific postulated accident scenarios indicate the need for the confinement ESF.

NWMI PSAR Section 6.2, "Detailed Descriptions," describes the confinement ESF SSCs that will be incorporated into the NWMI production facility's design. These also include the derived confinement items relied on for safety (IROFS) and the dissolver offgas systems. Details include: accidents mitigated, system components, functional requirements, design basis, and test requirements. Information related to the exhaust system, the effluent monitoring system, radioactive release monitoring system and the confinement system mitigation effects, which can reasonably be left for later consideration, will be supplied in the final safety analysis report (FSAR) as part of an NWMI operating license (OL) application.

According to NWMI, the confinement consists of passive and active features designed to mitigate the consequences of accidents and to keep the radiological and chemical exposures to the public, the facility staff, and the environment within acceptable values described in 10 CFR Part 20, "Standards for Protection against Radiation," and 10 CFR 70.61, "Performance requirements." NWMI PSAR Section 6.2 provides the details of design, initiation, and operation of confinement ESF SSCs that are provided to mitigate the design-basis accidents discussed in NWMI PSAR Section 6.1. Confinement of hazardous chemical spills will be provided by berms located within the NWMI production facility.

NWMI PSAR Section 6.3, "Nuclear Criticality Safety in the Radioisotope Production Facility," describes NWMI's preliminary NCSP applicable to the design, construction, and operation of the NWMI production facility, including organization and administration, management measures, and technical practices related to nuclear criticality safety (NCS). Based on its commitments in NWMI PSAR Section 6.3, NWMI's NCSP will be consistent with the following American National Standards Institute/American Nuclear Society (ANSI/ANS) standards, as modified by exceptions in Regulatory Guide (RG) 3.71, "Nuclear Criticality Safety Standards for Fuels and Material Facilities" (Reference 32):

- ANSI/ANS-8.1, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors" (Reference 30),
- ANSI/ANS-8.3, "Criticality Accident Alarm System" (Reference 33),
- ANSI/ANS-8.7, "Nuclear Criticality Safety in the Storage of Fissile Materials" (Reference 34),
- ANSI/ANS-8.10, "Criteria for Nuclear Criticality Safety Controls in Operations with Shielding and Confinement" (Reference 35),
- ANSI/ANS-8.19, "Administrative Practices for Nuclear Criticality Safety" (Reference 36),
- ANSI/ANS-8.20, "Nuclear Criticality Safety Training" (Reference 37),
- ANSI/ANS-8.22, "Nuclear Criticality Safety Based on Limiting and Controlling Moderators" (Reference 38),

- ANSI/ANS-8.23, "Nuclear Criticality Accident Emergency Planning and Response" (Reference 39),
- ANSI/ANS-8.24, "Validation of Neutron Transport Methods for Nuclear Criticality Safety Calculations" (Reference 40), and
- ANSI/ANS-8.26, "Criticality Safety Engineer Training and Qualification Program" (Reference 41).

Commitments related to the design of the NWMI production facility and its SSCs are described in NWMI PSAR Section 6.3, to ensure that subcriticality will be maintained with an acceptable margin of safety under normal and credible abnormal conditions. These commitments include the establishment of engineered and administrative controls; adherence to the double contingency principle (DCP); the installation of a criticality monitoring system; performance of CSEs; the use of management measures such as training, assessments, procedures, postings, labeling, and configuration control; and emergency preparedness and response related to NCS.

6.3 Regulatory Basis and Acceptance Criteria

The staff reviewed NWMI PSAR Chapter 6.0 against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary design and performance of the NWMI production facility ESF systems for the issuance of a construction permit under 10 CFR Part 50. In accordance with paragraph (a) of 10 CFR 50.35, "Issuance of construction permits," a construction permit authorizing NWMI to proceed with construction of a production facility may be issued once the following findings have been made:

(1) NWMI has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final FSAR.

(3) Safety features or components, if any, which require research and development have been described by NWMI and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.

(4) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, "Reactor Site Criteria," the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

With respect to the last of these findings, the staff notes that the requirements of 10 CFR Part 100 is specific to nuclear power reactors and testing facilities, and therefore not applicable to the NWMI production facility. However, the staff evaluated the NWMI production facility's site-specific conditions using site criteria similar to 10 CFR Part 100, by using the guidance in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the

Licensing of Non-Power Reactors, Format and Content," (Reference 8) and NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," (Reference 9) and "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," (Reference 10) and "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors" (Reference 11). The staff's review in Chapter 2.0, "Site Characteristics," of this SER evaluated the geography and demography of the site; nearby industrial, transportation, and military facilities; site meteorology; site hydrology; and site geology, seismology, and geotechnical engineering to ensure that issuance of the construction permit will not be inimical to public health and safety.

6.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the NWMI production facility ESFs are as follows:

- 10 CFR 50.34, "Contents of applications; technical information," paragraph (a), "Preliminary safety analysis report."
- 10 CFR 50.35, "Issuance of construction permits."
- 10 CFR 50.40, "Common standards."
- 10 CFR Part 20, "Standards for Protection against Radiation."

6.3.2 Regulatory Guidance and Acceptance Criteria

The staff used its engineering judgment to determine the extent that established guidance and acceptance criteria were relevant to the review of NWMI's construction permit application, as much of this guidance was originally developed for completed designs of nuclear reactors. For example, in order to determine the acceptance criteria necessary for demonstrating compliance with the NRC's regulatory requirements in 10 CFR, the staff used:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 8).
- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (Reference 9).
- "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogenous Reactors," dated October 17, 2012 (Reference 10).

- "Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogenous Reactors," dated October 17, 2012 (Reference 11).

The ISG Augmenting NUREG-1537 updated and expanded the guidance, originally developed for non-power reactors, to address medical isotope production facilities. Taking into consideration the design and operational similarities between production facilities and fuel cycle facilities licensed under 10 CFR Part 70, applicable non-reactor guidance contained in NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility" (Reference 24) has been incorporated into the Final ISG Augmenting NUREG-1537 for medical isotope production facilities. In the ISG Augmenting NUREG-1537, the staff determined that the use of certain methodologies as described in 10 CFR Part 70, including the performance requirements of 10 CFR 70.61, and NUREG-1520, are an acceptable way of demonstrating adequate safety for a medical isotope production facility.

As appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers standards, ANSI/ANS standards) has been used in the staff's review of NWMI's PSAR. The use of additional guidance is based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG Augmenting NUREG-1537, Parts 1 and 2; and the NWMI PSAR. Additional guidance documents used to evaluate NWMI's PSAR are provided as references in Appendix B, "References," of this SER.

