UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE COMMISSION

In the Matter of	)	**Docket No. 50-609-CP**
NORTHWEST MEDICAL ISOTOPES, LLC	)	
(Medical Radioisotope Production Facility)	)	**January 1, 2018**

APPLICANT'S PRE-FILED TESTIMONY OF CAROLYN C. HAASS
NORTHWEST MEDICAL ISOTOPES, LLC
EVIDENTIARY HEARING

1. Witness Background

Question 1.1: Please state your name.

Carolyn C. Haass

Question 1.2: By whom are you employed?

I am employed by Northwest Medical Isotopes, LLC (NWMI).

Question 1.3: What is your position at NWMI?

I am the Chief Operating Officer and co-founder of NWMI with the charge to design, license, construct, and operate a medical radioisotope production facility (RPF). I lead and direct all company operations, strategic planning, business development, conflict management, and personnel management of over 100 employees and contract staff. My responsibilities include establishing and maintaining operating standards, regulatory compliance, and total quality management, while maintaining a current level of knowledge of industry-related trends and compliance standards to ensure a cohesive structure within the company.

Question 1.4: Describe your educational and professional background.

I have Bachelor of Science degrees in both Chemistry and Metallurgical Engineering from Colorado School of Mines (1984). Prior to joining NWMI, I worked at the Hanford Nuclear Reservation from 1991 to 2012. At Hanford, I worked in a variety of positions for the cleanup of the tank farms both as a regulator with the U.S. Department of Energy (DOE) and a contractor. Specifically, I managed complex nuclear and hazardous waste projects; oversaw technology development, project design, construction, and operations; developed long-term life-cycle technical, schedule, and cost integrated baselines; and performed associated risk and issue management. In addition, I have extensive communications experience in the nuclear and environmental industry, including day-to-day interface with regulators, safety boards, members of Congress, stakeholders, tribal nations, public, media, community leaders, and decision makers.

Question 1.5: What is the purpose of your testimony?

The purpose of my testimony is to support the findings that the U.S. Nuclear Regulatory Commission (NRC) must make as part of the evidentiary hearing for the construction permit (CP) for the NWMI RPF.

Question 1.6: Describe the structure of your testimony.

The structure of this testimony is as follows:

- Section 1 – General information on witness background
- Section 2 – Description of the Construction Permit Application (CPA), including project background, RPF description, applicant background information, and organization and structure
- Section 4 – NRC's review of the NWMI CPA for the RPF
- Section 4 – Addresses the safety and environmental findings for issuing a CP for the RPF
- Section 5 – Conclusions for issuing a CP for the RPF

2. Description of the Construction Permit Application

Project Background

Question 2.1: Describe the project related to the NWMI Construction Permit Application.

NWMI has established a network of domestic university research reactors to irradiate low-enriched uranium (LEU) targets, has designed extraction and purification chemistries, is designing and constructing an RPF to extract and purify molybdenum-99 (^{99}Mo), and intends to sell ^{99}Mo—ensuring a reliable, securable, and domestic supply of this critical medical isotope.

Question 2.2: Is there a domestic supply of ^{99}Mo?

Currently, there is no domestic supply of ^{99}Mo.

Question 2.3: Why is the NWMI RPF needed to produce ^{99}Mo?

Single photon emission computerized tomography (SPECT) is an advanced three-dimensional (3D) scanning technology used to diagnose and monitor a wide range of medical conditions, including coronary heart disease, cancers, kidney function, and various brain disorders. Worldwide, between 30 and 40 million patients per year benefit from noninvasive nuclear imaging scans that can detect disease at an early stage, determine the extent of disease, and track responses to therapy. ^{99}Mo is the parent isotope of technetium-99m (^{99m}Tc), which is the most widely used isotope in nuclear medicine imaging. ^{99m}Tc is the isotope of choice for SPECT because it has pure gamma emissions ideal for image detection, a useful range of chemical characteristics that enable many targeting molecules to be used, and a very short half-life (i.e., six hours).

These emission energies and short half-life combine to ensure that the radiation dose to the patient from each administered injection is at a low and safe level. Scans can also be made at a number of time points after injection, which can provide useful additional information. Such a short half-life, however, means that ^{99m}Tc cannot be stored. The isotope must be prepared a number of times every day by specialist nuclear pharmacies.

^{99}Mo, in the form of a ^{99}Mo/^{99m}Tc generator, has a longer half-life of around 66 hours and can be used in nuclear pharmacies for one to two weeks. The power of the ^{99}Mo declines by about 1 percent every hour, and nuclear pharmacies must regularly receive new ^{99}Mo/^{99m}Tc generators, with some receiving the generators multiple times a week. The ^{99}Mo used in generators must therefore be produced by a radiopharmaceutical company four to five times a week.

At present, almost all ^{99}Mo for medical use is produced by irradiating targets containing weapons-grade, high-enriched uranium (HEU) (20 percent and greater enriched uranium) in research and test reactors, some of which are over 50 years old. Unanticipated and extended shutdowns of some of these reactors have resulted in severe ^{99}Mo supply shortages in the United States (U.S.) and other countries. Some of these shortages have disrupted the delivery of medical care.

In addition, exacerbating the age of the majority of reactors used for irradiation of ^{99}Mo targets is that the facilities must convert from weapons-grade HEU targets to LEU (less than 20 percent enriched uranium) targets by 2018, a technically challenging and costly transition.

The world-wide reactor network is currently operating at or near capacity. The global ^{99}Mo supply chain is inherently fragile. The fragility stems from three factors:

1. ^{99}Mo and its daughter isotope ^{99m}Tc have short half-lives (66 and 6 hours, respectively) and therefore cannot be stockpiled. These radioisotopes need to be produced and delivered to the supply chain on a weekly or more frequent basis.
2. Global supply of ^{99}Mo relies on a small number of reactors (i.e., seven reactors) and a small number of ^{99}Mo suppliers (four ^{99}Mo suppliers).
3. With the exception of the OPAL reactor (Australia), which is only 10 years old, the remaining six reactors that are used to irradiate targets for ^{99}Mo production are on average 53 years old and experience frequent scheduled and unscheduled maintenance interruptions.

^{99}Mo production has been interrupted unexpectedly on numerous occasions since 2009 because of unplanned shutdowns of these aging reactors. These interruptions have caused ^{99}Mo supply shortages and in some cases, severe shortages.

Any unscheduled maintenance or other production disruption immediately translates into a supply disruption. Reliance on such a limited and aging resource results in an extremely delicate supply chain, the vulnerability of which was highlighted late in 2009 when an extended shutdown of the NRU Reactor (Canada) led to a critical ^{99}Mo shortage in North America, and the shutdown of the Petten high-flux reactor (HFR) (Netherlands) in August 2008, and from November 2013 to the present, caused ^{99}Mo shortages in North America and Europe.

In summary, the combination of an aging and soon to be decommissioned nuclear reactor fleet, growing market demand, and the increased risk to the supply chain from the HEU-to-LEU conversion present a unique and compelling domestic business opportunity.

NWMI believes that a U.S. source of ^{99}Mo will play a vital role in ensuring the availability of a reliable domestic and world-wide supply of isotopes for medical applications.

Question 2.4: Provide a high-level description of the NWMI RPF.

Figure 2-1 presents the process flow diagram for ^{99}Mo production. On a weekly basis, targets will be loaded around the reactor core and irradiated for approximately 6.5 days (approximately 156 hours). After irradiation, the targets are mechanically removed from the core and placed in a cask for cooling. The targets are then transported to the RPF using NRC-certified casks. Once the targets are received, the targets are delidded and poured into a nitric acid solution for dissolution.

