9.0 AUXILIARY SYSTEMS

This chapter of the Northwest Medical Isotopes, LLC (NWMI or the applicant) 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 auxiliary systems, as presented in Revision 3 of Chapter 9.0, "Auxiliary Systems," of the NWMI preliminary safety analysis report (PSAR), as supplemented with requests for additional information (RAIs) responses. The preliminary design description of the NWMI production facility auxiliary systems in PSAR Chapter 9.0 focuses on those structures, systems, and components (SSCs) and associated equipment that constitute the auxiliary safety systems and includes the overall design bases, system descriptions and classifications, including functional requirements and system architecture, operational analyses and safety functions, instrumentation and controls (I&C), and probable topics for technical specifications (TSs). 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, 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 of the *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.

9.1 Areas of Review

The staff reviewed NWMI PSAR Chapter 9.0 against applicable regulatory requirements using appropriate regulatory guidance and standards to assess the sufficiency of the preliminary design of the NWMI production facility auxiliary systems 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 auxiliary systems, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of the NWMI production facility auxiliary 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 bases. The information provided by the applicant in NWMI PSAR Chapter 9.0, was also evaluated to determine whether it was adequate to provide reasonable assurance that a 10 CFR Part 50 construction permit for the NWMI production facility could be issued in accordance with applicable regulatory requirements and guidance on the basis that the facility could be constructed without undue risk to the health and safety of the public. 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 TSs for the facility, with special attention given to those items which may significantly influence the final design. The staff documented its review of NWMI's probable subjects of TSs for the facility in Chapter 14.0, "Technical Specifications," of this SER.

9.2 Summary of Application

NWMI PSAR Section 9.1, "Heating Ventilation and Air Conditioning Systems" describes the heating, ventilation, and air conditioning (HVAC) systems that provide clean air to the NWMI production facility at required temperatures and humidity for personnel and equipment, handle process off-gassing, and act to contain airborne radioactivity or toxic material and limit their offsite release to protect the health and safety of workers and the public. The information in PSAR Section 9.1 includes the design bases, system description, including drawings and specifications of principal components and any special materials, operational analysis and safety function, I&C requirements, and probable topics for TSs.

NWMI PSAR Section 9.1.1, "Design Basis," addresses the design basis elements of the ventilation system and the offgas treatment system (OTS). The PSAR states that the ventilation system is designed to provide confinement of hazardous chemical fumes and airborne radiological materials and conditioning of the NWMI production facility environment for facility personnel and equipment. It enumerates five specific ventilation system design basis elements. Additionally, the PSAR states that the OTS will provide primary system functions to protect on-site and off-site personnel from radiological and other industrial related hazards, listing seven specific OTS design basis functions. Additional design basis information is provided in NWMI PSAR Chapter 3.0, "Design of Structures, Systems, and Components."

NWMI PSAR Section 9.1.2, "System Description," describes the NWMI production facility ventilation system, including the air supply, process ventilation and exhaust subsystem. The PSAR describes the system of cascading ventilation zones with successively lower atmospheric pressures through which air flows from areas of lowest concentration of contaminants to the highest. The clean zone, mostly occupied spaces, is at a positive pressure, fed by the air supply subsystem.

The air supply subsystem draws in outside air and heats or cools it as required for the space or equipment being supplied. The various exhaust systems draw from various zones and spaces to maintain the desired differential pressures between zones and across high-efficiency particulate air (HEPA) filters and to collect radioactive and chemical contaminates in the air for treatment before release to the environment. NWMI states in the PSAR that various means, mainly HEPA filtration and activated carbon, will help ensure that air exhausted to the atmosphere meets Title 40 of the *Code of Federal Regulations* Part 61, "National Emission Standards for Hazardous Air Pollutants," 10 CFR Part 20, "Standards For Protection against Radiation," and applicable State law. The exhaust stack is to be monitored for effluents to ensure compliance. NWMI PSAR Table 9-1, "Facility Areas and Respective Confinement Zones," lists all of the spaces in the production facility and shows in which ventilation/confinement zone it is located.

NWMI PSAR Section 9.1.2.1, "Confinement," describes the confinement function, explaining that confinement, an engineered safety feature of the HVAC system, is the boundary that surrounds radioactive materials and the associated ventilation system. In this section, Figures 9-1, "Ground Level Confinement"; 9-2, "Upper Level Confinement"; and 9-3, "Lower Level Confinement," are floor plans of the ground level, upper level, and lower level, respectively, of the NWMI production facility , showing the various confinement zone boundaries.

NWMI PSAR Section 9.1.2.2, "Supply Air System," describes the supply air subsystem followed by Figure 9-4, "Ventilation System Diagram 1," and Figure 9-5, "Ventilation System Diagram 2,"

which are one-line, piping and instrumentation diagrams (P&ID) schematically showing the system configuration, including ducting, fans/blowers, filters, dampers, and instrumentation such as flow cell venturis, differential pressure cells, and pressure cells.

NWMI PSAR Section 9.1.2.3, “Exhaust Air System,” provides a functional description of the exhaust systems, including those for Zone I, Zones II and III, the laboratory exhaust system, and the process vessel ventilation treatment system. Supplemented by Figure 9-6, “Process Flow Diagram for Process Vessel Ventilation Treatment,” a flow diagram (functional block diagram) of the process vessel ventilation treatment system, NWMI PSAR Section 9.1.2.3.4, “Process Vessel Ventilation Treatment System,” describes the process vessel ventilation treatment system. Major components of the process vessel ventilation treatment system are the iodine removal units (IRUs), which employ iodine guard beds. IRUs and iodine guard beds are described in general terms in the PSAR. The several subsystems comprising the iodine removal system for the NWMI production facility are discussed, including the following:

- IRU for target dissolution offgas system
- IRU for uranium (U), molybdenum (Mo), and waste accumulation tanks
- General process vessel vent
- Waste handling systems

NWMI PSAR Section 9.1.2.4, “Cleanroom Subsystem,” covers the cleanroom subsystem. NWMI PSAR Section 9.1.2.5, “Physical Layout and Location,” provides a brief general description of the location of the major ventilation system components, such as air handling units, supply and exhaust fans, filter plenums, and heat recovery coils.

PSAR Section 9.1.2.6, “Principles of Operation,” is a discussion of the ventilation system principles of operation.

PSAR Section 9.1.3, “Operational Analysis and Safety Function,” states that NWMI PSAR Chapter 11.0, “Radiation Protection and Waste Management,” and Chapter 13.0, “Accident Analysis,” provide an analysis of normal and off-normal operation of the production facility HVAC system. NWMI PSAR Section 9.1.3 also discusses how the system provides defense-in-depth and what portions and functions have been defined as items relied on for safety (IROFS).

NWMI PSAR Section 9.1.4, “Instrumentation and Control Requirements,” states that HVAC system control and monitoring is discussed in NWMI PSAR Chapter 7.0, “Instrumentation and Control Systems.” NWMI PSAR Table 9-2, “Indications for Facility Ventilation System Parameters,” summarizes the system parameters and indicates whether they are monitored or alarmed. NWMI PSAR Section 9.1.4 further states that the system sequence of operation will be developed and provided in the operating license (OL) application.

NWMI PSAR Section 9.1.5, “Required Technical Specifications,” states that TSs associated with the ventilation system, if applicable, will be discussed in PSAR Chapter 14.0, “Technical Specifications,” as part of the OL application. Topics that may potentially become TSs are included in Chapter 14.0 of the NWMI PSAR.

NWMI PSAR Section 9.2, “Material Handling,” consists of a single paragraph, which states, “The RPF does not handle or store reactor fuel. Material handling activities are discussed in

[PSAR] Chapter 4.0, 'Radioisotope Production Facility Description,' Sections 4.3 and 4.4, and are analyzed in Chapter 13.0."

NWMI PSAR Section 9.3, "Fire Protection Systems and Programs" describes the NWMI production facility fire protection systems and programs.

NWMI PSAR Section 9.3.1, "Design Basis," states that the fire protection system design provides detection and suppression of fires in the production facility, including notification, transmitting the notification to the central alarm station and control room, suppressing small fires, and preventing small fires from becoming large fires. Additional information on the design basis is provided in NWMI PSAR Chapter 3.0.