6.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The staff performed an evaluation of the technical information presented in NWMI PSAR Chapter 6.0 to assess the sufficiency of the preliminary design and performance of the NWMI production facility ESFs for the issuance of a construction permit, in accordance with 10 CFR 50.35(a). The sufficiency of the preliminary design and performance standards of the NWMI production facility ESFs is determined by ensuring that the design and performance standards meet applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 6.3, "Regulatory Basis and Acceptance Criteria," of this SER. A summary of the staff's technical evaluation is described in Section 6.5, "Summary and Conclusions," of this SER.

The staff's review also compared the NWMI PSAR Chapter 6.0 documented ESFs and IROFS to the NWMI PSAR Chapter 13.0 unmitigated accident analysis results, IROFS selected to mitigate the bounding accidents, and the success of the selected IROFS and ESFs in reducing the analyzed accident consequences.

For the purposes of issuing a construction permit, the preliminary design of the ESFs may be adequately described at a functional or conceptual level. The staff evaluated the sufficiency of the preliminary design of the ESFs based on the applicant's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety. The staff's evaluation of the preliminary design of the ESFs does not constitute approval of the safety of any design feature or specification. Such approval, if granted, would occur after an evaluation of the final design of the ESFs, as described in the FSAR submitted as part of the NWMI OL application.

6.4.1 Summary Description

The staff evaluated the sufficiency of NWMI's summary description of its production facility's ESFs, as described in NWMI PSAR Section 6.1, for the issuance of a construction permit using the guidance from Section 6.1, "Summary Description," of NUREG-1537, Parts 1 and 2.

In NWMI PSAR Section 6.1, NWMI briefly describes the IROFS that constitute the confinement ESFs in the facility design.

NWMI PSAR Section 6.2 and its subsections provide detailed descriptions of the safety features that are in place to mitigate the accidents identified in NWMI PSAR Chapter 13.0, Section 13.1.3, "Preliminary Hazards Analysis Results." The confinement ESF consists of the following IROFS:

- Hot cell shielding boundary (reduces direct radiation exposure),
- Hot cell confinement boundaries (confines fissile and high dose solids, liquids, and gases, in addition to controlling gaseous releases to the environment), and
- Administrative and passive design features to provide subcritical control of fissionable material.

Based on its review, the staff finds that the summary description of the NWMI production facility ESFs contains enough information for an overall understanding of the functions and relationships of the ESFs to the preliminary design of the facility.

Therefore, the staff concludes that the summary description of the NWMI production facility ESFs, as described in NWMI PSAR Section 6.1, is sufficient to meet the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50.

6.4.2 Confinement

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility's confinement and related systems as described in NWMI PSAR Section 6.2.1, "Confinement," for the issuance of a construction permit in part, by reviewing confinement mitigation requirements, the defined confinement envelope, and detailed descriptions of the ESFs associated with confinement. Additionally, the staff evaluated the passive and active ESF components, under normal and abnormal operational conditions. The detailed functional requirements, design bases, probable subjects of TSs, and testing requirements are not provided in the PSAR, and can reasonably be left for later consideration as these details are not anticipated to significantly impact construction, and will be supplied in the FSAR as part of the OL application. The staff's review of the facility ventilation system is described in further detail in SER Section 9.4.1, "Heating, Ventilation, and Air Conditioning Systems."

Consistent with the review procedures of NUREG-1537, Part 2, Section 6.2.1, "Confinement," the staff: (1) reviewed the accident scenarios analyzed in NWMI PSAR Chapter 13.0 and evaluated whether the confinement will sufficiently mitigate consequences; (2) reviewed design and functional bases against analyzed accidents; and (3) compared diffusion and dispersion of released airborne radionuclides. More specifically, the staff evaluated the following elements of the NWMI production facility's confinement:

- Design bases and functional description of the required mitigative features of the confinement ESF IROFS, derived from the accident scenarios. The accident scenarios are documented in NWMI PSAR Chapter 13.0 and was also the subject of several staff

RAIs. NWMI responded to these RAIs with a commitment to revise and reanalyze the accident scenarios, with the final results to be documented in the FSAR. The preliminary accident scenarios presented in NWMI PSAR Chapter 13.0 documented that the confinement system would be credited to operate and would minimize the release of radiological material to the environment in the event of an accident and reduce the off-site radiological consequences to less than 10 CFR Part 20 release limits during normal and abnormal operations.

- Discussion and analyses, keyed to drawings, of how the structure provides the necessary confinement analyzed in NWMI PSAR Chapter 13.0, with cross reference to other NWMI PSAR sections for discussion of normal operations including Chapter 4.0, “Radioisotope Production Facility Description,” and Chapter 11.0, “Radiation Protection and Waste Management.”

- Discussion of the required limitations on release of confined effluents to the environment.

- Surveillance methods, test requirements, and test intervals are not included in the PSAR, but will be developed by NWMI during final design and documented in the FSAR TSs to ensure operability and availability of the confinement ESF IROFS.

NWMI PSAR Section 6.2.1 provides descriptions of the safety features that are in place to mitigate the accidents identified in Chapter 13.0, Section 13.1.3. The confinement ESF consists of the following general components and their respective functional requirements:

- Confinement system enclosure structures such as sealed flooring, diked areas, and catch basins to contain liquid or solid accidental releases. The staff finds that these structures are used to isolate and confine radioactive material in the event of an accident, thereby preventing the inadvertent spread of contamination.

- Ventilation ducting to provide and maintain negative air pressure in the hot cell and ventilation duct system. Exhaust stack with a radioactivity monitoring system to provide dispersion of radionuclides in normal and abnormal releases. The staff finds that the preliminary confinement system design relies upon several areas of increasing negative pressure zones, intended to always draw from confinement areas of potentially less contamination to confinement areas of potentially increased contamination, prior to being exhausted out the stack.

- Bubble-tight isolation dampers to prevent the inadvertent spread of radiological material. The staff finds that the bubble-tight isolation dampers are arranged to isolate and confine radioactive material in the event of an accident, thereby preventing the inadvertent spread of contamination.

- Zone I exhaust filter trains that remove greater than 99.9 percent of any radiological particulates and remove greater than 90 percent of iodine from the process ventilation stream. The staff finds that the Zone I exhaust filter design efficiencies are greater than the filter efficiencies credited in the mitigated accident analyses documented in NWMI PSAR Chapter 13.0. Therefore, the NWMI PSAR Chapter 13.0 mitigated accident analyses are conservative by overestimating the dose consequence to the public.

- Two 100 percent capacity exhaust fans for redundancy. The staff finds that the Zone I exhaust system design employs two trains of exhaust fans, so as not to be susceptible to single failures.