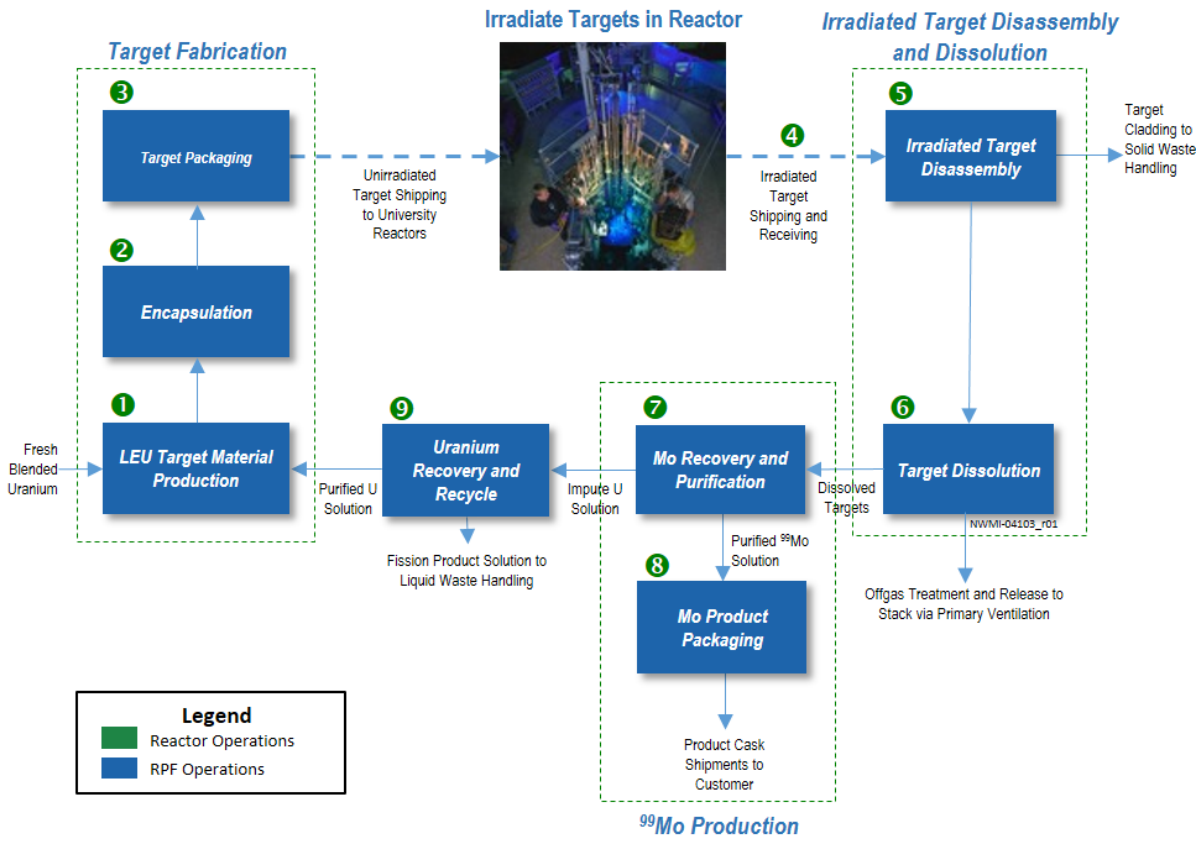


Figure 2-1. Molybdem-99 Production Process Flow Diagram

Any gases produced from the dissolution step are trapped and held until no longer an environmental concern and then vent through an offgas treatment system. The resulting solution is then separated into liquids containing unused uranium and ^{99}Mo. During the second stage, the ^{99}Mo liquid is passed through several exchange columns to extract purified ^{99}Mo and rinse out the majority of other byproducts.

The RPF is being designed to have a maximum operational processing capability of 38 targets per week in two different batches, including eight targets from the University of Missouri Research Reactor (MURR) and approximately 30 targets from the Oregon State TRIGA Reactor (OSTR) or a third university reactor. The nominal or typical operational processing capability would be one batch per week of either 8 to 12 targets from MURR or approximately 30 targets from OSTR or a third university reactor. In other words, the RPF will be capable of producing up to 3,000 six-day curies (Ci) (average) and 4,500 six-day Ci (maximum) of ^{99}Mo. RPF operations include the following general process steps (which correspond with Figure 2-1).

Target Fabrication

1. LEU target material is fabricated using a combination of fresh LEU and recycled uranium.
2. Target material is encapsulated using metal cladding to contain the LEU and fission products produced during irradiation.
3. Fabricated targets are packaged and shipped to university reactors for irradiation.

Target Receipt, Disassembly, and Dissolution

4. After irradiation, targets are shipped back to the RPF.
5. Irradiated targets are disassembled and metal cladding is removed.
6. Targets are then dissolved into a solution for processing.

Molybdenum Recovery and Purification

7. Dissolved LEU solution is processed to recover and purify ^{99}Mo.
8. Purified ^{99}Mo is packaged in certified shipping containers and shipped to a radiopharmaceutical distributor.

Uranium Recovery and Recycle

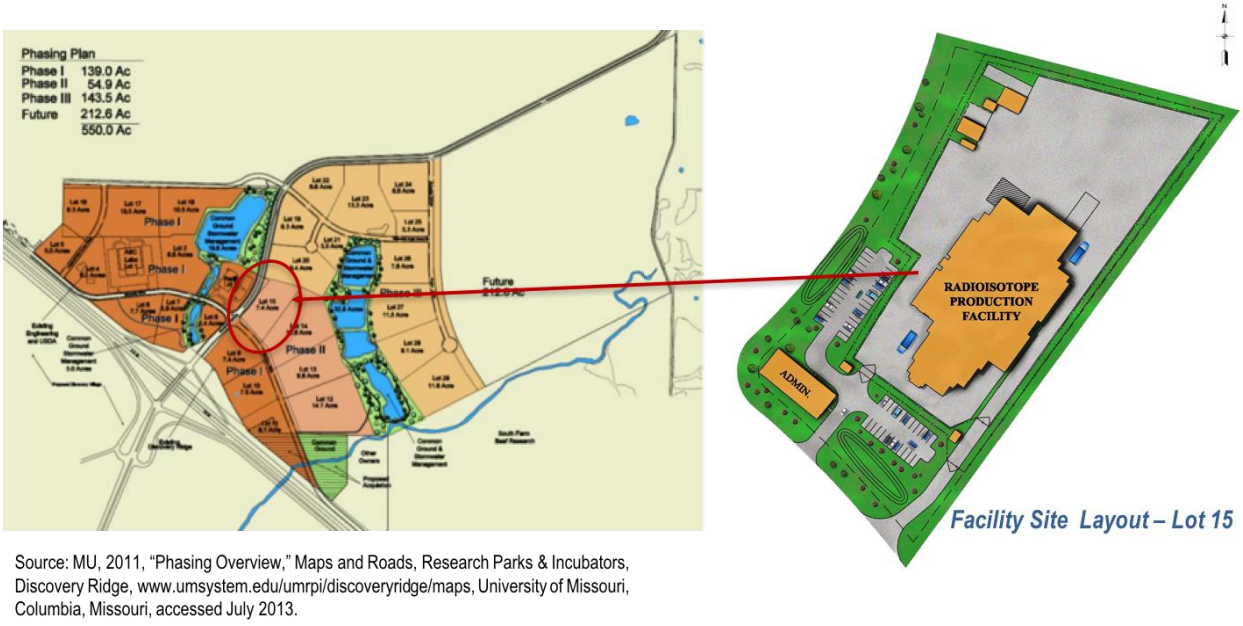
9. LEU solution is treated to recover uranium and remove trace contaminants and is recycled back to Step 1 to be made into new targets via the target fabrication system.

The RPF operating and process characteristics are described in more detail in Chapter 4.0 of NWMI-2013-021, *Construction Permit Application for Radioisotope Production Facility* (CPA).

Because the ^{99}Mo and target byproducts are radioactive, all processing is performed in shielded laboratories and hot cells using robotic manipulators. The industry-standard procedures are safe and efficient, allowing for more than 90 percent of the ^{99}Mo to be captured from the targets. The hot cells are arranged into several independent production lines, allowing for redundancy, simplified maintenance scheduling, and cost-effective expansion.

Question 2.5: Where is the proposed RPF site?

The proposed 3.0 hectare (ha) (7.4-acre) site of the RPF is situated in Boone County, within the University of Missouri (MU) Discovery Ridge Research Park (Discovery Ridge) in Columbia, Missouri, north of Discovery Ridge Drive. This site in central Missouri is approximately 201 kilometers (km) (125 miles [mi]) east of Kansas City and 201 km (125 mi) west of St. Louis. The site is 7.2 km (4.5 mi) south of U.S. Interstate Highway 70, just to the north of U.S. Highway 63. The Missouri River lies 15.3 km (9.5 mi) to the west of the site. Figure 2-2 shows the location of the RPF site within Discovery Ridge and a layout of the RPF.



Source: MU, 2011, "Phasing Overview," Maps and Roads, Research Parks & Incubators, Discovery Ridge, www.umsystem.edu/umrpi/discoveryridge/maps, University of Missouri, Columbia, Missouri, accessed July 2013.

Figure 2-2. Radioisotope Production Facility Siting at Discovery Ridge Research Park and Radioisotope Production Facility Layout

Question 2.6: What is the license being sought for the RPF.

NWMI is applying to the NRC to obtain a license for a production facility under Title 10, *Code of Federal Regulations* (CFR) Part 50 (10 CFR 50), "Domestic Licensing of Production and Utilization Facilities." The 10 CFR 50 license application for the RPF is being prepared following the guidance in Part 1 of NUREG-1537, *Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors – Format and Content.*

The NRC has determined that a radioisotope separation and processing facility, which also conducts separation of special nuclear material (SNM), will be considered a production facility and as such, will be subject to licensing under 10 CFR 50. A significant portion of the NWMI RPF involves the disassembly of irradiated LEU targets, separation and purification of fission product ^{99}Mo, and the recycle of LEU that is licensed under 10 CFR 50.