NWMI PSAR Section 9.3.2, "System Description," includes the fire suppression subsystem, the fire detection and alarm subsystem, fire extinguishers, operational analysis and safety function, the production facility fire areas, other related production facility systems, and related architectural features. The discussion in the PSAR provides a functional description of the system.

NWMI PSAR Section 9.4, "Communication Systems" provides a preliminary, high-level, functional overview of the NWMI production facility communication system. It discusses the design basis and provides a high-level functional description of the systems, explaining that production facility communication systems will relay information during normal and emergency conditions for general operations and emergencies within the production facility.

NWMI PSAR Section 9.5, is "Possession and Use of Byproduct, Source, and Special Nuclear Material." The design basis for possession and use of byproduct, and special nuclear material (SNM), as given in NWMI PSAR Section 9.5.1, "Design Basis," is that the NWMI production facility is designed to ensure that (a) no uncontrolled release of radioactive materials (solid, liquid, or airborne) from the facilities can occur and (b) personnel exposures to radiation, including ingestion or inhalation, do not exceed limiting values in 10 CFR Part 20, and are consistent with the NWMI as-low-as-is-reasonably-achievable (ALARA) program as described in NWMI PSAR Chapter 11.0.

NWMI PSAR Section 9.5.2, "System Description," defines SNM, byproduct material, and source material, states the types of byproduct and SNM to be handled in the RPF, and states that no source material will be present.

NWMI PSAR Section 9.5.3, "Operational Analysis and Safety Function," states that the criticality safety of SNM is discussed in NWMI PSAR Chapter 4.0, "Radioisotope Production Facility Description," and Chapter 6.0, "Engineered Safety Features," and the material control and accounting of SNM is discussed in NWMI PSAR Chapter 12.0, "Conduct of Operations," Section 12.13, "Material Control and Accounting Program." The byproduct materials associated with the NWMI production facility process are addressed in NWMI PSAR Chapter 4.0, and byproduct materials within the waste processing and storage areas are described in NWMI PSAR Section 9.7.2, "Control and Storage of Radioactive Waste," and NWMI PSAR Chapter 11.0, Section 11.2, "Radioactive Waste Management."

NWMI PSAR Section 9.5.4, "Instrumentation and Control Requirements," states that I&C requirements for the processes associated with the possession and use of byproduct materials and SNM for the NWMI production facility are discussed in NWMI PSAR Chapter 7.0, and NWMI PSAR Section 12.13.

NWMI PSAR Section 9.5.5, “Required Technical Specifications,” states, “The technical specifications associated with the possession and use of byproduct materials and SNM, if applicable, will be discussed in [FSAR] Chapter 14.0 as part of the Operating License Application.”

NWMI PSAR Section 9.6, “Cover Gas Control in Closed Primary Coolant Systems,” describes the production facility systems that handle radioactive gases from process vessels. The information in NWMI PSAR Section 9.6 includes the design bases, system description, operational analysis and safety function, and I&C requirements.

NWMI PSAR Section 9.6.1, “Design Basis,” states that information on the design basis of cover gas control in the closed primary coolant system is provided in NWMI PSAR Chapter 3.0, Section 3.5.2.7, “Radioisotope Production Facility Specific System Design Basis Functions and Values.”

NWMI PSAR Section 9.6.2, “System Description,” explains how the cover gas control function is accomplished in the process chilled water system by the “sweep” gas system supplied to the cooling water tanks by the plant air supply system. The process vessel vent system collects the purge gas from each of the tanks and merges the collected vent subsystems into the main facility ventilation system for treatment and filtration.

NWMI PSAR Section 9.6.3, “Operational Analysis and Safety Function,” references NWMI PSAR Chapter 13.0, which discusses the potential for ignition of combustible solids and liquids or explosive gasses in close proximity to process streams.

NWMI PSAR Section 9.6.4, “Instrumentation and Control Requirements,” states that I&C requirements for cover gas control in the closed primary coolant system are discussed in NWMI PSAR Chapter 7.0.

NWMI PSAR Section 9.6.5, “Required Technical Specifications,” states that the TS associated with cover gas control in the closed primary coolant system, if applicable, will be discussed in Chapter 14.0 of the final safety analyses report (FSAR) as part of the OL application. Topics that may potentially become TSs are included in Chapter 14.0 of the NWMI PSAR and evaluated by the staff in Chapter 14.0 of this SER.

NWMI PSAR Section 9.7, “Other Auxiliary Systems,” describes the auxiliary systems not captured in other chapters of the NWMI PSAR in Sections 9.7.1 through 9.7.4, as listed below. The information in these PSAR sections includes the design basis, system description, operational analysis and safety function, I&C requirements, and potential topics for TSs of the other auxiliary systems. The other auxiliary systems, described in NWMI PSAR Section 9.7, that are important to the safety of workers and the public, and the protection of the environment include the following:

- Utility Systems (NWMI PSAR Section 9.7.1)
- Control and Storage of Radioactive Waste (NWMI PSAR Section 9.7.2)
- Analytical Laboratory (NWMI PSAR Section 9.7.3)
- Chemical Supply (NWMI PSAR Section 9.7.4)

NWMI PSAR Section 9.7.1, states, in part, “The utility systems will provide heating, cooling, process water, compressed gases, instrument, motive force, and other functions to support

uranium processing, waste handling, and ventilation," for the NWMI production facility. The utility systems include the following subsystems as described in the associated NWMI PSAR subsections:

- Process Steam (NWMI PSAR Section 9.7.1.2.1)
- Chilled Water (NWMI PSAR Section 9.7.1.2.2)
- Demineralized Water (NWMI PSAR Section 9.7.1.2.3)
- Plant and Instrument Air (NWMI PSAR Section 9.7.1.2.4)
- Gas (industrial/process) Supply (NWMI PSAR Section 9.7.1.2.5)
- Purge Gas (NWMI PSAR Section 9.7.1.2.6)

NWMI PSAR Section 9.7.1.1, "Design Basis," states that the utility systems design basis is provided in Chapter 3.0, Section 3.5.2.7.

NWMI PSAR Section 9.7.1.2, "System Description," provides the system descriptions for the utility systems, including various diagrams, system piping and instrumentation diagrams (P&IDs), and tables.

NWMI PSAR Section 9.7.1.3, "Operational Analysis and Safety Function," states that PSAR Chapter 13.0 presents the associated accident analysis, discussing defense-in-depth measures and IROFS.

NWMI PSAR Section 9.7.1.4 "Instrumentation and Control Requirements," states that utility system I&C requirements are discussed in PSAR Chapter 7.0.

NWMI PSAR Section 9.7.1.5, "Required Technical Specifications," states that utility system TSs, if applicable, will be discussed in Chapter 14.0, "Technical Specifications," of the FSAR as part of the OL application. Topics that may potentially become TSs are included in Chapter 14.0 of the NWMI PSAR.

NWMI PSAR Section 9.7.2 states that the radioactive waste control and storage systems for the production facility are designed to ensure that (1) any potential malfunctions do not cause accidents or uncontrolled release of radioactivity, and (2) in the event of radioactivity release, potential radiation exposures would not exceed 10 CFR Part 20 limits and remain consistent with ALARA.

NWMI PSAR Section 9.7.2.1, "Design Basis," states that the waste handling system design basis is provided in Chapter 3.5.2.7.

NWMI PSAR Section 9.7.2.2, "System Description," provides the system descriptions for radioactive control and storage systems, including various diagrams, system P&IDs, and tables. These systems include: (a) high-dose liquid handling; (b) low-dose liquid handling; (c) spent resin de-watering; (d) solid waste encapsulation; (e) high-dose waste decay; (f) high-dose waste handling; (g) waste handling; and (h) waste staging and shipping building.

NWMI PSAR Section 9.7.2.3, "Operational Analysis and Safety Function," refers to PSAR Chapter 13.0 which presents the associated accident analysis and identifies IROFS.