NWMI PSAR Section 6.2.1.7, “Derived Confinement Items Relied on for Safety,” identifies specific SSCs that are designated as IROFS and will have associated TSs necessary to ensure operation in the production facility:

- Primary offgas relief system to mitigate target offgas system malfunctions, including loss of power during target dissolution operations (IROFS RS-09). The staff finds that the primary offgas system relies on vacuum pumps to maintain a vacuum from the irradiated target dissolver process vessels in order to capture the gaseous effluent from the irradiated target dissolution process vessels. The design uses a redundant pressure relief tank to contain the offgas in the event of an upset condition or loss of power. This redundancy will prevent any release of irradiated target offgas in the event of an accident.

- Active radiation monitoring and isolation of low-dose waste transfer to mitigate the potential spills of high-dose process liquids outside the hot cell shielding boundary (IROFS RS-10). The staff finds that continuous radiation monitoring of the low-dose waste transfer piping would prevent an accidental transfer of waste with a higher dose than desirable from the hot cell to the low-dose waste tank. The continuous radiation monitoring system must provide a low-dose permissive signal to allow movement of the piping isolation valves.

- Cask local ventilation during closure lid removal and docking preparations to mitigate irradiated target cladding failures during transportation, releasing gaseous radionuclides within the cask containment boundary (IROFS RS-13). The staff finds that the ventilation system is expected to provide worker protection in the event of an irradiated target cladding failure and uncontrolled release of radioactive material while the targets are inside the transfer cask and the cask lid is being removed as part of the cask unloading procedures.

- Cask docking port enabling sensor to mitigate the potential failure of the cask lift after removal of the shield plug with irradiated targets in the cask (IROFS RS-15). The staff finds that this system would protect the worker from a direct radiation exposure accident that could occur if the cask is not mated securely to the cask unloading port.

- Process vessel emergency purge system to mitigate hydrogen deflagration or detonation in a process vessel (IROFS FS-03). The staff finds that this is a redundant, passive backup system to provide nitrogen purge gas to prevent an explosive hydrogen gas buildup in the event that any irradiated target process system tanks or piping normal purge gas would malfunction.

- Irradiated target cask lifting fixture to mitigate a dislodged irradiated target shipping cask shield plug during target unloading activities (IROFS FS-04). The staff finds that the cask lifting fixture passively functions to prevent any cask tipping in the unlikely event of a seismic event during cask handling operations where the cask lid would not be installed on the cask.

- Exhaust stack height to mitigate process solutions spills and sprays and carbon fire (IROFS FS-05). The exhaust stack height is credited to disperse any release of radioactive material from the confinement system. The staff finds that Zone I exhaust stack height has been credited in the NWMI PSAR Chapter 13.0 mitigated accident analyses

- Double wall piping to mitigate leaks in piping that passes between confinement enclosures (IROFS CS-09). The staff finds the use of double wall piping to be employed where process piping transfers radioactive material between confinement enclosures (hot cells) to be an effective method of preventing spills or sprays in the event of a single failure, and thereby preventing accidental release of radioactive materials outside of the designed confinement system. An additional safety feature of the double wall piping design is expected to provide passive gravity drain from the piping annulus to leak collection tanks.

- Backflow prevention devices and safe-geometry day tanks to mitigate the potential backflow of process material located inside a confinement boundary to a vessel located outside the confinement via connected process piping due to process upset (IROFS CS-18 and CS-18). The staff finds the use of back flow preventers to be installed on process lines entering confinement areas to be an effective method of preventing accidental exposure of workers to direct radiation hazard solutions in the event of a process upset within the confinement areas.

Based on its review, the staff finds that the level of detail provided on the confinement in the production facility is adequate and supports the preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 6.2.1, allowing the staff to find that: (1) the scenarios for potential accidents at the facility have been analyzed by the applicant. Mitigation of consequences by a confinement system has been proposed in the PSAR analyses for any accident that could lead to potential unacceptable radiological exposures to the public, the facility staff, or the environment. The preliminary designs and functional descriptions of the confinement ESF provide reasonable assurance that the consequences will be limited to the levels found acceptable in the accident analyses of NWMI PSAR Chapter 13.0; and (2) the radiological consequences from accidents to the public, the facility staff, and the environment will be reduced by the proposed confinement ESF to values that do not exceed the applicable limits of 10 CFR Part 20 and are as far below the regulatory limits as is reasonably achievable.

Therefore, the staff concludes that the preliminary design of the NWMI production facility's confinement ESF is sufficient to meet applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration, and will be provided in the FSAR, because it will not significantly alter the construction of the facility. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR.

6.4.3 Containment

The staff evaluated the sufficiency of NWMI's treatment of containment in the production facility, as described in NWMI PSAR Section 6.2.2, "Containment," for the issuance of a construction permit using the guidance and acceptance criteria of Section 6.2.2, "Containment," of

NUREG-1537, Parts 1 and 2. NWMI PSAR Section 6.2.2 states that the accident analysis has not identified a need for a containment system.

The staff's review of the NWMI PSAR Chapter 13.0 unmitigated and mitigated analyses of potential facility accidents confirmed that the credited operation of the confinement system (e.g., Zone I exhaust and filters) provides sufficient reduction of the bounding accident dose consequences so that the mitigated dose consequences to the public are less than the acceptable limits specified by 10 CFR 20.1301, "Dose limits for individual members of the public."

Based on its review, the staff finds that, because NWMI provides a confinement ESF to keep the potential risk to the public from accidents low, containment is not required for normal operation or accident mitigation. The safety analyses in NWMI PSAR Chapter 13.0 show that confinement provides sufficient mitigation for accidents and, therefore, that containment is not necessary.

6.4.4 Emergency Cooling System

The staff evaluated the sufficiency of NWMI's treatment of emergency cooling systems, as described in NWMI PSAR Section 6.2.3, "Emergency Cooling System," for the issuance of a construction permit using the guidance and acceptance criteria of Section 6.2.3, "Emergency Core Cooling System," of NUREG-1537, Parts 1 and 2. As stated in NWMI PSAR Section 6.2.3, "the current accident analysis described in Chapter 13.0 has not identified a need for an emergency cooling system as an engineered safety feature."

Based on its review of the accident analysis provided in NWMI PSAR Chapter 13.0, the staff finds that there are no accidents requiring emergency cooling and, therefore, that an emergency cooling system is not required to mitigate the consequences of an accident in the NWMI production facility.

6.4.5 Nuclear Criticality Safety

The staff evaluated the sufficiency of the NWMI production facility's NCS design criteria and methods, as described in NWMI PSAR Section 6.3, as supplemented by the applicant's responses to RAIs, computer code validation report, and a sampling of preliminary CSEs, for the issuance of a construction permit using the guidance and acceptance criteria from Section 6b.3, "Nuclear Criticality Safety for the Processing Facility," of the ISG Augmenting NUREG-1537, Part 2, which is based on Chapter 5, "Nuclear Criticality Safety," of NUREG-1520 (Reference 24). Specifically, the pertinent portions of Section 6b.3 of this ISG were drawn from Section 5.4.3, "Regulatory Acceptance Criteria," of NUREG-1520.