The proposed action is the issuance of an NRC license under 10 CFR 50 that would authorize NWMI to construct and operate a ^{99}Mo RPF at a site located in Columbia, Missouri. The RPF will:

- Receive irradiated LEU targets (from a network of university research or test reactors)
- Process irradiated LEU targets for dissolution, recovery, and purification of ^{99}Mo
- Recover and recycle LEU to minimize radioactive, mixed, and hazardous waste generation
- Treat/package wastes generated by RPF process steps to enable transport to a disposal site
- Provide areas for associated laboratory and other support activities

Additional RPF operational activities are subject to other NRC regulations, including 10 CFR 70, "Domestic Licensing of Special Nuclear Material," to receive, possess, use, and transfer SNM, and 10 CFR 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," to process and transport ^{99}Mo for medical applications. RPF operations will also include the fabrication of LEU targets, which will be licensed under 10 CFR 70 (applied for under a separate license application submittal). These targets will be shipped to NWMI's network of research or test reactors for irradiation (considered a connected action) and returned to the RPF for processing. The LEU used for production of the LEU target materials will be obtained from DOE and from LEU reclaimed from processing the irradiated targets. Any byproduct materials produced or extracted in the RPF will be licensed under 10 CFR 30.

Question 2.7: Describe the structure and organization of the Construction Permit Application.

The CPA is organized as follows. Part One of the CPA included an Enclosure 4 with General and Financial Information, which provides general information in accordance with 10 CFR 50.33; fee information in accordance with 10 CFR 50.30(e) and 170.21 (Schedule of Fees); and a Classified Information Agreement in accordance with 10 CFR 50.37. Parts One and Two of the CPA included the environmental review (Chapter 19.0) in accordance with 10 CFR 51 and the remainder of the preliminary safety analysis report (PSAR) (Chapters 1.0 to 18.0), which provides the technical information in accordance with 10 CFR 50.34. The CPA is organized as follows:

Chapter 1.0 – The Facility

Chapter 2.0 – Site Characteristics

Chapter 3.0 – Design of Structures, Systems, and Components

Chapter 4.0 – Irradiation Unit and Radioisotope Production Facility Description

Chapter 5.0 – Cooling Systems

Chapter 6.0 – Engineered Safety Features

Chapter 7.0 – Instrument and Control Systems

Chapter 8.0 – Electrical Power Systems

Chapter 9.0 – Auxiliary Systems

Chapter 10.0 – Experimental Facilities

Chapter 11.0 – Radiation Protection Program and Waste Management

Chapter 12.0 – Conduct of Operations

Chapter 13.0 – Accident Analysis

Chapter 14.0 – Technical Specifications

Chapter 15.0 – Financial Qualifications

Chapter 16.0 – Other License Considerations

Chapter 17.0 – Decommissioning and Possession-Only License Amendments

Chapter 18.0 – Highly Enriched to Low Enriched Uranium Conversion

Chapter 19.0 – Environmental Review

Applicant Background Information

Question 2.8: Identify the applicant for the RPF and their roles and responsibilities.

NWMI is the applicant and owner for the CP for the RPF. NWMI is a privately held company that was created for the purpose of designing, constructing, and operating the RPF. NWMI is incorporated in the state of Oregon. NWMI is managed under the direction of a Board of Managers and through the Executive Officers of the company.

Question 2.9: When did applicant submit the Construction Permit Application? Were any exemptions requested?

NWMI applied to the NRC to obtain a license for a production facility under 10 CFR 50. The 10 CFR 50 license application for the RPF is being prepared following the guidance in Part 1 of NUREG-1537. The NRC has determined that a radioisotope separation and processing facility, which also conducts separation of SNM, will be considered a production facility and as such, will be subject to licensing under 10 CFR 50.

Additional RPF operational activities are subject to other NRC regulations, including 10 CFR 70 (to receive, possess, use, and transfer SNM), and 10 CFR 30 (to process and transport ^{99}Mo for medical applications). RPF operations will also include the fabrication of LEU targets, which will be licensed under 10 CFR 70 (applied for under a separate license application submittal). These targets will be shipped to NWMI's network of research or test reactors for irradiation (considered a connected action) and returned to the RPF for processing. Any byproduct materials produced or extracted in the RPF will be licensed under 10 CFR 30.

NWMI was granted an exemption from certain requirements of 10 CFR 2.101(a)(5), "Filing of Application," by the Commission to submit our construction permit application in two parts (Fowler, 2013 and Lynch, 2013). This exemption was published in the Federal Register (FR) on October 24, 2013 (78 FR 63501).

NWMI submitted Part One of a two-part application for a CP on February 5, 2015 (Haass, 2015a), to allow the construction of the RPF in Columbia, Missouri. The NRC acknowledged receipt of Part One of the application for a CP under 10 CFR 50 in a notice published in the FR on April 21, 2015 (80 FR 22227). The NRC accepted Part One of the NWMI CPA for docketing (Balazik 2015), and a notice of docketing was published in the FR on June 8, 2015 (80 FR 32418).

NWMI submitted Part Two of the CPA on July 20, 2015 (Haass, 2015b), which provided the remainder of the PSAR required by 10 CFR 50.34(a), "Contents of applications; technical information." NWMI updated the Part Two CPA, which incorporated the responses to NRC requests for additional information (RAI) and Advisory Committee for Reactor Safeguards (ACRS) comments, and submitted the revised application on September 8, 2017 (Haass, 2017). The NRC issued the final Safety Evaluation Report (SER) for the NWMI RPF in November 2017 (NRC, 2017).

NWMI intends to submit one integrated Operating Licensing Application (OLA) for the entire RPF that will cover both 10 CFR 50 and 10 CFR 70 activities. This OLA will be submitted to the NRC in the third quarter of 2018.

Question 2.10: Did the Construction Permit Application address all applicable NRC regulations?

Yes. The NWMI CPA provided the information required by applicable NRC regulations, including:

- 10 CFR 50.30, "Filing of applications for licenses; oath or affirmation"
- 10 CFR 50.33, "Contents of applications; general information"
- 10 CFR 50.34, "Contents of applications; technical information"

- 10 CFR 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions"

Question 2.11: What other licenses, permits or approvals are needed for the design and construction of the RPF?

NWMI is entering a highly regulated industry and is subject to both Federal and State regulations. Necessary permits, inspections, and/or regulatory approvals include:

- RPF must be licensed under the following NRC regulations for the processing of irradiated targets to produce ^{99}Mo:
  - 10 CFR 30 – Byproduct Material License
  - 10 CFR 40 – Source Material License (i.e., LEU is a source)
  - 10 CFR 50 – Construction Permit and Operating License
  - 10 CFR 70 – Special Nuclear Material License
  - National Environmental Policy Act – Site approval
- RPF will be permitted by the following regulatory authorities:
  - Boone County Regional Sewer District
  - Boone County Resource Management Department
  - City of Columbia
  - Missouri Department of Health and Senior Services
  - Missouri Department of Natural Resources
  - U.S. Army Corps of Engineers
  - U.S. Department of Transportation
  - U.S. Environmental Protection Agency

- Consultation will also be required for the construction and operation of the RPF with:
  - Missouri Department of Conservation
  - Missouri State Department of Historic Preservation
  - Tribal Nations (e.g., Osage Nation and Iowa Tribe of Oklahoma)
  - U.S. Fish and Wildlife

Question 2.12: Were there other companies or organizations that provided significant contributions in preparing the Construction Permit Application or supporting NWMI's response to the NRC's review of the Construction Permit Application?

Yes. NWMI has formal contractor relationships with chosen leading industry experts for the development of specialized processes. The relationships are formalized with a Master Services Agreement requiring measures of exclusivity to NWMI. These contractors provided significant facility design, development and preparation of the CPA, response to NRC staff RAIs, and participation in ACRS meetings. The contractors include the following.

Atkins Energy, Inc. (Atkins Energy) – The U.S. commercial headquarters of Atkins is in Columbia, South Carolina, with Commercial Nuclear and Specialty Engineering division offices in Columbia, South Carolina, and Hudson, Wisconsin. Atkins Energy focuses on nuclear reactor core design, reactor safety analysis, criticality safety analysis, deep penetration radiation shielding, health physics and radiation safety, seismic analysis for nuclear facilities, fire protection, probabilistic risk analysis, process hazards analysis, materials control and accountability, integrated safety analysis, licensing, severe accident modeling, and graphical logic analysis solution system (GLASS) development. For NWMI, Atkins Energy is providing criticality safety analysis, integrated safety analysis, fire hazards analysis, materials control and accountability program development, natural phenomenon hazards assessment, radiation protection program development, thermal hydraulic analysis, and several GLASS applications.

Merrick & Company – Founded in 1955 and headquartered in Denver, Colorado, Merrick & Company (Merrick) specializes in the areas of nuclear, national security, energy, life sciences, infrastructure, and geospatial services. For nuclear services, Merrick provides the following core competencies: radioactive materials processing, handling, research, development, research equipment, systems, facilities, manufacturing systems, treatment systems, design-fabrication and design-build, hot cells and enclosures, gloveboxes, radioactive chemical laboratories, controlled environment test chambers, commercial nuclear power plant systems and infrastructure, and specialized research equipment.