NWMI PSAR Section 9.7.2.4, "Instrumentation and Control Requirements," states that radioactive waste system I&C requirements are discussed in PSAR Chapter 7.0.

NWMI PSAR Section 9.7.2.5, “Required Technical Specifications,” states that radioactive waste system TSs, if applicable, will be discussed in Chapter 14.0 of the FSAR as part of the OL application. Topics that may potentially become TSs are included in Chapter 14.0 of the PSAR.

NWMI PSAR Section 9.7.3, “Analytical Laboratory,” provides a high-level, functional description of the analytical laboratory, in which samples from various stages of Mo-99 production, and U recycling processes of the production facility are analyzed.

NWMI PSAR Section 9.7.3.1, “Design Basis,” provides that the analytical laboratory will enable analysis of (1) mass, concentration, and purity of SNM, (2) concentration of Mo-99 product and product impurities, (3) process stream chemical and radionuclide concentrations, and (4) chemical and radionuclide analysis for waste handling and disposition.

NWMI PSAR Section 9.7.3.2, “System Description,” provides that the laboratory will be equipped with the necessary equipment with which to analyze hazardous (including radioactive) process samples, including hoods, glove boxes, counters for analysis apparatus and instruments, and storage for tools, equipment and supplies. This subsection provides NWMI PSAR Figure 9-35, “Analytical Laboratory Layout.”

NWMI PSAR Section 9.7.3.3, “Operational Analysis and Safety Function,” refers to NWMI PSAR Chapter 13.0, which contains the relevant accident analysis. Defense-in-depth measures focus on adherence to procedures for sampling, analysis, waste/residue disposal, and radiological, chemical, and equipment safety. No IROFS were identified by NWMI for the analytical laboratory.

NWMI PSAR Section 9.7.3.4, “Instrumentation and Control Requirements,” states that analytical laboratory I&C requirements are discussed in NWMI PSAR Chapter 7.0.

NWMI PSAR Section 9.7.3.5, “Required Technical Specifications,” states that analytical laboratory TSs, if applicable, will be discussed in Chapter 14.0 of the FSAR as part of the OL application. Topics that may potentially become TSs are included in Chapter 14.0 of the NWMI PSAR.

NWMI PSAR Section 9.7.4, “Chemical Supply,” states that the chemical supply system provides for storage and supply of chemicals to process systems.

NWMI PSAR Section 9.7.4.1, “Design Basis,” states that the system is designed to supply solutions in the required concentrations for use in the NWMI production facility processes, including target dissolution, Mo-99 recovery and purification, and waste management.

NWMI PSAR Section 9.7.4.2, “System Description,” states that the system comprises tanks and cabinets for storage of flammable materials, storage and segregation of incompatible materials, and storage of solid process chemicals. The system description is illustrated by various diagrams and tables.

PSAR Section 9.7.4.3, “Operational Analysis and Safety Function,” refers to NWMI PSAR Chapter 13.0, for the chemical supply system-related accident analysis, discusses defense-in-depth safety measures, including compliance with relevant provisions of U.S.

Environmental Protection Agency and Occupational Safety and Health Administration regulations, and lists preliminary designated IROFS.

NWMI PSAR Section 9.7.4.4, "Instrumentation and Control Requirements," states that the chemical supply system I&C requirements are discussed in NWMI PSAR Chapter 7.0.

NWMI PSAR Section 9.7.4.5, "Required Technical Specifications," states that the chemical supply system TSs, if applicable, will be discussed in Chapter 14.0 of the FSAR as part of the OL application. Topics that may potentially become TSs are included in Chapter 14.0 of the NWMI PSAR.

9.3 Regulatory Basis and Acceptance Criteria

The staff reviewed NWMI PSAR Chapter 9.0 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 auxiliary 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 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.

9.3.1 Applicable Regulatory Requirements

The applicable regulatory requirements for the evaluation of the NWMI production facility auxiliary systems 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."

9.3.2 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 Homogeneous 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 Homogeneous Reactors," dated October 17, 2012 (Reference 11).

The ISG Augmenting NUREG-1537, Parts 1 and 2 updated and expanded the guidance, originally developed for non-power reactors, to address medical isotope production facilities. For example, whenever the word "reactor" appears in NUREG-1537, Parts 1 and 2 it can be understood to mean "radioisotope production facility" as applicable. In addition, the ISG, at page vi, states that use of Integrated Safety Analysis methodologies as described in 10 CFR Part 70 and NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility" (Reference 24), application of the radiological and chemical consequence likelihood criteria contained in the performance requirements of 10 CFR 70.61, "Performance requirements," designation of IROFS, and establishment of management measures are acceptable ways of demonstrating adequate safety for a medical isotope production facility. The ISG also states that applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features and alternate methods of assuring the availability and reliability of safety features. The ISG notes that the use of the term "performance requirements" when referring to 10 CFR Part 70, Subpart H, does not mean that the performance requirements in Subpart H are required for a RPF license, only that their use may be found acceptable. NWMI used this ISG to inform the design of its facility and prepare its PSAR. The staff's use of reactor-based guidance in its evaluation of the NWMI PSAR is consistent with the ISG Augmenting NUREG-1537.

As appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers standards, American National Standards Institute/American Nuclear Society 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.

9.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The staff performed an evaluation of the technical information presented in NWMI PSAR Chapter 9.0 to assess the sufficiency of the preliminary design and performance of the NWMI production facility auxiliary systems for the issuance of a construction permit, in accordance with 10 CFR Part 50. The sufficiency of the preliminary design of the NWMI production facility auxiliary systems is determined by ensuring the design is consistent with the design bases, which meet the applicable regulatory requirements, guidance, and acceptance criteria, as discussed in Section 9.3, "Regulatory Basis and Acceptance Criteria," of this SER. A summary of the staff's technical evaluation is described in Section 9.5, "Summary and Conclusions," of this SER.

For the purposes of issuing a construction permit, the preliminary design of the NWMI production facility auxiliary systems may be adequately described at a functional or conceptual level. The staff evaluated the sufficiency of the preliminary design of the NWMI production facility auxiliary systems 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 NWMI production facility auxiliary systems 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 NWMI production facility auxiliary systems, as described in the FSAR submitted as part of NWMI's OL application.

9.4.1 Heating, Ventilation, and Air Conditioning Systems

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility HVAC systems, as described in NWMI PSAR Section 9.1, for the issuance of a construction permit in accordance with the applicable guidance as cited in Section 9.3 of this SER, including the information on design basis, system description, operational analysis and safety function, I&C requirements, and topics of required TSs. The purpose of the review of the preliminary design of the HVAC systems is to (a) verify that the design bases reflect all applicable functional, structural, and safety requirements, all applicable/relevant regulatory requirements and guidance, and all applicable/relevant industry guidance, endorsed or recognized by the staff, and (b) verify that the preliminary design is consistent with the design bases and provides reasonable assurance that construction of the facility can be conducted such that the as-built facility is consistent with the approved design. Thus, emphasis in the review at this stage was placed on evaluating the completeness and consistency of design basis information.

NWMI PSAR Section 9.1.1 provides the design basis for the NWMI production facility HVAC systems with additional design basis information given in PSAR Chapter 3.0. The PSAR also states that the ventilation system is designed to provide confinement of hazardous chemical fumes and airborne radiological materials and conditioning of the production facility environment for facility personnel and equipment.

NWMI PSAR Section 9.1.2 provides a discussion of the NWMI production facility ventilation system. NWMI states that the ventilation system will maintain a series of cascading pressure zones to draw air from the cleanest areas of the facility to the most contaminated areas. Zone IV will be a clean zone that is independent of other ventilation zones and will be positively pressurized with respect to the atmosphere. Zone III will be the cleanest of the potentially contaminated zones. It is considered to be a tertiary confinement barrier and includes the walls, floor, ceiling, and doors of the corridor that surround the operating galleries and the mechanical mezzanine. Zone II is the secondary confinement subsystem and includes the walls, floors, ceilings, and doors of the laboratories including gloveboxes, HEPA filter rooms, and the Zone II ventilation exhaust subsystem. Zone I is the initial confinement barrier and includes gloveboxes, vessels, tanks, piping, hot cells and the Zone I exhaust subsystem.