Consistent with the review procedures of the ISG Augmenting NUREG-1537, Part 2, Section 6b.3, the staff reviewed the applicant's NCSP, including its organization and administration, management measures, and technical practices, as well as a sampling of preliminary CSEs. For the purposes of issuing a construction permit, the staff determined that it was not necessary for NWMI's NCSP to meet all of the acceptance criteria provided in Section 6b.3 of the ISG Augmenting NUREG-1537, Part 2. The staff's review of NWMI PSAR Section 6.3 evaluated the adequacy of pertinent commitments to the design of processes within the NWMI production facility.

Since the design and analyses of the NWMI production facility are in preliminary stages, the scope of the staff's evaluation focused on the NCS design criteria and methods that will be utilized to perform NCS analyses and design the facility so as to maintain subcriticality in fissile material processes within the facility. This section of the SER pertains to the analysis and design methods used to ensure that the facility will remain subcritical under normal and credible abnormal conditions by an acceptable margin of safety. As explained in Chapter 1.0, "The Facility," of this SER, the target fabrication process described in the PSAR will take place in an area separate from the production facility and, as described by NWMI, is not encompassed by the definition of a 10 CFR Part 50 production facility. Activities that are within the scope of this SER review and for which the staff makes 10 CFR Part 50 findings for the issuance of a construction permit consist of all processes within the facility associated with the handling and use of irradiated fissionable material, including irradiated target handling, disassembly, and dissolution, hot cell operations, Molybdenum-99 (Mo-99) recovery, solid and liquid waste processing, and auxiliary operations, such as offgas ventilation, from removal of irradiated targets from their shipping containers until purified material is reintroduced into the target fabrication line. During the course of reviewing NWMI's NCSP, the staff needed additional information to evaluate the adequacy of NWMI's principal design criteria and design bases, in accordance with the requirements of 10 CFR 50.34(a)(3). Therefore, in RAIs 6.3-10 through 6.3-16 (Reference. 13), the staff requested that the applicant provide additional information to demonstrate how it satisfied the acceptance criteria of the ISG Augmenting NUREG-1537, Part 2, Section 6b.3. As discussed below, these RAIs covered the adequacy of the applicant's commitments and the implementation of those commitments in performing NCS evaluations and computer code validation.

The applicant committed to establishing an NCSP meeting the requirements as set forth in the ANSI/ANS standards listed in Section 6.2 above, as modified with the exceptions stated in NRC RG 3.71. NWMI PSAR Section 6.3 states that, for the purpose of design and construction, no deviations from these standards were identified. NWMI PSAR Section 6.3 enumerates roles and responsibilities for the NCSP and staff performing NCS duties. During design and construction, these responsibilities consist mainly of performing criticality analyses and establishing controls to ensure subcriticality under normal and credible abnormal conditions and satisfy the DCP, based on the preliminary design of the facility and any subsequent modifications to that design. Supporting tasks include development of program procedures, peer reviews of CSEs, training and qualification, and criticality code validation. NCS staff consists of an NCS manager, NCS representative, and qualified NCS engineers. NWMI stated that management and staff having NCS responsibilities will satisfy minimum initial qualifications and will be subject to periodic requalification. The PSAR states that training and qualification of personnel with NCS responsibilities will be done in accordance with ANSI/ANS-8.26, which has been endorsed by the NRC in RG 3.71.

During design and construction, NCSP staff will perform periodic inspections and assessments to ensure that activities are in accordance with program and regulatory requirements. These assessments will be in accordance with written procedures and consistent with the requirements as set forth in ANSI/ANS-8.1 and 8.19. In addition, management assessments of the NCSP will be performed by the NCS manager and NCS staff. This will consist of periodic audits by senior applicant management independent of the NCS organization, as well as a triennial external audit to verify program effectiveness. This will be performed by a qualified senior NCS engineer external to the applicant's organization.

The PSAR states that NCS controls are established in reviewed and approved CSEs and implemented in criticality prevention specifications, operating procedures, and postings. This will be done consistent with the ANSI/ANS standards listed in SER Section 6.2 above, in particular ANSI/ANS-8.19. The applicant's described approach is in accordance with industry standards and best practices and is therefore acceptable to the staff. Design and process changes will be documented and reviewed by the NCS representative or an NCS Engineer to ensure that they are within the scope of the existing approved CSE, or else will be reviewed and approved under the applicant's change control process. The change process will be consistent with ANSI/ANS-8.19 and the requirements of 10 CFR 50.59, "Changes, tests, and experiments." All dimensions, nuclear properties, and other features relied on for criticality safety will be documented and verified prior to operation. While the PSAR is not requesting approval to operate the facility at the construction stage, design and configuration control is essential to ensure criticality safety all through the design and construction process. The applicant's commitments in that regard are in accordance with ANSI/ANS-8.19 and standard industry practice and are therefore acceptable to the staff. The staff is tracking these commitments in Appendix A, "Post Construction Permit Activities – Construction Permit Conditions and Final Safety Analysis Report Commitments," of this SER.

In NWMI PSAR Section 6.3, the applicant states that it will document the controlled parameters, limits, and controls in CSEs. Preliminary CSEs are listed in NWMI PSAR Section 6.3.1.1, "Preliminary Criticality Safety Evaluations," along with a list of controlled parameters (NWMI PSAR Table 6-5, "Controlled Nuclear Criticality Safety Parameters") and a description of the double contingency controls (NWMI PSAR Tables 6-6 through 6-13). There is also a detailed description of IROFS in NWMI PSAR Section 6.3.1.2, "Derived Nuclear Criticality Safety Items Relied on for Safety." The staff finds that the controlled parameters in PSAR Table 6-5 appear consistent with the typical control strategy for a nuclear processing facility. For the majority of the processes listed, criticality safety relies on a combination of mass, geometry and/or volume, and interaction control. Geometry is controlled in all but waste liquid processing, consistent with the industry-accepted and NUREG-1520 stated preference for reliance on passive geometry. Similarly, mass is controlled in all but hot cell uranium purification, providing two independent parameters that must fail before criticality is possible. Concentration is controlled in several liquid processing units through control of the fissile mass in solution. Specific criteria for how these parameters will be controlled and how they will be modeled in criticality analysis have been provided in an RAI response (Reference 64). Section 6b.3 of the ISG Augmenting NUREG-1537 specifies that the applicant should commit to technical practices for the control and modeling of controlled parameters. The staff considers these methods to be part of the design basis for the facility, and reviewed these commitments against the acceptance criteria in Section 6b.3 of the applicant's integrated safety analysis (ISA). The commitments were consistent with this guidance, and therefore are acceptable to the staff. The staff also reviewed a representative CSE to verify proper implementation of controls, as discussed below.