AEM Consulting, LLC – AEM Consulting, LLC (AEM), a small business incorporated in 2002, provides nuclear services for government and industry. AEM staff have over 300 years of cumulative experience in nuclear process engineering and operations, including uranium and plutonium processing and fission product separation techniques. For NWMI, AEM served as the project manager for the development of the RPF conceptual design and will provide process engineering for the RPF preliminary and final design and operations.

McCarthy Building Company – McCarthy Building Company (McCarthy) was established in 1864 and has a long history of building facilities in the U.S. and throughout the world. McCarthy specializes in building projects that improve people's lives, including healthcare, education, commercial, high performance/ green, government, heavy civil, hospitality, entertainment, parking, science and technology, and water/ wastewater facilities. The company has specialized commercial and government construction experience with advanced technology and manufacturing (e.g., nuclear, pharmaceutical, Level 4 laboratories).

Portage Inc. – Portage, Inc. (Portage) provides comprehensive engineering and technical solutions for environmental, infrastructure, and energy projects. Since incorporating in 1992, Portage has grown to a staff of more than 400 highly skilled technical and professional personnel and has broad experience managing projects involving radioactive, hazardous, mixed and industrial waste, including characterization, excavation, packaging, transportation, and offsite disposal, particularly for large-scale government cleanup projects. For NWMI, Portage provides environmental and waste management support.

General Description of the NWMI RPF

Question 2.13: Provide a general description of the NWMI RPF.

A building model view of the RPF is provided in Figure 2-3. The administration and support area will provide the main personnel access to the RPF and include personnel support areas such as access control, change rooms, and office spaces.

The first level (excluding the tank pit area) and second levels of the RPF are currently estimated to comprise approximately 4,282 square meters (m^2) (46,088 square feet [ft^2]) and 1,569 m^2 (16,884 ft^2) of floor space, respectively. The processing hot cell and waste management temporary storage floor space area is approximately 544 m^2 (5,857 ft^2). The maximum height of the building is 19.8 meter (m) (65 ft), with a maximum stack height of 22.9 m (75 ft). The depth of the processing hot cell below-grade, without footers, is 4.6 m (15 ft) of enclosure height in rooms containing process equipment. The site is enclosed by perimeter fencing to satisfy safeguards and security and other regulatory requirements.

Figure 2-3. Building Model of the Radioisotope Production Facility

The building will be divided into material accountability areas that are regulated by 10 CFR 50 and 10 CFR 70, as shown in Figure 2-4. The target fabrication area will be governed by 10 CFR 70, and the remainder of the production areas (irradiated target receipt bay, hot cells, waste management, laboratory, and utilities) will be governed by 10 CFR 50.

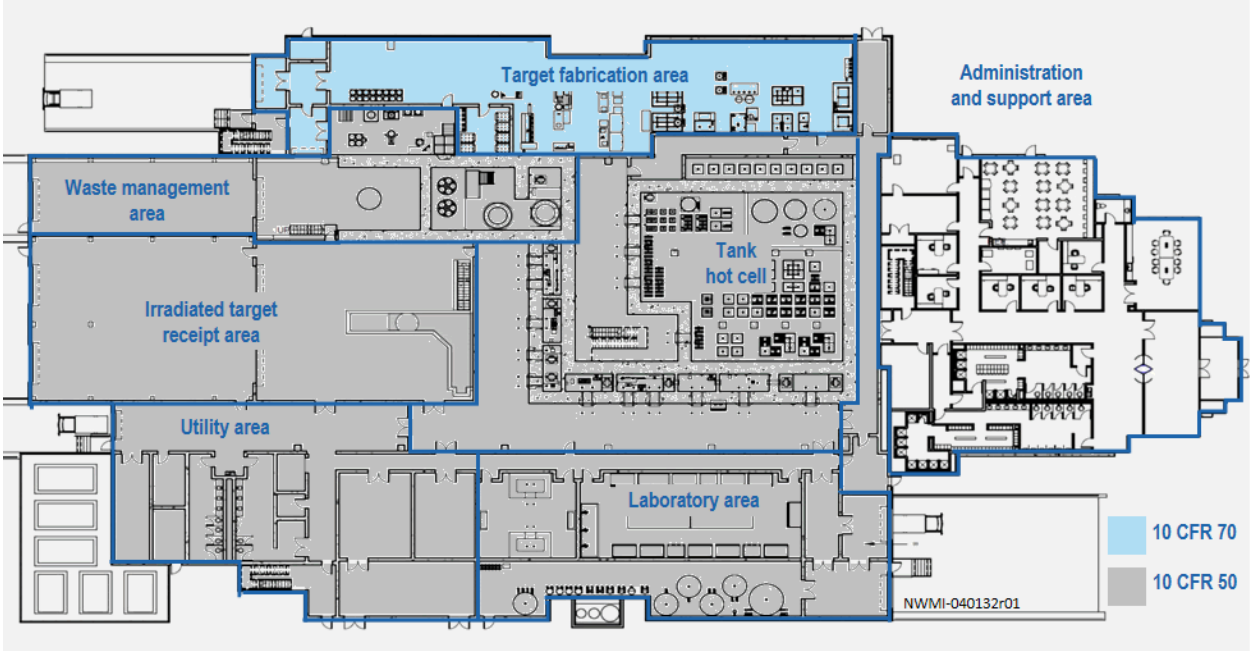


Figure 2-4. General Layout of the Radioisotope Production Facility

Figure 2-4 is first level general layout of the RPF and presents the seven major areas, including the target fabrication area, irradiated target receipt area, tank hot cell area, laboratory area, waste management area, utility area, and administrative support area

Additional detailed facility information is provided in NWMI-2013-021, Chapter 4.0, "Radioisotope Production Facility Description."

Question 2.14: What is the general layout of the RPF on the proposed site?

Figure 2-5 shows the layout of the NWMI site, including the RPF.

Figure 2-5. Radioisotope Production Facility Site Layout

Question 2.15: What are the principal characteristics of the proposed site?

Prominent features of the proposed site are shown in **Error! Reference source not found.**, including the highways, rivers, and other local bodies of water within an 8 km (5-mi) radius from the center of the facility. The principal characteristics of the site are described in detail in NWMI-2013-021, Chapter 2.0, "Site Characteristics."

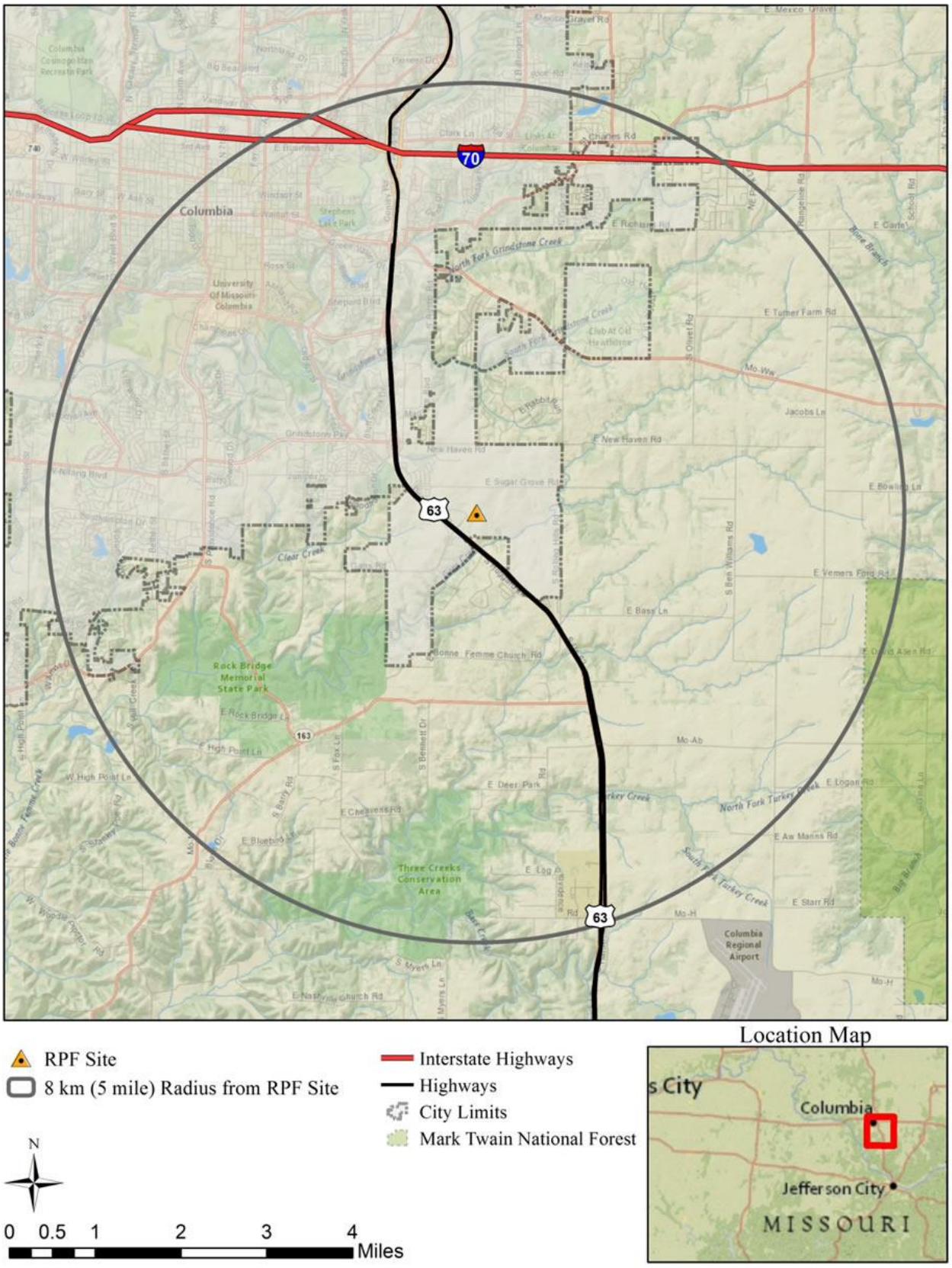


Figure 2-6. Prominent Features of the Site Area

Question 2.16: In general, what are the principal design criteria for the RPF?