NWMI PSAR Section 9.1.2.3.1, “Zone I Exhaust System,” states, in part, “Space temperature control will not be provided for Zone I spaces unless thermal loads are expected to cause temperatures to exceed equipment operating ranges without additional cooling.” To gain an understanding of the HVAC temperature control for the Zone 1 ventilation system, the staff requested additional information in RAI 9.1-5. In its response to RAI 9.1-5 (Reference 57), the applicant states, “The need for 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.” The staff finds the HVAC preliminary design basis is acceptable because it ensures acceptable temperature and humidity control and the staff also finds that the applicant’s response deferring the answer to the question to the OL is acceptable for purposes of the issuance of a construction permit as per 10 CFR 50.35(a)2.

The staff evaluated the diagrams and tables provided in NWMI PSAR Section 9.1.2 to determine whether the level of completeness of the design as presented and consistency with the system description is sufficient and acceptable at this stage. The staff finds that the system diagrams and tables provided are acceptable because they provide an understanding of the HVAC airflow to prevent an inadvertent diffusion or other uncontrolled release of radioactive material from the production facility and supports the HVAC design basis and is sufficient for the purposes of issuance of a construction permit for the NWMI production facility.

9.4.1.1 Operational Analysis

The staff evaluated the operational analyses and safety functions addressed in NWMI PSAR Section 9.1.4, which states that PSAR Chapters 11.0 and 13.0 provide an analysis of normal and off-normal operation of the production facility HVAC system. NWMI PSAR Chapter 11.0, Section 11.1.1.1, "Airborne Radiation Sources," presents the normal release analysis. NWMI PSAR Chapter 13.0, Section 13.2, "Analysis of Accidents with Radiological and Criticality Safety Consequences," evaluates various accident sequences that involve failure of the ventilation components, radiological spills, and the release of high-dose solutions, vapors, or gases from within the hot cell liquid confinement, secondary confinement, or shielding boundary.

Defense-in-Depth

NWMI PSAR Section 9.1.3 explains that failure of the air balance system is not in itself an accident, but represents the failure of a system designed to mitigate other accidents that lead to an airborne release of radionuclides in the form of particulates or gases. Systems that will mitigate these releases include the primary confinement and primary OTS, which will capture particulates, absorb iodine, and absorb Xenon and Krypton and other gaseous radionuclides, to slow the release allowing decay to more stable isotopes. Uranium solutions will also be processed in closed systems with filtered process ventilation systems to remove the small amounts of activity normally released.

Items relied on for Safety

Based on the NWMI PSAR Chapter 13.0 analysis, the hot cell secondary confinement (Zone I exhaust ventilation subsystem) is designated as an IROFS (RS-03, "Hot Cell Secondary Confinement Boundary"). The operations, equipment, and components of this system are to ensure the confinement of hazardous materials during normal and abnormal conditions, including natural phenomena, fires, and explosions. Components of the dissolver offgas subsystem and the process vessel ventilation system are also designated as IROFS.

Safety Functions

NWMI PSAR Section 9.1.3 states that the safety functions of the confinement system are discussed in more detail in NWMI PSAR Chapter 6.0, Section 6.1, "Summary Description." NWMI PSAR Chapter 13.0 evaluates a fire that could cause the carbon retention beds to ignite, leading to the release of radionuclides into the exhaust stack. Based on analysis of this accident, the exhaust stack height was identified as an IROFS (FS-05, "Exhaust Stack Height"). This analysis is discussed in more detail in NWMI PSAR Chapter 13.0. This passive engineered control is designed and fabricated with a fixed height for safe release of gaseous effluents. NWMI PSAR Section 9.1.2.3.1, "Zone I Exhaust System," states that the height of the exhaust stack is 23 meters (75 feet).

Based on its review of NWMI PSAR Section 9.1.3 and the other related PSAR references, the staff finds that the information provided on operational analysis and safety function of the HVAC system is acceptable because it ensures that sources of airborne radioactive material are diluted, diverted, and filtered, and is sufficient for the purposes of issuance of a construction permit for the NWMI production facility. Further details of the HVAC system can reasonably be left for later consideration in the FSAR once the final design is completed. The impacts of the changes to the HVAC system from the preliminary design to the final design will be evaluated by the staff in the FSAR and associated documents during the OL application review.

9.4.1.2 Instrumentation and Controls

The staff evaluated the NWMI production facility HVAC I&C requirements addressed in NWMI PSAR Section 9.1.4, which explains that HVAC system control and monitoring is discussed in NWMI PSAR Chapter 7.0 (see staff evaluation in SER Section 7.0). NWMI PSAR Table 9-2 summarizes the HVAC system parameters and whether they are monitored or alarmed. NWMI PSAR Section 9.1.4 states that the system sequence of operation will be developed and provided in the OL application. Based on its review, the staff finds that the information on HVAC system I&C in NWMI PSAR Section 9.1.4 is acceptable because it provides details on the operating and design features of the HVAC system and is sufficient for the purposes of issuance of a construction permit for the NWMI production facility. Further details of the HVAC system I&C can reasonably be left for later consideration in the FSAR. The staff will evaluate the FSAR and associated documents during the OL application review.

9.4.1.3 Summary of Findings

Based on its review, the staff finds that the level of detail of the information provided on the NWMI production facility HVAC systems demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.2, “Ventilation System,” allowing the staff to make the following findings:

(1) A review of the preliminary design bases and functional and safety characteristics of the HVAC systems shows that the proposed systems are adequate to control the release of airborne radioactive effluents during the full range of the production facility operations in compliance with the regulations.

(2) The applicant has discussed all sources of radioactive material that could become airborne in the NWMI production facility from a full range of facility operations. The analyses provide reasonable assurance that the radioactive material is controlled by the HVAC system and could not inadvertently escape from the NWMI production facility. They provide reasonable assurance that the distributions and concentrations of the airborne radionuclides in the NWMI production facility are limited by operation of the HVAC system so that during the full range of NWMI production facility operations, no potential occupational exposures would exceed the design bases derived in Chapter 11.0 of the NWMI PSAR.

(3) The applicant has considered the height and flow rate of the stack that exhausts production facility air to the unrestricted environment for the design-basis dose rates derived in Chapter 11.0 of the NWMI PSAR for the maximum exposed personnel in the unrestricted environment.

(4) The HVAC system is an integral part of the confinement system at the production facility. The design of the confinement system and analysis of its operation provide reasonable assurance that it will function to limit normal airborne radioactive material to the extent analyzed in this chapter and Chapter 11.0 of the NWMI PSAR. The potential radiation doses, therefore, should not exceed the limits of 10 CFR Part 20 and are consistent with NWMI's ALARA program.

Therefore, the staff concludes that the preliminary information from the design of the NWMI production facility HVAC system, as described in NWMI PSAR Section 9.2, is sufficient to give the staff an understanding of how the application meets the 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 in the FSAR. The staff will confirm that the final design conforms to an acceptable set of design bases during the evaluation of NWMI's FSAR.

9.4.2 Handling and Storage of Reactor Fuel

NWMI PSAR Section 9.2 states that the production facility does not handle or store reactor fuel. Material handling activities are discussed in NWMI PSAR Chapter 4.0, Section 4.3, "Radioisotope Extraction System," and Section 4.4, "Special Nuclear Material Processing and Storage," and are analyzed in Chapter 13.0. The staff finds that this section is not applicable to the NWMI production facility for the reasons stated.

9.4.3 Fire Protection Systems and Programs

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility fire protection systems and programs, as described in NWMI PSAR Section 9.3, for the issuance of a construction permit by reviewing the design bases and components of the system using the guidance and acceptance criteria from Section 9.3, "Fire Protection Systems and Programs," of NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of NUREG-1537, Part 2, Section 9.3, the staff evaluated the discussions of potential fires; provisions for early detection, including during those times when areas are not occupied; methods for isolating, suppressing, and extinguishing fires; passive features designed into the production facility to limit fire consequences; response organization training and availability to fight fires as detailed in the emergency plan; designs of production facility systems that can ensure safe production facility shutdown in the event of fire; and potential radiological consequences to the public, the staff, and the environment if firefighting efforts are unsuccessful.