The applicant also stated that it would follow the accepted preference of passive over active and engineered over administrative controls. The staff finds that the controls listed in the remainder of NWMI PSAR Chapter 6.0 appear to largely follow this preferred hierarchy of controls. However, a determination of the adequacy of the double contingency controls and IROFS cannot be done apart from a review of the underlying contingencies and accident sequences, which depend on the specific process, its controlled parameters, and spectrum of credible abnormal conditions. It therefore requires review of the CSEs that contain the safety analysis and basis for the controls. Because of this, the staff finds that detailed review of the adequacy of the double contingency controls and IROFS in NWMI PSAR Tables 6-6 through 6-13 and Section 6.3.1.2 can reasonably be left for later consideration, and will be provided, in the FSAR submitted as part of the OL application. During its construction permit review, the staff did not review all of the CSEs, but instead reviewed a representative CSE for the facility to confirm the correct implementation of NWMI's approach. To understand the basis for the double contingency controls in the PSAR and to verify that criticality safety is adequately incorporated into the preliminary design of the facility, the staff reviewed CSE NWMI-2015-CSE-008, "NWMI Preliminary Criticality Safety Evaluation: Hot Cell Uranium Purification," Rev. A (Reference 48). Other CSEs listed pertain to the target fabrication area or auxiliary systems that support both target fabrication and the production facility.

NWMI-2015-CSE-008 describes the criticality safety basis for purification of the uranyl nitrate solution following Mo-99 extraction, and prior to reuse as feed material in the target fabrication area. The process equipment consists of favorable geometry collection tanks, ion exchange columns, thermosiphon evaporators, associated offgas and waste collection tanks, and piping. Favorable geometry is maintained throughout the process, with the spacing and arrangement of safe individual units also controlled. Optimum concentration and reflection up to full flooding of the hot cell is assumed in process tanks and piping, as determined by the applicant's parametric study in the supporting criticality calculation document, NWMI-2015-CRITCALC-006. The CSE states that the uranium in the purification process should not exceed a specified concentration under normal conditions, and that NWMI-2015-CRITCALC-006 analyzed the uranium concentration over a specified range. The staff performed confirmatory analysis, which showed that the optimum concentration for 20 weight percent (wt%) uranium-235 (U-235) uranyl nitrate in a 6-inch (15.24-centimeters (cm)) diameter column with 1-inch (2.54-cm) tight-fitting water reflection occurs around 575 grams of uranium per liter. Moreover, a single such column is still safely subcritical with a calculated effective neutron multiplication factor (k_{eff}) of approximately 0.67. The applicant's parametric study therefore includes the optimum concentration for an array of solution-bearing columns.

Given the substantial margin of subcriticality on individual units and 36-inch (91.44-cm) spacing between most process vessels, tank risers, and piping, the only scenarios leading to criticality are those involving a loss of geometry control, primarily through solution leaks or backflow to unfavorable geometry. In the event of a leak (Scenario C1 from the CSE), uranyl nitrate solution will spread out into a slab on the hot cell floor. The floor is epoxy-sealed and verified flat. Based on the total volume of process vessels available and surface area of the floor, the applicant determined that a catastrophic failure of all process vessels would cause solution to collect in a slab 1.73 cm (0.68 inch) deep. The applicant stated that the single parameter limit for slab depth is 3.76 cm (1.48 inch), indicating that there is a substantial safety margin. The staff did not have the calculations upon which this limit was based, but noted that this value is much less than the safe slab depth for uranyl nitrate. ANSI/ANS-8.1, which has been endorsed in NRC RG 3.71 contains a single-parameter slab depth of 11.9 cm (4.68 inch) for uranyl nitrate enriched up to 10 wt% U-235. With an extrapolation to 20 wt% U-235, the slab depth is reduced somewhat but still will greatly exceed either the applicant's limit of 3.76 cm (1.48 inch) or the actual solution depth of 1.73 cm (0.68 inch). Reaching such a depth would require failure of all process vessels in the unit simultaneously. In addition, the model conservatively assumed that all process vessels remained full, despite having spilled their contents to the floor. The staff therefore concludes that the area will remain subcritical with a substantial margin even in the event of a catastrophic failure of all process vessels.

The other scenario of concern is backflow from favorable to unfavorable geometry equipment. Backflow into the unfavorable geometry offgas treatment system, steam condensate or cooling water return system, water and chemical reagent supply system, fresh resin supply system, or process gas system is considered in Scenarios C3 and C5 through C8. For each scenario, at least two engineered backflow prevention barriers are credited, such that at least two unlikely, independent, and concurrent failures must occur before concentrated solution can backflow to unfavorable geometry, consistent with the DCP. These barriers include passive overflows, air breaks, double block-and-bleed valves, and tank venting. For the steam and cooling water supply system, an intermediate cooling loop is employed, along with process monitoring to detect leaks in either the primary or secondary loop. For the water and chemical reagent supply systems, favorable geometry day tanks equipped with air breaks are used. For the process gas systems, the gas is maintained at a higher pressure than vented process vessels; in the event of loss of pressure, a passive over loop seal prevents backflow to the unfavorable geometry gas supply system. For the fresh resin supply system, a double block-and-bleed valve and paddle blank will be used to satisfy the DCP. While the proper valve alignment and paddle blank installation is considered administrative, the reliability of these measures is enhanced by requiring that the affected equipment be locked and that supervisors verify that the affected equipment is in the proper configuration. Together, these enhanced administrative controls are each sufficient to ensure that each contingency is at least “unlikely.” The applicant justified the use of administrative controls by stating that the use of passive features, such as passive overflows or air breaks, is not practical because the operation requires the process vessels to be pressurized. The staff reviewed the various scenarios resulting in backflow from favorable to unfavorable geometry and concludes that the controls are sufficient to provide for double contingency protection against backflow and are consistent with the preference for passive controls wherever practical. Moreover, the strategy to prevent backflow is consistent with the typical industry practice for solution-processing facilities and is therefore acceptable to the staff. Based on its review of the Hot Cell Uranium Purification System CSE, the staff concludes that the control strategies for scenarios leading to criticality were consistent with industry best practices, were adequate to ensure subcriticality under normal and credible abnormal conditions (except as noted below for certain flooded cases impacted by a reduction in the Upper Subcritical Limit (USL)), and were in compliance with the DCP.