The NWMI RPF design is based on applicable standards, guides, codes, and criteria and provides reasonable assurance that the RPF structures, systems, and components (SSC), including electromechanical systems:

- Are built and will function as designed and required by the analyses in NWMI-2013-021, Chapter 13.0, "Accident Analysis"
- Ensure acceptable protection of the public health and safety and environment from radiological risks (e.g., radioactive materials, exposure) resulting from operations
- Protect against potential hydrological (water) damage
- Protect against seismic damage
- Provide surveillance activities and technical specifications required to respond to or mitigate consequences of seismic damage
- Have technical specifications developed to ensure that safety-related functions of electromechanical systems and components are operable and protect the health and safety of workers, the public, and environment

The design basis and facility SSCs for the RPF are based on defense-in-depth practices. Defense-in-depth is a design philosophy, applied from the beginning and through completion of the design, that is based on providing successive levels of protection such that health and safety are not wholly dependent on any single element of the design, construction, maintenance, or operation of the facility. The net effect of incorporating defense-in-depth practices is a conservatively designed facility and systems that exhibit higher tolerances to failures and external challenges. The risk insights obtained through performance of accident analysis can then be used to supplement the final design by focusing attention on the prevention and mitigation of the higher risk potential accidents.

NWMI addressed the following baseline design criteria for the RPF.

- **Quality standards and records** – Design is being developed and implemented in accordance with management measures to provide adequate assurance that items relied on for safety (IROFS) will be available and reliable to perform the intended functions when needed. Appropriate records of these items must be maintained by or under the control of the licensee throughout the life of the facility.
- **Natural phenomena hazards** – Design will provide for adequate protection against natural phenomena with consideration of the most severe documented historical events for the site.
- **Fire protection** – Design will provide for adequate protection against fires and explosions.
- **Environmental and dynamic effects** – Design will provide for adequate protection from environmental conditions and dynamic effects associated with normal operations, maintenance, testing, and postulated accidents that could lead to loss of safety functions.
- **Chemical protection** – Design will provide for adequate protection against chemical risks produced from licensed material, facility conditions that affect the safety of licensed material, and hazardous chemicals produced from licensed material.
- **Emergency capability** – Design will provide for emergency capability to maintain control of:
  - Material and hazardous chemicals produced from licensed material
  - Evacuation of on-site personnel
  - On-site emergency facilities and services that facilitate the use of available off-site services
- **Utility services** – Design will provide for continued operation of essential utility services.
- **Inspection, testing, and maintenance** – Design of IROFS will provide for adequate inspection, testing, and maintenance to ensure availability and reliability to perform intended function when needed.

- **Criticality control** – Design will provide for criticality control, including adherence to the double-contingency principle.
- **Instrumentation and controls** – Design will provide for inclusion of instrumentation and control (I&C) systems to monitor and control the behavior of IROFS.
- Facility and system design and facility layout will be based on defense-in-depth practices. The design will incorporate, to the extent practicable:
  - Preference for the selection of engineered controls over administrative controls to increase overall system reliability
  - Features that enhance safety by reducing challenges to IROFS

Details of the RPF design criteria and associated systems and components are addressed in Chapter 3.0, "Design of Structures, Systems, and Components," Sections 3.1 and 3.5, respectively, of the CPA (NWMI-2013-021).

Question 2.17: What are the operating characteristics for the RPF?

The RPF operates as a series of batch operations. The irradiated targets are received in shipping casks and loaded into the target receipt hot cell. The targets are dissolved as nominally four target batches (if irradiated at MURR) or eight target batches (if irradiated at OSTR).

The ^{99}Mo recovery and purification process is a batch series of ion exchange columns, and the uranium recovery and recycle unit operations are also performed as a series of multiple batch steps. The RPF includes systems and components for handling and storing wastes generated during this process. Detailed operating characteristics of the RPF are discussed in more detail in Chapter 4.0 (NWMI-2013-021).

Question 2.18: What are the engineered safety features for the facility?

Engineered safety features (ESF) are active or passive features designed to mitigate the consequences of accidents and keep radiological exposures to workers, the public, and environment within acceptable values.

The ESFs associated with confinement of the process radionuclides and hazardous chemicals for the RPF are summarized in Table 2-1, including the accidents mitigated, SSCs used to provide the ESFs, and references to subsequent sections providing a more detailed ESF description.

Confinement is a general ESF that is credited as being in place as part of the preliminary hazards analysis (PHA) described in NWMI-2013-021, Chapter 13.0. Additional IROFS associated with the confinement system were derived from the accident analyses in Chapter 13.0. The derived IROFS are also listed in Chapter 6.0, "Engineered Safety Features," Table 6-1, with reference to more detailed descriptions in Section 6.2.1.

Table 2-1. Summary of Confinement Engineered Safety Features (2 pages)

Engineered safety feature	IROFS	Accident(s) mitigated	SSCs providing engineered safety features	CPA detailed description section
Confinement includes: • Hot cell liquid confinement boundary • Hot cell secondary confinement boundary • Hot cell shielding boundary	RS-01 RS-03 RS-04	• Equipment malfunction and/or maintenance • Hazardous chemical spills	• Confinement enclosures including penetration seals • Zone I exhaust ventilation system, including ducting, filters, and exhaust stack • Zone I inlet ventilation system, including ducting, filters, and bubble-tight isolation dampers • Ventilation control system • Secondary iodine removal bed • Berms	6.2.1.1 through 6.2.1.6
Confinement IROFS Derived from Accident Analyses and Potential Technical Specifications				
Primary offgas relief system	RS-09	Dissolver offgas failure during dissolution operation	• Pressure relief device • Pressure relief tank	6.2.1.7.1
Active radiation monitoring and isolation of low-dose waste transfer	RS-10	Transfer of high-dose process liquid outside the hot cell shielding boundary	Radiation monitoring and isolation system for low-dose liquid transfers	6.2.1.7.2
Cask local ventilation during closure lid removal and docking preparations	RS-13	Target cladding leakage during shipment	Local capture ventilation system over closure lid during lid removal	6.2.1.7.3
Cask docking port enabler	RS-15	Cask not engaged in cask docking port prior to opening docking port door	Sensor system controlling cask docking port door operation	6.2.1.7.4

Table 2-1. Summary of Confinement Engineered Safety Features (2 pages)

Engineered safety feature	IROFS	Accident(s) mitigated	SSCs providing engineered safety features	CPA detailed description section
Process vessel emergency purge system	FS-03	SSC damage due to hydrogen deflagration or detonation	Backup bottled nitrogen gas supply	6.2.1.7.5
Irradiated target cask lifting fixture	FS-04	Dislodging the target cask shield plug while workers present during target unloading activities	• Cask lifting fixture design that prevents cask tipping • Cask lifting fixture design that prevents lift from toppling during a seismic event	6.2.1.7.6
Exhaust stack height	FS-05	• Equipment malfunction resulting in liquid spill or spray • Carbon bed fire	• Zone I exhaust stack	6.2.1.7.7
Double-wall piping	CS-09	Solution spill in facility area where spill containment berm is neither practical nor desirable for personnel chemical protection purposes	Double-wall piping for selected transfer lines	6.2.1.7.7
Backflow prevention devices Safe geometry day tanks	CS-18 CS-19	High worker exposure from backflow of high-dose solution	Backflow prevention devices located on process lines crossing the hot cell shielding boundary	6.2.1.7.9
Dissolver offgas iodine removal unit[a]	–	• Potential limiting control for operation • Primary iodine control system during normal operation	Dissolver offgas iodine removal units (DS-SB-600A/B/C)	6.2.1.8
Dissolver offgas primary adsorber[a]	–	• Potential limiting control for operation • Primary noble gas control system during normal operation	Dissolver offgas primary adsorber units (DS-SB-620A/B/C)	6.2.1.7.5
Dissolver offgas vacuum receiver or vacuum pump[a]	–	• Potential limiting control for operation • Motive force for dissolver offgas	• Dissolver offgas vacuum receiver tanks (DS-TK-700A/B) • Dissolver offgas vacuum pumps (DS-P-710A/B)	6.2.1.8.3

[a] Examples of candidate technical specification rather than engineered safety feature.