As described in NWMI PSAR Section 9.3 the fire protection system at the production facility is divided into two subsystems: the fire suppression subsystem and the fire detection and alarm subsystem. Along with fire rated walls and assemblies, these subsystems are designed to provide notification of a fire event, suppress small fires, and prevent small fires from becoming large fires.

The fire suppression subsystem, described in NWMI PSAR Section 9.3.2.1, "Fire Suppression Subsystem," consists of an automatic sprinkler system, a HEPA filter plenum deluge, glovebox fire suppression, and fire hydrants. NWMI states that the automatic sprinkler system is designed in accordance with National Fire Protection Association (NFPA) 13. The need for installation of sprinklers in the hot cells will be determined and finalized in the FSAR.

Because of the possibility of runoff fire water containing hazardous materials, a fire runoff storage system will be used to hold runoff water for sampling prior to release to the environment. Additionally, the production facility will be equipped with HEPA filters. The HEPA filter fire protection system consists of heat detectors in the ducts that, when high temperature are detected, will activate a water cooling system. If the HEPA filters ignite, a direct water spray onto the filter can be manually activated.

NWMI states that four fire hydrants will be located on the exterior of the building at each corner. The PSAR states that the hydrant subsystem is designed in accordance with NFPA 24, "Standard for the Installation of Private Fire Service Mains and Their Appurtenances," and the International Fire Code, 2012 Edition. Fire hydrants will be connected to the municipal water supply. NWMI will determine during final design whether facility operations will use an on-site dedicated fire water supply and/or use the City of Columbia fire water supply. This item is being tracked as a regulatory commitment by the applicant in Appendix A.4, "Regulatory Commitments Identified through Meeting with the Advisory Committee on Reactor Safeguards Northwest Medical Isotopes Subcommittee," of this SER.

The fire detection and alarm subsystem, described in NWMI PSAR Section 9.3.2.2, "Fire Detection and Alarm Subsystem," consists of various fire detection and notification systems. The primary method of detecting fires is through fire suppression device monitoring that will provide notification of a sprinkler or deluge valve activating, indicating a possible fire in that area. In areas like computer rooms or egress hallways, where water damage is a concern or life safety is especially important, smoke and heat detectors will be used. Heat detectors will also be used in gloveboxes and smoke detectors will be installed in some ventilation systems as necessary to prevent spread of smoke and contaminants to the environment or between areas in the production facility. The performance of fire detection systems can be affected by radiation or the presence of dust, and thus it is important to choose the right system for the environment in which it will be used. NWMI stated that the selection of specific detection systems will be included in the FSAR and will be informed by relevant standards. The fire protection system will have an associated central alarm panel. Alarms will be relayed to the Columbia Fire Department via the central alarm station.

The fire protection and alarm system will be powered by a dedicated circuit. In the event of a power outage, 24 hours of backup battery power will be available in accordance with NFPA standards.

As described in NWMI PSAR Section 9.3.3.1, "Radioisotope Production Facility Fire Areas," the production facility is divided into fire areas based on the hazards present with the objective of limiting the spread of fire, protecting personnel, and minimizing damage to the production facility. Fire areas are separated by at least two-hour fire rated barriers. All penetrations and fire doors in a barrier have the same fire rating as the barrier. Fire-rated barriers are designed and will be constructed in accordance with NFPA 221, "Standard for High Challenge Fire Wall, Fire Walls, and Fire Barrier Walls," and the International Building Code. The staff finds that the use of NFPA 221 is an acceptable way to demonstrate that the design basis for fire barriers is adequate.

The PSAR states that the Columbia Fire Department will respond in the event of a fire. The department will be notified of a fire either automatically through smoke or heat detectors or manually though a fire alarm pull station. The Columbia Fire Department also services the University of Missouri - Columbia Research Reactor (MURR) and is familiar with hazardous and

radioactive materials. The time within which the fire department must respond will be determined in the OL application. The staff finds acceptable that the fire department, which the PSAR states will respond to the production facility in the event of a fire and has a base knowledge of radiation hazards as related to the suppression of fires as it serves the MURR facility.

NWMI examines potential fire hazards and ignition sources (both internal and external) for the different areas of the facility in the construction permit application. NWMI states that the fire protection system is not necessary to prevent or mitigate high or intermediate consequence accidents in the production facility. The staff evaluated the accident analyses related to potential fire hazards and ignition sources as part of its review of Chapter 13.0, which is documented in Chapter 13.0 of this SER.

9.4.3.1 Summary of Findings

Based on its review, the staff finds that the level of detail provided in the NWMI PSAR on the fire protection systems demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.3 allowing the staff to make the following findings:

(1) Fire-rated barriers between fire areas will be two-hour rated assemblies at a minimum and provide adequate protection against spread of fires from one area to another.

(2) The fire department serves the MURR and has a base knowledge of nuclear facility hazards as related to the suppression of fires.

(3) The ventilation system is designed to prevent the spread of contamination, through the use of fire dampers and HEPA filters, during the event of a fire. The final ventilation system design and operation will be evaluated with the submission of the FSAR.

(4) The fire suppression and detection systems, insofar as the systems are currently designed, provide protection against fires and fire spread because they are designed to meet NFPA requirements. The fire hazard analysis and fire protection training plan will be reviewed when the NWMI FSAR is submitted. Future consideration of selection of systems and finalization of the design can reasonably be left for later consideration in the FSAR and OL application.

Therefore, the staff concludes that the preliminary design of the NWMI production facility fire protection systems and programs, as described in NWMI PSAR Section 9.3, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. The staff will confirm that the final design conforms to this design basis during the evaluation of NWMI's FSAR.

9.4.4 Communication Systems

In accordance with applicable guidance cited in Section 9.3 of this SER, the staff evaluated the sufficiency of the preliminary design of the NWMI production facility communication systems, as described in NWMI PSAR Section 9.4 for the issuance of a construction permit, including the design basis, system description, operational analysis and safety function, I&C requirements, and topics for potential TSs.

Consistent with the review procedures in NUREG-1537, Part 2, the staff considered the design basis of the communication systems in order to ensure the full range of communication that will be used in the NWMI production facility during normal and emergency conditions. Thus, in this portion of the review, the staff evaluated the completeness and consistency of design basis information for a preliminary design.

NWMI PSAR Section 9.4.1, "Design Basis," states that the communications system design basis is to provide communications during normal and emergency conditions between vital areas of the production facility. The section further states that this communications capability will include the ability of operators or other designated staff members to announce an emergency and provide two-way communications between all operational areas and the control room. Design of the telecommunication system will also comply with Electronic Industries Alliance and Telecommunications Industry Association requirements.

NWMI PSAR Section 9.4.3, "Operational Analysis and Safety Function," states that PSAR Chapter 13.0 identifies and evaluates adverse events and accident sequences. The accident analysis has not identified the need to credit the communication systems.

The staff evaluated the system description of the NWMI production facility communication systems to determine its adequacy for issuance of a construction permit and in particular, its consistency with its design basis. The staff finds that the information provided in the PSAR description is consistent with the design basis information because the system is designed to provide communications during emergency and normal operations and has the capability for operators or other designated NWMI staff to announce and provide two-way communication between the NWMI staff during emergencies. The evaluation of the detailed communication systems can reasonably wait for later consideration and will be reviewed in the FSAR submitted as part of the OL application. Therefore, the staff finds the preliminary information sufficient and acceptable for the purposes of the issuance of a construction permit in accordance with 10 CFR Part 50.

9.4.4.1 Summary of Findings

Based on its review, the staff finds that the level of detail provided on the NWMI production facility communication systems demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.4, allowing the staff to make the following findings:

(1) The production facility communication systems are designed to provide two-way communication between all locations essential for safe facility operation.

(2) The communication systems enable facility-wide announcement of emergencies.

Therefore, the staff concludes that the preliminary design of the NWMI production facility communication systems, as described in NWMI PSAR Section 9.4, is sufficient and meets the 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 in the FSAR. The staff will confirm that the final design conforms to this design basis during the evaluation of NWMI's FSAR.