In addition to reviewing a representative CSE for hot cell uranium purification in the production facility, the staff also reviewed the applicant’s validation methodology and results, as documented in its validation report, NWMI-2014-RPT-006, “MCNP 6.1 Validations with Continuous Energy ENDF/B-VII.1 Cross-Sections” (Reference 49). The applicant states in NWMI PSAR Section 6.3 that the validation will follow the requirements as set for in “shall statements” of ANSI/ANS-8.1 and ANSI/ANS-8.24, which include methods and practices related to criticality code validation that have been endorsed in NRC RG 3.71, and which are therefore acceptable to the staff. Specific commitments related to validation are included in NWMI PSAR Section 6.3.1.1. The staff reviewed these commitments and the Validation Report identified above. The MCNP 6.1 code, using the ENDF/B-VII.1 cross section library, is widely used and accepted in the nuclear industry. NWMI PSAR Section 6.3.1.1 states that the design of the facility will be based on a minimum margin of subcriticality (MoS) of 0.05. This is combined with the bias and bias uncertainty determined in the validation study to determine an appropriate USL. The bias and uncertainty were determined by the applicant using a non-parametric method because the underlying condition of data normality was determined to not be satisfied. The statistical method NWMI used to determine bias and bias uncertainty is widely used and accepted in the nuclear industry and by the NRC (e.g., NUREG/CR-6361, “Criticality Benchmark Guide for Light-Water-Reactor Fuel in Transportation and Storage Packages,” and NUREG/CR-6698, “Guide for Validation of Nuclear Criticality Safety Calculational Methodology” (References 50 and 51)). The USL and range of parameters for which the code is considered validated—referred to as the validated Area of Applicability (AOA)—must be adhered to when using criticality calculations in deriving the criticality safety basis of the facility, and are therefore part of the design basis of the facility.

The MCNP 6.1 code, ENDF/B-VII.1 cross section library, and statistical methods in the Validation Report, are widely accepted in the nuclear industry. Overall, the staff finds that the applicant's validation is consistent with industry practice, the aforementioned standards, and NRC regulations and guidance. The staff noted that use of the code to model systems at 20 wt% enrichment is somewhat unusual, and therefore examined the benchmark experiments to ensure that there were sufficient benchmarks similar to those conditions expected to be encountered in the facility to support the use of a minimum subcritical margin of 0.05. The applicant's benchmarks were all drawn from the industry-accepted, "International Handbook of Evaluated Criticality Safety Benchmark Experiments" (IHECSBE) (Reference 52). The IHECSBE is developed and maintained under the International Criticality Safety Benchmark Evaluation Project run out of Idaho National Laboratory. The experiments contained therein have been evaluated to be of benchmark quality for the validation of criticality safety calculational methods. Code bias and bias uncertainty in general vary depending on physical parameters such as the enrichment, moderator-to-uranium ratio, and neutron energy spectrum. In addition to these continuous parameters, bias and uncertainty may also vary with the inclusion of different moderating, reflecting, and neutron absorbing materials. Therefore, the applicant divided the selected IHECSBE benchmarks into several groups to determine if there was a statistically significant difference between them, and also to look for trends as a function of the various continuous parameters mentioned above. Based on the distribution of experiments as a function of the parameters and any trends observed, the applicant derived an AOA in the Validation Report, which was included in the NWMI PSAR as Table 6-4, "Area of Applicability Summary." The staff examined the trending analysis as discussed below.

The staff noted that the applicant divided the benchmarks into low, intermediate, and high enrichment categories, and determined a separate USL for each. For the purpose of trending the bias—consistent with the definitions used in the IHECSBE—low enrichment is less than 10 wt% U-235, intermediate enrichment is between 10 and 30 wt% U-235, and high enrichment is greater than 30 wt% U-235. The applicant divided the data into these three categories, and also performed a linear regression fit of the calculated k_{eff} as a function of enrichment to determine if there was a trend in the bias. The bias appeared to be very consistent across the three different enrichment ranges. While low and high enriched benchmarks were included to investigate any trends in the bias, only the results for the intermediate cases had an impact on the final USL, which included an 0.05 MoS. This is because only the lowest calculated k_{eff} value is used in determining the USL, and that occurs in the intermediate enrichment set of benchmarks.

In addition to enrichment, the applicant trended the calculated k_{eff} against the hydrogen-to-fissile (H/X) ratio and the neutron energy, characterized by the average neutron energy causing fission (ANECF). While there was a slight trend in bias as a function of ANECF, the trend was slight and adequately bounded by the USL. The other parameters exhibited no significant trend. The applicant further divided the data into different subgroups according to moderator type, reflector type, and chemical form. For each case, the applicant stated that there was no significant trend.

To evaluate this hypothesis, the staff performed its own statistical analysis of the different subgroups, as well as by two subgroupings not evaluated in the validation report (grouping by neutron absorber type and homogeneous vs. heterogeneous). First, the staff used the applicant's statistical methods to determine a USL for each subgroup as a function of the five different parameters (moderator, reflector, chemical form, neutron absorber, and homogeneity). For each subdivision of the benchmark data, the staff concluded that the USLs for almost every subgroup were very close and still bounded by the overall USL.

Next, the staff performed a more detailed analysis using the two-sample t-test for two subgroups or one-way analysis of variation for more than two subgroups. At the 95 percent confidence level, the applicant's null hypothesis—that there is no trend—was thus ruled out by the staff for some of the data. In particular, the tests demonstrated a significant difference for some subdivisions by reflector, chemical form, and homogeneity. The test for subdivision by neutron absorber (which was not performed by the applicant) demonstrated that there was a particularly significant difference. The staff examined any subsets of the data that exhibited a large negative bias to see if it was of concern, and finds that those subsets either were still adequately bounded by the overall USL or represented conditions that were no longer considered applicable to anticipated calculation needs for the current facility design.

The staff did not find the applicant's conclusion of no significant trend of k_{eff} against the H/X ratio to be fully supported and determined that there were some statistically significant differences as a function of reflector, chemical form, homogeneity, and neutron absorber type, these differences were bounded by the presence of a net positive bias in the benchmarks as a whole—which was conservatively ignored by the applicant—and by margin in the overall USL. In addition, the validation approach included many different systems in the analysis to look for trends, but many of the observed differences are considered irrelevant by the staff when compared to anticipated conditions supporting the current facility design as reflected in the AOA table.

Finally, the staff compared the AOA definition table, Table 13 of the Validation Report, and Table 6-4 of the NWMI PSAR, against the distribution of benchmarks with respect to the various continuous and discrete parameters mentioned above. The staff finds that the validated AOA was consistent with or conservatively bounded (i.e., was narrower than) the range of parameters covered by the evaluated benchmark experiments.