CPA = construction permit application
IROFS = item relied on for safety.
SSC = structures, systems, and components.

The current design approach does not anticipate requiring containment or an emergency cooling system as ESFs, as discussed in Chapter 6.0, Sections 6.2.2 and 6.2.3.

Nuclear criticality safety and associated controls are discussed in Chapter 6.0, Section 6.3. The currently defined criticality safety controls are derived from a combination of preliminary criticality safety evaluations and accident analyses, which are described in Chapter 13.0. The criticality safety analyses produce a set of features needed to satisfy the double-contingency requirements for nuclear criticality control. These features are evaluated by major systems within the RPF and listed by major system in Chapter 6.0, Section 6.3.1.1, Table 6-6 through Table 6-13. The accident analyses in Chapter 13.0 identify IROFS for the prevention of nuclear criticality, which are summarized in Table 2-2, with reference to more detailed descriptions in Section 6.3.1.2.

Table 2-2. Summary of Criticality Engineered Safety Features (2 pages)

Engineered safety feature	IROFS	SSC features providing engineered safety features	CPA detailed description section
Interaction control spacing provided by passively designed fixtures and workstation placement	CS-04	Defines spacing between SSC components using geometry to prevent nuclear criticality	6.3.1.2.1
Pencil tank, vessel, or piping safe geometry confinement using the diameter of tanks, vessels, or piping	CS-06	Defines dimensions of SSCs using geometry to prevent nuclear criticality	6.3.1.2.2
Pencil tank geometry control on fixed interaction spacing of individual tanks	CS-07	Defines spacing between different SSCs using geometry to prevent nuclear criticality	6.3.1.2.3
Floor and sump geometry control on slab depth, and sump diameter or depth for floor dikes	CS-08	Defines sump geometry and dimensions for SSCs using geometry to prevent nuclear criticality	6.3.1.2.4
Double-wall piping	CS-09	Defines transfer line leak confinement in locations where sumps under piping are neither feasible nor desirable	6.3.1.2.5
Closed safe-geometry heating or cooling loop with monitoring and alarm	CS-10	Closed-loop heat transfer fluid systems to prevent nuclear criticality or transfer of high-dose material across shielding boundary in the event of a leak into the heat transfer fluid	6.3.1.2.6
Simple overflow to normally empty safe-geometry tank with level alarm	CS-11	Overflow to prevent nuclear criticality from fissile solution entering non-geometrically favorable ventilation equipment	6.3.1.2.7
Condensing pot or seal pot in ventilation vent line	CS-12	Seal pots to prevent nuclear criticality from fissile solution entering non-geometrically favorable ventilation equipment	6.3.1.2.8
Simple overflow to normally empty safe geometry floor with level alarm in the hot cell containment boundary	CS-13	Overflow to prevent nuclear criticality from fissile solution entering non-geometrically favorable ventilation equipment	6.3.1.2.9
Active discharge monitoring and isolation	CS-14	Information to be provided in the Operating License Application	6.3.1.2.10
Independent active discharge monitoring and isolation	CS-15	Information will be provided in the Operating License Application	6.3.1.2.11

Table 2-2. Summary of Criticality Engineered Safety Features (2 pages)

Engineered safety feature	IROFS	SSC features providing engineered safety features	CPA detailed description section
Backflow prevention device	CS-18	Backflow prevention to preclude fissile or high dose solution from crossing shielding boundary to non-geometrically favorable chemical supply tanks and prevent nuclear criticality	6.3.1.2.12
Safe geometry day tanks	CS-19	Alternate backflow prevention device	6.3.1.2.13
Evaporator or concentrator condensate monitoring	CS-20	Prevent nuclear criticality from high-volume transfer to non-geometrically favorable vessels in solutions with normally low fissile component concentrations	6.3.1.2.14
Processing component safe volume confinement	CS-26	Defines volume of SSCs to prevent nuclear criticality	6.3.1.2.15
Closed heating or cooling loop with monitoring and alarm	CS-27	Closed-loop, high-volume heat transfer fluid systems to prevent nuclear criticality or transfer of high-dose material across shielding boundary in the event of a leak into the heat transfer fluid with normally low fissile component concentrations	6.3.1.2.16

CPA = construction permit application. SSC = structures, systems, and components.
IROFS = item relied on for safety.

Question 2.19: How will the applicant and the NWMI RPF comply with NRC regulations, including those in 10 CFR 20, and that the health and safety of the public will not be endangered.

The CPA was based on NRC regulations and applicable portions of NRC guidance, such as interim staff guidance (ISG) augmenting NUREG-1537 (NRC, 2012) and NUREG-series publications. The NRC staff reviewed the CPA and evaluated the application against the applicable regulations in 10 CFR 50 and 10 CFR 20, "Standards for Protection Against Radiation." The NRC staff considered applicable portions of its guidance. Based on the CPA and the NRC staff's review, documented in the NWMI RPF SER (NRC, 2017) and the Final Environmental Impact Statement (FEIS) (NUREG-2209, *Final Environmental Impact Statement for the Construction Permit for the Northwest Medical Isotopes Radioisotope Production Facility*), NWMI concludes that, for the purpose of issuing the CP for the RPF, the applicable standards and requirements of the Commission's regulations have been met. Compliance with these regulations ensures that the health and safety of the public will not be endangered.

Question 2.20: Describe the process used to develop the Integrated Safety Analysis using 10 CFR 70.61.

The integrated safety analysis (ISA) process (adapted for this application as allowed in the ISG [NRC, 2012]) consists of conducting a PHA of a system using a combination of written process descriptions, process flow diagrams (PFD), process and instrument drawings (P&ID), and supporting calculations to identify events that could lead to adverse consequences. Those adverse consequences are evaluated qualitatively by the ISA team members to identify the likelihood and severity of consequences using guidance on event frequencies and consequence categories consistent with the regulatory guidelines.

Each event with an adverse consequence that involves licensed material or its byproducts is evaluated for risk using a risk matrix that enables the user to identify unacceptable intermediate- and high-consequence risks (per 10 CFR 70.61, "Performance Requirements"). For the unacceptable intermediate- and high-consequence risks events, the IROFS developed to prevent or mitigate the consequences of the events and an event tree analysis are used to demonstrate that the risk can be reduced to acceptable frequencies through preventative or mitigative IROFS.

Fault trees and failure mode and effects analysis can be used to (1) provide quantitative failure analysis data (failure frequencies) for use in the event tree analysis of the IROFS, as necessary, or (2) quantitatively analyze an event from its basic initiators to demonstrate that the quantitative failure frequency is already highly unlikely under normal standard industrial conditions, thus not needing the application of IROFS. Once the IROFS are developed, management measures are identified to ensure that the IROFS failure frequency used in the analysis is preserved and the IROFS are able to perform the associated intended function when needed.

Question 2.21: Describe the development of the upper subcritical limit and how it was applied to the development of the criticality safety evaluations.

Nuclear criticality safety limits established for controlled parameters in the NWMI facility processes will ensure that all nuclear processes are subcritical, including an adequate margin of subcriticality for safety in accordance with ISG, Part 2, Section 6.b.3 (NRC, 2012). Monte-Carlo N-Particle (MCNP) calculation results used to set limits on parameters are compared to the upper subcritical limit (USL) established in the NWMI MCNP code validation report (NWMI-2014-RPT-006, *MCNP 6.1 Validations with Continuous Energy ENDF/B-VII.1 Cross-Sections*), after applying a 2σ calculation uncertainty.

The USL includes the method bias and uncertainty established in NWMI-2014-RPT-006 and a 0.05 Δk margin of subcriticality. In addition, the area of applicability, also established in NWMI-2014-RPT-006, is checked to ensure that the NWMI RPF process model physics and materials are within the bands of applicability. If either the physics or materials are outside the bands of applicability, an additional margin of subcriticality will be applied.

Question 2.22: Describe the methodology used to develop the bounding shielding requirements of the NWMI RPF.

The shielding analysis demonstrates that the RPF will comply with the regulatory requirements of 10 CFR 20. The intent of the shielding design is to limit the dose rate for the highest source term to 5 millirem (mrem)/hour (hr) at 30 centimeters (cm) from the most accessible the surface. Assuming an individual is working at this location for 200 hr/year, this will limit the total dose equivalent received to 1 roentgen equivalent in man (rem), which is half of the preliminary NWMI ALARA (as low as reasonably achievable) annual dose equivalent limit of 2 rem.

To evaluate the necessary shielding required to maintain these limits, a series of photon-spectrum source terms were generated for the following primary locations or process streams:

- Hot cell (dissolution) wall and window

- Target fabrication incoming material
- Offgas treatment
- High-dose waste container

Each of these process streams represents the expected maximum inventory for a given location requiring a bioshield within the RPF. A source term was estimated for each system based on the highest estimated radioactive material content entering the RPF and moving through each system, as designed at the minimum expected time from the end of irradiation. This source term was used to generate a photon energy spectrum indicative of the radioactive material inventory at a given time, which was then used by the particle transport code to estimate the thickness of the shielding material needed.