9.4.5 Possession and Use of Byproduct, Source, and Special Nuclear Material

The staff evaluated the sufficiency of the preliminary design of NWMI's program for possession and use of byproduct, source, and SNM in the production facility for the issuance of a construction permit. The staff reviewed NWMI PSAR Section 9.5, to gain an understanding of how byproduct materials, and irradiated SNM are processed; the types and quantities of radionuclides authorized; the rooms, spaces, equipment, and procedures to be used; the general types of uses, such as research and development, processing, or packaging for shipment; the provisions for controlling and disposing of radioactive wastes, including special drains for liquids and chemicals, and air exhaust hoods for airborne materials; the relationship between these auxiliary facility designs and the physical security and emergency plans; and probable topics for TSs and their bases, including testing and surveillance, using the guidance and acceptance criteria from Section 9.5, "Possession and Use of Byproduct, Source, and Special Nuclear Material," of NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of NUREG-1537, Part 2, Section 9.5, the staff evaluated the design bases, system description, operational analysis and safety function, and topics for potential TSs. The staff compared the design bases for the auxiliary systems that process byproduct material in the production facility with other chapters of NWMI PSAR, especially Chapters 11.0 and 12.0, and evaluated agreement with the acceptance criteria of NUREG-1537, Part 2, Section 9.5.

Based on its review, the staff finds that the production facility design with respect to the byproduct and SNM that will be used in the production facility demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.5, allowing the staff to make the following findings:

(1) The auxiliary facilities and systems are designed for the possession and use of byproduct and SNM produced by the facility. The design bases include limits on potential personnel exposures that are in compliance with 10 CFR Part 20 and are consistent with the facility ALARA program.

(2) The design provides reasonable assurance that uncontrolled releases of radioactive material to the public will not occur.

Therefore, the staff concludes that the preliminary design of the NWMI program for the possession and use of byproduct, source, and SNM in the production facility, as described in NWMI PSAR Section 9.5, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis can reasonably be left for later consideration in the FSAR.

9.4.6 Cover Gas Control in Closed Primary Coolant Systems

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility cover gas control system within the process coolant system described in NWMI PSAR Section 9.6 for the issuance of a construction permit using the guidance and acceptance criteria from Section 9.6, "Cover Gas Control in Closed Primary Coolant Systems," of NUREG-1537, Parts 1 and 2, and other relevant guidance as cited in Section 9.3 of this SER.

Consistent with the review procedures of NUREG-1537, Part 2, Section 9.6, the staff evaluated the cover gas control systems to ensure that:

- The design and functional description conforms to the design bases.

- The design, functions, and potential malfunctions of the systems that perform the cover gas function should not cause accidents to the facility or uncontrolled releases of radioactivity.

- In the event radioactive material is released by the operation of the systems that perform this function, potential radiation exposures should not exceed the limits of 10 CFR Part 20 and should be consistent with the facility ALARA program.

NWMI PSAR Section 9.6 provides a high-level functional description of the NWMI production facility cover gas process function, addressing design basis, system description, operational analysis and safety function, and I&C. The systems in the production facility that constitute the "closed primary coolant system," are two of the three process chilled water systems used to cool process vessels. Within the process chilled water systems that use cover gas, the cover gas function is performed by the plant air supply system (NWMI PSAR Section 9.7.1.2.4), the cooling water collection tanks, and the process vessel vent system (NWMI PSAR Section 9.1.2.3.4) to ensure that hydrogen and oxygen mixtures produced by radiolytic decomposition of process vessel cooling water in the process chilled water system (NWMI PSAR Section 9.7.1.2.2) are diluted by sweep/purge gas and kept below 25 percent of the lower flammability limit (LFL) of 5 percent for hydrogen gas. NWMI states that this function is designed to prevent hydrogen explosions that could result in damage/injury to production facility SSCs/personnel and possibly uncontrolled releases of radioactivity. The staff reviewed the design basis value of reducing hydrogen buildup below 25 percent of the LFL and finds that it is acceptable for a preliminary design. Potential accidents related to hydrogen buildup are evaluated by NWMI in its integrated safety analyses (ISA) and discussed in Chapter 13.0 of the SER

NWMI PSAR, Section 9.6.1 states that information on the design basis of cover gas control in the closed primary coolant system (process-chilled water system) is provided in Chapter 3.0, Section 3.5.2.7.

9.4.6.1 Operational Analysis and Safety Function

NWMI PSAR Section 9.6.3 states that the associated accident analysis is in PSAR Chapter 13.0 and that the tanks associated with the cooling system are not anticipated to require IROFS controls. The staff evaluated the accident analyses in Chapter 13.0 of the NWMI PSAR.

9.4.6.2 Instrumentation and Control Requirements

NWMI PSAR Section 9.6.4 states that I&C requirements for cover gas control in the closed primary coolant system (i.e., process chilled water) are discussed in NWMI PSAR Chapter 7.0.

9.4.6.3 Summary of Findings

Based on its review, the staff finds that the level of detail provided on the NWMI production facility function of cover gas control in closed primary coolant systems satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.6, allowing the staff to make the following findings:

(1) The preliminary design is consistent with the design basis. Specifically, the coolant collection tanks, sweep/purge gas system, plant air supply system, and process vessel vent system are designed to work together to capture and treat the expected offgases at their anticipated concentrations of constituents under normal and accident conditions and to ensure that the design-basis pressures and especially the design maximum allowable hydrogen concentration can be maintained.

(2) Processing (diluting) and disposing of radiolytic gases have been incorporated into the design to ensure the safety of personnel and to prevent the release of radioactivity due to hydrogen explosions.

(3) The coolant collection tanks, sweep/purge gas system, plant air supply system, and process vessel vent system have been designed to perform the cover gas control in closed primary coolant systems functions required by the design bases.

Therefore, the staff concludes that the preliminary design of the NWMI production facility cover gas control in closed primary coolant systems, as described in NWMI PSAR Section 9.6, is sufficient to meet the 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 in the FSAR. The staff will confirm that the final design conforms to the design basis during the evaluation of NWMI's FSAR.

9.4.7 Other Auxiliary Systems

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility's other auxiliary systems, as described in NWMI PSAR Section 9.7, for the issuance of a construction permit by reviewing the systems (described below), using the guidance and acceptance criteria from Section 9.7, "Other Auxiliary Systems," of NUREG-1537, Parts 1 and 2 and the ISG Augmenting NUREG-1537. The staff review covered design bases, system descriptions, operational analysis and safety functions, and I&C requirements to verify that:

- The preliminary designs of the other production facility auxiliary systems are consistent with their design bases.

- Any malfunction could not create conditions or events that could cause an unanalyzed accident or uncontrolled release of radioactive material beyond those analyzed in Chapter 13.0 of the PSAR.

- The auxiliary system could not prevent safe production facility shutdown.

Consistent with the review procedures of NUREG-1537, Part 2, Section 9.7, the staff compared the design and functional descriptions of the other auxiliary systems with their design bases. The staff reviewed the discussion and analyses of the functions and potential malfunctions with respect to safe production facility operation and shutdown, the effect on production facility safety systems, and the potential for these auxiliary systems to initiate or affect the uncontrolled release of radioactive material.

Fundamental to the review of the preliminary design of the NWMI production facility's other auxiliary systems are (1) verifying that the design bases reflect all applicable functional, structural, and safety requirements, all applicable/relevant regulatory requirements and

guidance, and all applicable/relevant industry guidance, endorsed or recognized by the staff, and (2) that the preliminary design is consistent with the design bases and provides reasonable assurance that construction of the production facility can be conducted such that the as-built facility is consistent with the approved design.