Verifying that design calculations fall within the validated AOA is done as part of each calculation document. The staff verified that results fell within the validated AOA in the calculation document supporting the CSE reviewed as discussed above, NWMI-2015-CRITCALC-006, Rev. A, "Hot Cell Tank Pit" (Reference 54). This document contains a table comparing its criticality calculations to the AOA table in the Validation Report. All parameters were within bounds, except for calculations involving high values of H/X. These calculations represent highly overmoderated systems. The spectrum is essentially fully thermalized and no additional changes will occur for values beyond the range of the benchmarks considered in the validation. The thermal cross sections of all relevant nuclides (mainly hydrogen, U-235, and uranium-238 (U-238)) are well-known and included in many validation benchmarks. The staff reviewed the applicant's AOA comparison and justification for extrapolating H/X and, based on the foregoing information, finds them to be acceptable. The applicant has stated in NWMI PSAR Section 6.3 that it would document any extrapolation beyond the AOA and justify whether additional margin is needed.

The staff also reviewed the basis for the applicant's MoS of 0.05. The applicant states that a value of 0.05 has been widely used in typical low-enriched uranium (LEU) processing facilities, which it identifies as uranium enriched to less than 20 wt% U-235. The enrichment to be used in the NWMI production facility is just slightly less than 20 wt% U-235. While this meets the definition of LEU in 10 CFR 50.2, "Definitions," NUREG-1520, Revision 2, Appendix B, "Justification for Minimum Margin of Subcriticality for Safety," refers to a typical fuel processing facility limited to about 5 wt% U-235 in stating that a MoS value of 0.05 "has generally been found acceptable for most typical low-enriched fuel cycle facilities without a detailed technical justification." NWMI's facility is not a typical fuel cycle facility in that it is processing irradiated special nuclear material (SNM) and proposes to use a higher uranium enrichment range than comparable fuel cycle facilities in the nuclear industry.

Therefore, a technical justification for the MoS, in light of the relative lack of critical benchmarks in the intermediate enrichment range, as well as the increased sensitivity of k_{eff} to system parameters as enrichment is increased, is needed. The applicant's justification that the neutron spectrum softens with increasing enrichment due to decreasing parasitic absorption on U-235 is overgeneralized. The applicant does not, for example, account for equipment dimensions being reduced for higher enrichments so as to stay within the validation USL. Thus, at higher enrichments there is typically greater neutron leakage from individual units, which can lead to a hardening of the neutron spectrum depending on boundary conditions. Therefore, a general conclusion about shifts in the neutron spectrum with increasing enrichment does not take into account all of the different variables that can vary from one system to another. Such spectral shifts are significant because the pertinent cross sections are less well-known as the neutron energy leaves the thermal range and enters the epithermal or intermediate energy (resonance) range, which could impact the MoS determined to be acceptable.

While there were few benchmarks around 20 wt% U-235, the staff noted that there were many around 10 wt% or 30 wt% U-235. In the staff's experience, the range in enrichment that may be considered applicable is fairly broad. Table 2.3 of NUREG/CR-6698 (Reference 51) indicates that for 20 wt% U-235 calculations, benchmarks from 5 to 35 wt% U-235 are considered applicable. Interpolation of the data over the range of 10 to 30 wt% U-235 indicates that the bias varies smoothly over this range and no deviations from a linear regression fit to the bias is in evidence (except for the added benchmarks discussed below). Nor would any sudden deviation be expected, because both the U-235 and U-238 cross sections are well-characterized and have been benchmarked throughout the validation and a change in enrichment is merely a change in the relative proportions of these well-benchmarked nuclides. Therefore, the staff finds neither any empirical evidence for, nor any theoretical reason to expect, any unusual deviation from a straight-line fit to the bias over this range. In addition, the analytical methods used to calculate k_{eff} for the facility were observed, as discussed above, to be consistent with standard industry practices, which ensure acceptable conservative margin. Moreover, the non-parametric statistical method used to determine the USL is considered to be conservative, as it is based on the lowest calculated k_{eff} for the benchmarks evaluated. For the NWMI production facility, most of the benchmarks analyzed had a slight net positive bias, which is conservatively ignored. Four benchmarks from the IEU-SOL-THERM-001 benchmark set calculated low, with an average negative bias of around 0.015. These four benchmarks were conducted near the design enrichment of 20 wt% U-235, but otherwise had physical characteristics dissimilar to those of the NWMI production facility. These unusual characteristics included having uranyl sulfate in the fissile solution, being graphite-reflected, and containing borated polyethylene as a neutron absorber. Therefore, despite having the same enrichment, the staff does not consider these benchmarks to be highly applicable to the applicant's facility. The effect of these benchmarks is to skew the benchmark distribution such that the benchmarks do not pass the normality test, necessitating use of the conservative non-parametric method. The net effect is to reduce the USL by 0.0166. Whether these IEU-SOL-THERM-001 benchmarks are deemed to represent a real bias effect applicable to the applicant's facility or are spurious, the use of the non-parametric margin introduces added conservatism in determining the USL. Based on the applicant's use of conservative modeling practices, and its conservative validation methodology, the staff has reasonable assurance that a MoS of 0.05 is acceptable to ensure subcriticality of the applicant's proposed facility under normal and credible abnormal conditions.

The reduction in the final USL occurred when the additional benchmarks were incorporated into NWMI's Validation Report. The staff noted that some of the flooded cases in NWMI-2015-CRITCALC-006 had calculated k_{eff} values below the original USL but above the new USL. With the reduction in USL caused by the inclusion of the IEU-SOL-THERM-001 benchmarks, it is therefore possible that some calculations and design analysis for this or other areas will need to be redone. Therefore, in order to confirm that the applicant will integrate the revised USL in the criticality calculations and design analysis of the facility, the staff recommends that the construction permit include the following condition:

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 NWMI PSAR prior to each area being completed, and shall be done consistent with the 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 FSAR.

Besides the preventive controls to ensure subcriticality and to satisfy double contingency, the applicant also included in its design a CAAS, as stated in NWMI PSAR Section 6.3.1.1. NWMI PSAR Section 2.5, "Geology, Seismology, and Geotechnical Engineering," and NWMI PSAR Section 4.3.2.2.5, "Special Nuclear Material Description," states that the CAAS will be installed wherever SNM is handled, processed, or stored. The applicant states that the CAAS will be consistent with ANSI/ANS-8.3, as modified by NRC RG 3.71. The CAAS will be capable of detecting a criticality that produces an absorbed dose in soft tissue of 20 rad of combined neutron and gamma radiation at an unshielded distance of 2 meters in one minute, and that each area in which SNM is stored, handled, or used should be covered by two such detectors. The staff finds that these statements are consistent with the requirements of 10 CFR 70.24, "Criticality accident requirements," paragraph (a) and guidance in NRC RG 3.71, which endorses ANSI/ANS-8.3, and are therefore acceptable to the staff.