The final minimum thickness of a concrete shield structure is the greater of the: (1) thickness determined based on radiation shielding requirements, and (2) thickness determined based on structural requirements.

Question 2.23: Describe the instrumentation, control, and electrical systems.

The RPF preliminary I&C configuration includes the SNM preparation and handling processes (e.g., target fabrication, and uranium recovery and recycle), radioisotope extraction and purification processes (e.g., target receipt and disassembly, target dissolution, molybdenum [Mo] recovery and purification, and waste handling), process utility systems, criticality accident alarm system, and systems associated with radiation monitoring.

The SNM processes will be enclosed predominately by hot cells except for the target fabrication area. The facility process control (FPC) system will provide monitoring and control of the process systems within the RPF. In addition, the FPC system will provide monitoring of safety-related components within the RPF. The process strategy for the RPF involves the use of batch or semi-batch processes with relatively simple control steps.

The building management system (BMS) will monitor the RPF ventilation system and mechanical utility systems. The BMS primary functions will be to monitor the facility ventilation system and monitor and control (turn on and off) the mechanical utility systems.

The ESF systems will operate on actuation of an alarm setpoint reached for a specific monitoring instrument/device. For redundancy, this will be in addition to the FPC system or BMS ability to actuate ESF as needed. Each ESF safety function will use hard-wired analog controls/interlocks to protect workers, the public, and environment. The ESF parameters and alarm functions will be integrated into and monitored by the FPC system or BMS.

The FPC system will perform as the overall production process controller. This system will monitor and control the process instrumented functions within the RPF, including monitoring of process fluid transfers and controlled inter-equipment pump transfers of process fluids. The controls systems are described further in Chapter 7.0, "Instrumentation and Control Systems" (NWMI-2013-021).

The normal electric power system is designed to provide reasonable assurance that use or malfunction of electrical power systems will not damage the RPF or prevent safe RPF shutdown. The two underground feeders will be located on each side of the switchgear and will typically carry approximately half of the electrical load. However, each underground feeder will be capable of carrying the entire load of the facility. The RPF also has a non-safety standby electrical power system to reduce or eliminate process downtime due to electrical outages.

Uninterruptible power supply (UPS) systems will be provided for selected systems for the RPF, as identified Chapter 8.0, "Electrical Power Systems" (NWMI-2013-021). UPS systems include unit device, rack-mounted, and/or larger capacity cabinet units (a large battery room as part of the UPS system is not planned). These UPS systems will service loads requiring uninterruptable power on a short-term basis. The UPS systems will be backed up by the on-site diesel generator to extend the duration of power available to connected loads. A combination of UPSs and the standby electrical power system will provide emergency electrical power (defined in Chapter 8.0, Section 8.2).

Question 2.24: Describe the RPF cooling water system.

Cooling water systems are used to control the temperature of process solutions in the RPF from process activities and the heat load resulting from radioactive decay of the fission product inventory. The RPF is located at a separate site, independent from the reactors used to irradiate the targets. Therefore, the RPF cooling system does not influence operation of a reactor primary core cooling system.

Chilled water is used as the primary cooling fluid to process vessels. A central process chilled-water loop is used to cool three secondary loops: one large geometry secondary loop in the hot cell, one criticality-safe geometry secondary loop in the hot cell, and one criticality-safe geometry secondary loop in the target fabrication area. The central process chilled-water loop relies on air-cooled chillers, while the secondary loops are cooled by the central chilled-water system through plate-and-frame heat exchangers. Selected process demands require cooling at less than the freezing point of water. These demands are met with water-cooled refrigerant chiller packages, cooled by the secondary chilled water loops.

The Chapter 5.0, "Coolant Systems," analysis and description show that the cooling water system is designed such that the system will function in a manner, whether operational or not, consistent with occupational safety and protection of the public and environment. Therefore, the cooling function is not considered an IROFS. A description of the coolant systems for the RPF is provided in Chapter 9.0, "Auxiliary Systems," Section 9.7.

Question 2.25: List any other auxiliary systems which are part of the RPF.

The RPF has the following auxiliary systems:

- Fire protection systems
- Communication systems
- Possession and use of byproduct, source, and SNM
- Cover gas control in the closed primary coolant system
- Other auxiliary systems, including utility systems, analytical laboratory, and chemical supply

Question 2.26: Describe the RPF radioactive waste management and radiation protection programs.

The NWMI RPF has a radiation protection program to protect the radiological health and safety of workers. The program complies with the regulatory requirements of 10 CFR 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," 10 CFR 20, and 10 CFR 70. This program includes the elements of an ALARA program, radiation monitoring and surveying, exposure control, dosimetry, contamination control, and environmental monitoring. Additional details are provided in Chapter 11.0, "Radiation Protection and Waste Management," Section 11.1.2.

The radiation protection program provides a complete list of expected radiation and radioactive sources, including airborne, liquid, and solid sources. The radiation protection program also requires the development and implementation of procedures, identifies monitoring instrumentation and techniques, and specifies practices to be employed to verify compliance with the radiation dose limits and other applicable requirements. The basis and plans used to develop procedures for assessing and controlling radioactive wastes and the ALARA program are included.

Control of gaseous, liquid, and solid radioactive wastes in the RPF is described in Chapter 9.0, Sections 9.6 and 9.7. The NWMI waste management program for radioactive wastes resulting from normal operations and maintenance of the RPF, including the required procedures, ensure that radiation exposures and releases of radioactive materials are adequately assessed and controlled. The waste management program addresses the following elements:

- Philosophy and approach to waste management
- Basis of procedures and technical specifications
- Organization, staffing, and associated training
- Document control and records management
- Review and audit committees for radioactive waste management activities
- Plans for shipping, disposal, and long-term waste storage

Question 2.27: Does the Construction Permit Application form and content for the RPF conform to NRC's regulatory guidance?

NWMI prepared the CPA to be consistent with established regulatory guidance and acceptance criteria that were relevant to the CPA; much of the guidance was originally established for completed designs of nuclear reactor and fuel cycle facilities. The guidance that NWMI used to develop our CPA included:

- *Final Interim Staff Guidance Augmenting NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," Parts 1 and 2, for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors* (NRC, 2012)
- NUREG-0800, *Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants*
- NUREG-0849, *Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors*
- NUREG-1520, *Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility*
- NUREG-1537, *Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors - Format and Content* (Part 1)
- NUREG-1537, *Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria* (Part 2)

3. NRC Review of the NWMI RPF Construction Permit Application

Question 3.1: Did the NRC staff document its safety and environmental reviews of the Construction Permit Application for the RPF?

Yes. The NRC documented its safety review in the SER issued on November 16, 2017 (NRC, 2017), and documented its environmental review in the FEIS issued on May 31, 2017 (NUREG-2209).

Question 3.2: What were the NRC staff conclusions?

In the SER, the staff concluded the following in the information provided by the applicant and documented in the SER:

1. *Applicable standards and requirements of the AEA and Commission regulations have been met.*
2. *The acceptance criteria in or referenced in NUREG-1537 or the ISG Augmenting NUREG-1537, have been satisfied for a preliminary design supporting a construction permit application.*
3. *Required notifications to other agencies or bodies related to this licensing action have been duly made.*
4. *The design of the facility includes adequate margins of safety and there is reasonable assurance that the final design will conform to the design basis.*
5. *There is reasonable assurance that the production facility can be constructed in conformity with the permit, the provisions of the AEA, and the Commission's regulations.*
6. *NWMI identified credible accidents based on the preliminary design and designed IROFS to provide for the prevention of accidents or the mitigation of consequences of accidents. The staff has evaluated the accident analyses presented by NWMI in the PSAR and determined that NWMI identified appropriate preliminary controls to demonstrate, with reasonable assurance, that the performance objectives contained in 10 CFR 70.61 for the production facility can be met.*

7. *Releases of radioactive materials and wastes from the facility are not expected to result in concentrations outside the limits specified by 10 CFR Part 20, Subpart D, "Radiation Dose Limits for Individual Members of the Public," and are as low as is reasonably achievable.*
8. *The financial information, technical analyses and programs, and organization as described in the application demonstrate that NWMI is financially and technically qualified to engage in the construction of its proposed facility in accordance with the Commission's regulations*
9. *The preliminary emergency plan provides reasonable assurance that NWMI will be prepared to assess and respond to emergency events.*
10. *The application presents information at a level of detail that is appropriate for general familiarization and understanding of the proposed facility.*
11. *The application describes the relationship of specific facility design features to the major processes that will be ongoing at the facility. This description includes the building locations of major process components and drawings illustrating the layout of the buildings and structures within the controlled area boundary that are used for the description.*
12. *The application describes the major chemical or mechanical processes involving licensable quantities of radioactive material based, in part, on integrated safety analysis methodology. This description includes the building locations of major process components and brief accounts of the process steps.*
13. *Issuance of the construction permit will not be inimical to the common defense and security or to the health and safety of the public. Therefore, the staff finds that, subject to certain conditions, the preliminary design and analysis of the NWMI production facility, as described in the NWMI PSAR, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR Part 50. Appendix A to this SER identifies certain permit conditions that the staff recommends the Commission include, if the construction permit is issued.*

Question 3.3: Has the Advisory Committee on Reactor Safeguards conducted a review of the RPF Construction Permit Application?