The other NWMI production facility auxiliary systems that are important to the safety of workers and the public, and for the protection of the environment, include the following:

- Utility systems (NWMI PSAR Section 9.7.1)
- Control and storage of radioactive waste (waste management) NWMI PSAR Section 9.7.2)
- Analytical laboratory (NWMI PSAR Section 9.7.3)
- Chemical supply (NWMI PSAR Section 9.7.4)

9.4.7.1 Utility Systems

NWMI PSAR Section 9.7.1, "Utility Systems," states:

> The utility systems will provide heating, cooling, process water, compressed gases, instrument, motive force, and other functions to support uranium processing, waste handling, and ventilation. The utility systems will include the following subsystems:
>
> - Process steam
> - Process chilled water
> - Demineralized water
> - Plant and instrument air
> - Gas supply, which supplies nitrogen, helium, hydrogen, and oxygen
> - Purge/sweep gas

NWMI states that the utility systems are designed to ensure that any potential malfunctions do not cause accidents in the production facility or an uncontrolled release of radioactivity. The systems are designed to ensure that in the event radioactive material is released by the operation of one of these systems, potential radiation exposures would not exceed the limits of 10 CFR Part 20 and are consistent with the NWMI ALARA program. NWMI states that no function or malfunction of the auxiliary systems will interfere with or prevent safe shutdown of the production facility.

NWMI PSAR Section 9.7.1 states that the design basis for the utility system is provided in NWMI PSAR Chapter 3.0, Section 3.5.2.7.

NWMI PSAR Section 9.7.1.2 provides a functional description of each of the utility systems, including the diagrams, system P&IDs, and tables cited in Section 9.2, "Summary of Application," of this SER.

NWMI PSAR Section 9.7.1.3 states that PSAR Chapter 13.0 evaluates the accident sequences that involve fissile solution or solid materials being introduced into systems not normally designed to process these solutions or solid materials. The accident analysis associated with utilities addresses fissile solution leaks across a mechanical boundary between process vessels or backflows into a utility system, addressing defense-in-depth measures and identifying IROFS.

NWMI PSAR Section 9.7.1.4 states that utility system I&C requirements are discussed in NWMI PSAR Chapter 7.0.

Based on its review of the NWMI production facility utility systems, the staff finds that the level of detail in NWMI PSAR Section 9.7.1 demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.7. Detailed design information of the safety aspects of the utility systems will be reviewed by the staff in the FSAR submitted as part of the OL application.

Therefore, the staff concludes that the preliminary design of the NWMI production facility utility systems, as described in NWMI PSAR Section 9.7.1, is sufficient and meets the 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 in the FSAR. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR.

9.4.7.2 Control and Storage of Radioactive Waste

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility radioactive waste control and storage systems, as described in NWMI PSAR Section 9.7.2, for the issuance of a construction permit using the guidance and acceptance criteria from Section 9.7 of NUREG-1537, Parts 1 and 2.

NWMI PSAR Section 9.7.2.1 states that the design basis for the waste management system for the production facility is in NWMI PSAR Section 3.5.2.7. NWMI PSAR Section 3.5.2.7.6, “Waste Handling,” lists the design basis functions for this system as follows:

- Receive liquid waste that is divided into high-dose source terms and low-dose source terms to lag storage
- Transfer remotely loaded drums with high-activity solid waste via a solid waste drum transit system to a waste encapsulation cell
- Encapsulate solid waste drums
- Load drums with solidification agent and low-dose liquid waste
- Load high-integrity containers with solidification agent and high-dose liquid waste
- Handle and load a waste shipping cask with radiological waste drums/containers
- Safety-related functions:
  - Maintain sub-criticality conditions through mass limits
  - Prevent spread of contamination to manned areas of the facility that could result in personnel exposure to radioactive materials or toxic chemicals

- Provide shielding, distance, or other means to minimize personnel exposure to penetrating radiation

Design Basis Values

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

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

The waste management systems described in NWMI PSAR Section 9.7.2 addresses each of the design basis functions:

- Separate collection tanks provide separation of high-dose and low-dose liquid wastes. Lag storage is provided in each of the systems producing waste input to the high-dose collection tank. NWMI states that the high-dose liquid waste collection tank volume is sufficient to provide some additional lag storage.

- NWMI PSAR Section 9.7.2.2.4, "Solid Waste Encapsulation," describes operators using a drum transfer cart to move drums containing solid wastes through the maintenance gallery to the high-dose waste treatment hot cell where the drums are filled with cement grout. The final design will be evaluated at the FSAR stage to ensure that this manual operation is conducted consistent with the applicant's commitment to ALARA in radiation protection.

- Both high-dose liquid waste and low-dose liquid waste are described as being solidified. The solidification agent(s) proposed and the process(es) used to assure an acceptable solidified product meeting the waste acceptance criteria of the disposal site will be evaluated at the FSAR stage.

- NWMI PSAR Section 9.7.2.2.5, "High-Dose Waste Decay," describes high-dose waste decay capabilities. In its response to RAI 9.7-5b (Reference 20), the applicant provided decay times for both high-integrity containers (HICs) containing high-dose waste from MURR targets and HICs containing high-dose waste from Oregon State University TRIGA Reactor targets. Based on the information provided and the rate of HIC production also presented in the response, the high-dose decay cell should have adequate capacity for decay in storage and limited interruption of the ability to transport high-dose waste for disposal for a period of weeks. The staff will evaluate the storage capacity after the final design is completed and submitted in the FSAR as part of OL review.

- NWMI PSAR Section 9.7.2.2.7, "Waste Handling," provides a summary description of how waste containers are handled for loading into transportation casks.

NWMI PSAR Section 9.7.2.2 presents information regarding the systems and components used to perform the design basis functions.

NWMI PSAR Section 9.7.2 also includes a process flow drawing and states that operation of the high-dose liquid waste system is performed on a batch basis, with inputs to the system and

between successive components in the system being isolated, sampled, and analyzed before each transfer. The staff finds that this section of the PSAR provides sufficient information for a preliminary design to indicate that sufficient liquid waste storage and processing capacity should be available. The staff will evaluate the liquid waste storage and processing capacity as part of the review of the final design submitted in the FSAR.

NWMI PSAR Section 9.7.2.3 identifies the IROFS for the waste handling system as derived from the ISA summary.

NWMI PSAR Section 9.7.2.4 states that radioactive waste control and storage system I&C requirements are discussed in NWMI PSAR Chapter 7.0. NWMI PSAR Section 7.3.6, "Waste Handling System," provides generic design criteria, acknowledging that the detailed waste handling system controls are still being developed. NWMI PSAR Table 7-11, "Waste Handling System Control and Monitoring Parameters," provides a list of parameters to be monitored and the location of controls. Table 7-12, "Waste Handling System Interlocks and Permissive Signals," indicates that all interlocks and permissive signals will be controlled through programmable logic controllers and that none are considered safety related. NWMI stated that details of waste handling system controls will be provided along with the system performance analysis and conclusion for each waste process system in the OL application.

Based on its review, the staff finds that the level of detail provided in NWMI PSAR Section 9.7.2 on control and storage of radioactive waste demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.7, allowing the staff to make the following findings:

(1) The waste control and storage systems have been designed to perform functions required by the design bases.

(2) The potential malfunctions that could affect operations have been considered in the design of the waste control and storage systems.

Therefore, the staff concludes that the preliminary design of the NWMI production facility radioactive waste control and storage systems, as described in NWMI PSAR Section 9.7.2, is sufficient and meets the 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 in the FSAR. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR.

9.4.7.3 Analytical Laboratory

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility analytical laboratory, as described in NWMI PSAR Section 9.7.3, for the issuance of a construction permit using the guidance and acceptance criteria from Section 9.7 of NUREG-1537, Parts 1 and 2, and other relevant guidance as cited in Section 9.3 of this SER. Consistent with the review procedures of NUREG-1537, Part 2, Section 9.7 and the ISG Augmenting NUREG-1537, the staff evaluated the analytical laboratory, including design basis, system description, operational analysis and safety function, and I&C requirements to ensure that:

- The design and functional description conforms to the design bases.

- The design, functions, and potential malfunctions of the analytical laboratory should not cause accidents to the facility or uncontrolled releases of radioactivity.
- In the event radioactive material is released by the operation of the analytical laboratory, potential radiation exposures should not exceed the limits of 10 CFR Part 20 and should be consistent with the facility ALARA program.

- No function or malfunction of the analytical laboratory should interfere with or prevent safe shutdown of the production facility.