The applicant further states that the CAAS will consist of neutron and gamma radiation detectors, will account for intervening shielding and the minimum accident of concern, and will be designed to remain operational during design basis accidents (including providing for use of an uninterruptible power supply). The CAAS will be clearly audible in areas to be evacuatedor will provide alternative notification (e.g., strobing lights) to alert personnel to promptly evacuate. Operations will be rendered safe by shutdown and quarantine if CAAS coverage is lost and cannot be restored within a predetermined number of hours (to be determined on a case-by-case basis allowing for safe shutdown). If compensatory measures are to be used during CAAS outage, they will be included in the OL application. The staff finds that these statements are consistent with the standard industry practice as provided in ANSI/ANS-8.3 and with NRC guidance and are therefore acceptable to the staff.

The applicant states that the evaluation of CAAS coverage will be performed after the final design is complete but prior to startup. The applicant indicated that this analysis will be based on a one-dimensional deterministic, or point-kernel, method, considering the minimum accident of concern (defined as that leading to the threshold dose specified in 10 CFR 70.24(a), the aforementioned 20 rad/min at 2 meters) wherever practical. The point-kernel method is generally conservative in accounting for buildup and attenuation due to intervening shielding. Where this method cannot be practically employed, the applicant states that it will use three-dimensional Monte Carlo analysis. Both methods are widely used in the nuclear industry and are acceptable to the staff. However, the presence of permanently-installed shielding for the facility could interfere with the ability of detectors to detect the minimum accident of concern. If the evaluation is not completed prior to installation of permanent shielding or other structural materials, there is a potential that the final design may not satisfy the detector coverage requirements of 10 CFR 70.24(a), which can be satisfied by 10 CFR Part 50 facilities in lieu of those set forth in 10 CFR 50.68, “Criticality accident requirements.” Because the applicant must provide assurance that the CAAS design will have the capability to detect the minimum accident of concern given the installation of SSCs into the facility, the staff recommends that the construction permit include the following condition:

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 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 10 CFR 70.24(a). This condition terminates once NWMI submits its FSAR.

The installation of a CAAS implies a nontrivial risk of criticality. To protect workers and the public from the consequences of an inadvertent criticality, the applicant also describes its emergency preparedness and response activities in NWMI PSAR Section 6.3. These include the development of emergency procedures, coordination with offsite responders, training and evacuation drills, and provision for fixed and personnel dosimeters and radiation monitoring instrumentation. Emergency procedures will include specifying evacuation routes, making provision for medical treatment and decontamination of exposed individuals, and recovery. Specific requirements related to the impact of firefighting activities on criticality safety will be developed at the OL stage. The above provisions are consistent with the requirements of 10 CFR 70.24(b) and standard industry practice and NRC guidance, and are therefore acceptable to the staff. Additional provisions for responding to deviations involving NCS controls, including event investigation, external reporting, and corrective action, are also described. While emergency planning should be considered in the development of the final design, the staff finds that it can reasonably be left for later consideration, and the final emergency plan will be provided, in the FSAR at the OL stage when the final design is complete. The staff’s evaluation of NWMI’s preliminary emergency plan is discussed in Chapter 12, “Conduct of Operations,” Section 12.4.7, “Emergency Planning,” of this SER.

Based on the foregoing review and proposed permit conditions provided in this section of the SER, the staff finds that there is reasonable assurance that (1) NWMI described an NCSP that will, if properly implemented, ensure that all NWMI production facility processes are subcritical under both normal and credible abnormal conditions, and will comply with the DCP; and (2) the NWMI production facility will have a CAAS and associated emergency procedures to protect workers and the public from the consequences of inadvertent criticality.

6.4.6 Probable Subjects of Technical Specifications

In accordance with 10 CFR 50.34(a)(5), the staff evaluated the sufficiency of the applicant’s identification and justification for the selection of those variables, conditions, or other items which are determined to be probable subjects of TSs for the NWMI production facility ESFs, with special attention given to those items which may significantly influence the final design.

NWMI PSAR Chapter 14.0, “Technical Specifications,” states that the facility ISA process identified SSCs that are defined as IROFS. The importance of these SSCs will also be reflected in the TSs. Each IROFS will be examined and likely translated into a limiting condition for operation (LCO). This translation will involve identifying the most appropriate specification to ensure operability and a corresponding surveillance periodicity for the IROFS.

The PSAR also provided an outline for TSs that will be prepared during the development of the OL application. This outline includes actions, administrative controls, LCOs, limiting safety system settings, safety limits, and surveillance requirements.

In a response to RAI 14.0-1 (Reference 13), NWMI developed a table of potential items or variables that are expected topics of TSs. NWMI states in the response that this table will be included in Chapter 14.0 of the revised NWMI PSAR as Table 14-1 (Reference 56). The staff review of Revision 3 to NWMI PSAR Chapter 14.0 verified that the applicant’s proposed resolution was incorporated into the PSAR.

For criticality control purposes, the applicant proposes the following items as potential topics of TSs:

- Uranium mass limits on batches, samples, and approved containers
- Spacing requirements on targets and containers with SNM
- Floor and sump designs
- Hot cell liquid confinement
- Process tanks size and spacing
- Evaporator condensate monitor
- Criticality monitoring system
- In-line uranium content monitoring

Based on the information provided in NWMI PSAR Chapter 14.0, as supplement by an RAI response (Reference 64), the staff finds that the applicant’s identification and justification for the selection of those variables, conditions, or other items determined to be probable subjects of TSs for criticality control is sufficient and meets the applicable regulatory requirements for the issuance of a construction permit in accordance with 10 CFR Part 50. A detailed evaluation of TSs, including limiting conditions for operation and surveillance requirements, will be performed during the review of NWMI’s OL application.

6.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of the NWMI production facility ESFs, including probable subjects of TSs, as described in NWMI PSAR Chapter 6.0, and finds that the preliminary design of the ESFs, including the principal design criteria; design bases; and information relative to materials of construction, general arrangement, and approximate dimensions: (1) provides reasonable assurance that the final design will conform to the design basis, and (2) meets all applicable regulatory requirements and acceptance criteria in or referenced in the applicable guidance.

Based on these findings and subject to the conditions identified above, the staff makes the following conclusions for the issuance of a construction permit in accordance with 10 CFR Part 50:

(1) NWMI has described the proposed design of the NWMI production facility ESF systems, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public.

(2) Such further technical or design information as may be required to complete the safety analysis of the ESF systems, and which can be reasonably left for later consideration, will be supplied in the FSAR.

(3) There is reasonable assurance that: (i) safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

(4) There is reasonable assurance: (i) that the construction of the NWMI production facility will not endanger the health and safety of the public, and (ii) that construction activities can be conducted in compliance with the Commission's regulations.

(5) The issuance of a permit for the construction of the production facility would not be inimical to the common defense and security or to the health and safety of the public.