In addition, NUREG-1537, Part 1, Section 9.5, states, in part, that the applicant should discuss laboratories for the production facility. This discussion should address design basis, system description, operational analysis and safety function, I&C requirements, and required TSs for any such auxiliary laboratories. The applicant should specify the types and quantities of radionuclides authorized, as well as the general types of experiments or uses. Radiological design bases for handling radioactive materials and radioactive waste should be derived from Chapter 11.0 of the NWMI PSAR. These design bases may apply to chemical, fume, and air exhaust hoods; to drains for radioactive liquids; and to radiation shields. The discussions should show how the physical security and emergency plans apply to the licensed spaces and possession of byproduct materials. The applicant should discuss the bases for special operating procedures.

NWMI PSAR Section 9.7.3.3 states that NWMI PSAR Chapter 13.0 evaluates the accident sequences that involve miscellaneous chemical safety process upsets in areas without significant fissile or high-dose licensed material present (chemical storage areas and the laboratory). The accidents analyzed that are associated with the analytical laboratory include Accident Sequence S.R.31, “Chemical Burns from Contaminated Solutions during Sample Analysis.”

NWMI states that it will follow set protocols on sampling and analysis to identify the sampling locations, sampling techniques, containers to be used, transport routes to take, analysis procedures, reagents to use, equipment requirements, and disposal protocol for the sample residue material. Each of these procedures will be evaluated for standard safety protocols, including requirements in the safety datasheets for the chemicals used and safety requirements for the equipment used.

NWMI PSAR Section 9.7.3.4 states that analytical laboratory I&C requirements are discussed in NWMI PSAR Chapter 7.0. The staff evaluated analytical laboratory I&C requirements in Section 7.0 of this SER.

NWMI PSAR Section 9.7.3.5 states that analytical laboratory TSs, if applicable, will be discussed in Chapter 14.0 of the NWMI FSAR as part of the OL application. Topics for potential TSs were included in Chapter 14.0 of the NWMI PSAR and are evaluated by the staff in Chapter 14.0 of this SER. The staff finds that it is reasonable to identify and justify the selection of TSs once the design becomes final.

Based on its review, the staff finds that the level of detail provided in PSAR Section 9.7.3 on the NWMI production facility analytical laboratory demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.7, allowing the staff to make the following evaluations findings:

(1) The analytical laboratory has been designed to perform functions required by the design bases.

(2) The potential malfunctions that could affect operations have been considered in the design of the analytical laboratory.

Therefore, the staff concludes that the preliminary design of the NWMI production facility analytical laboratory, as described in NWMI PSAR Section 9.7.3, is sufficient and meets the 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 in the FSAR. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR.

9.4.7.4 Chemical Supply System

The staff evaluated the sufficiency of the preliminary design of the NWMI production facility chemical supply system, as described in PSAR Section 9.7.4, for the issuance of a construction permit using the guidance and acceptance criteria from Section 9.7 of NUREG-1537, Parts 1 and 2, the ISG augmenting NUREG-1537, and other relevant guidance as cited in Section 9.3 of this SER. Consistent with the review procedures of NUREG-1537, Part 2, Section 9.7, the staff evaluated the chemical supply system, including design basis, system description, operational analysis and safety function, and I&C requirements, to ensure that:

- The design of the chemical supply system is consistent with the design bases.

- No function or malfunction of the chemical supply system should interfere with or prevent safe shutdown of the production facility.

NWMI PSAR Section 9.7.4.1 states that the chemical supply system design basis for the production facility is to provide chemical solutions mixed to the required concentrations that are used within the target dissolution, Mo-99 recovery and purification, and waste management systems. The system will provide nitric acid (HNO_3), sodium hydroxide (NaOH), reductant and nitric oxide (NO_x) absorber solutions, hydrogen peroxide (H_2O_2), and fresh uranium ion exchange (IX) resin.

NWMI PSAR Section 3.5.2.7.24, “Chemical Supply System,” provides the following chemical supply system design basis functions:

- Provide storage capability for nitric acid, sodium hydroxide, reductant, and nitrogen oxide absorber solutions, hydrogen peroxide, and fresh uranium IX resin

- Segregate incompatible chemicals (e.g., acids from bases)

- Provide transfer capability for chemical solutions mixed to required concentrations and used in target dissolution, Mo-99 recovery and purification, and waste management systems

NWMI PSAR Section 3.5.2.7.24 provides the following chemical supply system design basis values:

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

NWMI PSAR Section 9.7.4.2 provides a functional description of the chemical supply system, including the diagrams and tables listed in Section 9.2 of this SER.

NWMI PSAR Section 9.7.4.3 states, in part, that "Chapter 13.0 evaluates accident sequences that involve miscellaneous chemical safety process upsets in areas without significant fissile or high-dose licensed material present (e.g., chemical storage areas and the laboratory). The backflow of fissile or radioactive solutions into auxiliary systems (e.g., chemical supply) was also analyzed and two preventive IROFS identified."

NWMI PSAR Section 9.7.4.3 further states, in part, that "Defense-in-depth - NWMI will comply with U.S. Environmental Protection Agency and Occupational Safety and Health Administration regulations for the design, construction, and operation of chemical preparation and storage areas in the production facility. Chemical handling procedures will be provided to operators to ensure safe handling of chemicals according to applicable regulatory requirements and consistent with the material safety datasheets."

NWMI PSAR Section 9.7.4.4 states that I&C requirements for the chemical supply system are discussed in NWMI PSAR Chapter 7.0.

NWMI PSAR Section 9.7.4.5 states that TSs for the chemical supply system, if applicable, will be discussed in Chapter 14.0 of the NWMI FSAR as part of the OL application. Topics for potential TSs were included in Chapter 14.0 of the PSAR and are evaluated by the staff in Chapter 14.0 of the SER. The staff finds that it is reasonable to identify and justify the selection of TSs once the design becomes final.

Based on its review, the staff finds that the level of detail provided in NWMI PSAR Section 9.7.4 on the NWMI production facility chemical supply system demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.7.

Therefore, the staff concludes that the preliminary design of the NWMI production facility chemical supply system, as described in NWMI PSAR Section 9.7.4, is sufficient and meets the 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 in the FSAR. The staff will confirm that the final design conforms to this design basis during the evaluation of the NWMI FSAR.

9.4.7.5 Summary of Findings

Based on its review, the staff finds that the level of detail provided in NWMI PSAR Section 9.7 on the NWMI production facility's other auxiliary systems demonstrates an adequate design basis for a preliminary design and satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 9.7, allowing the staff to make the following findings:

(1) The systems have been designed to perform the functions required by the design bases.

(2) The functions and potential malfunctions that could affect production facility operations or initiate uncontrolled releases of radioactive material have been considered in the design of the systems.

(3) The strategy and content of what will be required for TSs as discussed in PSAR Chapter 14.0 gives reasonable assurance that the systems will be operable, as required by the design bases.

Therefore, the staff concludes that the preliminary design of the NWMI production facility's other auxiliary systems, as described in NWMI PSAR Section 9.7, is sufficient and meets the 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, will be provided and can reasonably be left for later consideration, in the FSAR. The staff will confirm that the final design conforms to this design basis during the evaluation of NWMI's FSAR.

9.5 Summary and Conclusions

The staff evaluated the descriptions and discussions of the NWMI production facility's auxiliary systems, as described in NWMI PSAR Chapter 9.0, and finds that the preliminary design of the auxiliary systems, including the principal design criteria, design bases, and information relative to general arrangement, major SSCs, and a high-level functional description provides reasonable assurance that the final design will conform to the design basis and meets all applicable regulatory requirements and acceptance criteria in or referenced in the applicable guidance.

Based on these findings, the staff concludes the following regarding 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 auxiliary 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 compete the safety analysis of the auxiliary systems, and which can be reasonably left for later consideration, will be provided in the FSAR.

(3) There is reasonable assurance that the production facility can be constructed and operated at the proposed location without undue risk to health and safety of the public.

(4) The applicant provides reasonable assurance of compliance with the regulations including 10 CFR Part 20, and the health and safety of the public will not be endangered.

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