Yes. The ACRS provided an independent review and report to the Commission regarding the NWMI RPF CPA. Five meetings were held on June 19, July 11, August 22 and 23, and September 21, 2017. The ACRS Subcommittee on Radiation Protection and Nuclear Materials reviewed the PSAR and draft SER during meetings on June 23–24, August 19, and September 22, 2015. A full ACRS meeting was held on November 2, 2017, and the ACRS issued a letter on November 6, 2017 recommending that a CP be issued to NWMI (Bley, 2017).

Question 3.4: Have you reviewed SECY-17-0116, "Staff Statement in Support of the Uncontested Hearing for Issuance of Construction Permit for the Northwest Medical Isotopes, LLC Production Facility," dated November 16, 2017?

Yes.

Question 3.5: Do you agree with the staff's conclusions in SECY-15-0130 regarding the staff safety review, ACRS Report, exemptions, and the safety matters the staff considers to be "Nonroutine Unique Facility Features or Novel Issues"?

Yes.

Question 3.6: Does SECY-15-0130 address the safety and environmental findings that must be made to issue the CP for the RPF? What are the findings?

Yes. The staff concludes that there is sufficient information in the record to support the required findings to issue the CP. In summary, the NRC staff found that, subject to certain conditions (SER [NRC, 2017], Appendix A), the NWMI preliminary design and analysis of the RPF as described in the CPA, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a CP in accordance with 10 CFR 50. Each finding is discussed in additional detail in Section 4 of my testimony.

Question 3.7: Do you agree with the overall conclusions reached in SECY-15-0130?

Yes.

Question 3.8: Were any petitions to intervene submitted on the NWMI Construction Permit Application?

No.

4. Safety and Environmental Findings

Question 4.1: Describe the regulatory requirements applicable to the safety review of the RPF Construction Permit Application.

The regulatory requirements applicable to the safety review of the CPA are primarily contained in 10 CFR 50. Specifically:

- 10 CFR 50.2, "Definitions"
- 10 CFR 50.22, "Class 103 licenses; for commercial and industrial facilities"
- 10 CFR 50.33, "Contents of applications; general information," paragraph (f)
- 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 50.42, "Additional standard for class 103 licenses"
- 10 CFR 50.50, "Issuance of licenses and construction permits"
- 10 CFR 50.55, "Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses"
- 10 CFR 50.58, "Hearings and report of the Advisory Committee on Reactor Safeguards"
- Appendix C, "A Guide for the Financial Data and Related Information Required to Establish Financial Qualifications for Construction Permits and Combined Licenses"
- Appendix E, "Emergency Planning and Preparedness for Production and Utilization Facilities"

Other regulatory requirements applicable to the RPF CPA include:

- 10 CFR 20.1201, "Occupational dose limits for adults"
- 10 CFR 20.1301, "Dose limits for individual members of the public"
- 10 CFR 70.61, "Performance requirements"
- 10 CFR 70.62, "Safety program and integrated safety analysis"

Question 4.2: Summarize the NRC staff's safety review of the RPF Construction Permit Application.

The NRC staff's review is summarized in SECY-17-0116. Approximately 200 safety and environmental RAIs were developed by the NRC staff and responded to by NWMI. This number of RAI indicates the depth of the staff's review of the CPA for the RPF.

Question 4.3: What is the staff's conclusion in the SER regarding the RPF?

The SER concludes that:

"Therefore, the staff finds that subject to certain conditions, the preliminary design and analysis of the NWMI production facility, as described in the NWMI PSAR, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of a construction permit in accordance with 10 CFR 50. Appendix A to this SER identifies certain permit conditions that the staff recommends the omission include, if the construction permit is issued."

Question 4.4: Are the necessary findings in 10 CFR 50 met for the RPF?

Yes. Based on the staff's conclusions discussed in the response to Question 4.3, and as summarized in SECY-17-0116 (pages 20 through 26), each of the relevant findings in 10 CFR 50 have been met. Each finding is presented in more detail below.

Finding 1: *10 CFR § 50.35(a) – The applicant has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and*

has identified the major features or components incorporated therein for the protection of the health and safety of the public

Finding 2: *10 CFR § 50.35(a) – 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 safety analysis report.*

Finding 3: *10 CFR § 50.35(a): Safety features or components, if any, which require research and development have been described by the applicant and the applicant has identified, and there will be conducted, a research and development program reasonably designed to resolve any safety questions associated with such features or components.*

Finding 4: *10 CFR § 50.35(a) – 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.

(ii) Taking into consideration the site criteria contained in Part 100 of this chapter, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

Finding 5: *10 CFR § 51.105 (a) –*

(i) Determine whether the requirements of Sections 102(2) (A), (C), and (E) of NEPA and the regulations in Subpart A of 10 CFR Part 51 have been met.

(ii) Independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken.

(iii) Determine, after weighing the environmental, economic, technical, and other benefits against environmental and other costs, and considering reasonable alternatives, whether the construction permit should be issued, denied, or appropriately conditioned to protect environmental values.

(iv) Determine, in an uncontested proceeding, whether the NEPA review conducted by the staff has been adequate.

Question 4.5: Has the NRC staff reached a conclusion on all findings listed above?

Yes.

Question 4.6: Do you agree with the NRC staff's conclusion?

Yes.

5. Conclusions

Question 5.1: What are your overall safety conclusions regarding issuance of the Construction Permit?

The CPA contains sufficient information to demonstrate compliance with the applicable standards and requirements in the Act and the Commission's regulations. NWMI has sufficiently described the proposed design of the RPF in the CPA. Additional technical, design, and operational information will be supplied in the final safety analysis report (FSAR).

Appendix A.2 and Appendix A.5 of the SER (NRC, 2017) identify the issues that must be addressed as part of an OLA, and those items that are being tracked by NWMI and the NRC staff. There is reasonable assurance that safety questions will be satisfactorily resolved before the latest date stated for completion of construction of the RPF and that the proposed RPF can be constructed at the proposed location without undue risk to the health and safety of the public. Issuance of the CP for the RPF will not be inimical to the common defense and security or the health and safety of the public.

The review of the CPA by the NRC staff was adequate to support these conclusions.

Question 5.2: What are your overall environmental conclusions regarding issuance of the Construction Permit?

The environmental review conducted by the NRC staff pursuant to 10 CFR 51 has been adequate; the requirements of Sections 102(2) (A), (C), and (E) of NEPA have been satisfied; an independent weighing and balancing of the environmental, technical, and other costs and benefits of the RPF supports issuance of the CP and the requested CP should be issued.

Question 5.3: Does the Construction Permit Application for the RPF and the associated NRC staff's review of the application satisfy the requirements for issuance of the Construction Permit?

Yes.

Question 5.4: Does this conclude your testimony?

Yes.

TERMS

Acronyms and Abbreviations

3D	three-dimensional
^{99}Mo	molybdenum-99
^{99m}Tc	technetium-99m
ACRS	Advisory Committee on Reactor Safeguards
AEM	Consulting, LLC
ALARA	as low as reasonably achievable
Atkins Energy	Atkins Energy, Inc.
BMS	building management system
CFR	Code of Federal Regulations
CP	Construction Permit
CPA	Construction Permit Application
Discovery Ridge	Discovery Ridge Research Park
DOE	U.S. Department of Energy
ESF	engineered safety feature
FEIS	final environmental impact statement
FPC	facility process control
FR	Federal Register
FSAR	final safety analysis report
GLASS	graphical logic analysis solution system
HEU	high-enriched uranium
HFR	high flux reactor
I&C	instrumentation and control
IROFS	item relied on for safety
ISA	integrated safety analysis
ISG	Interim Staff Guidance
LEU	low-enriched uranium
McCarthy	McCarthy Building Company
MCNP	Monte-Carlo N-Particle
Merrick	Merrick & Company
Mo	molybdenum
MU	University of Missouri
MURR	University of Missouri Research Reactor
NRC	U.S. Nuclear Regulatory Commission
NRU	National Research Universal
NWMI	Northwest Medical Isotopes, LLC
OLA	Operating License Application
OPAL	Open Pool Australian Lightwater
OSTR	Oregon State TRIGA Reactor
P&ID	process and instrument drawing
PFD	process flow diagrams
PHA	preliminary hazards analysis
Portage	Portage, Inc.
PSAR	preliminary safety analysis report
RAI	request for additional information
RPF	radioisotope production facility
SER	safety evaluation report

SNM	special nuclear material
SPECT	single photon emission computerized tomography
SSC	structures, systems, and components
U.S.	United States
UPS	uninterruptible power supply
USL	upper subcritical limit

Units

Ci	curie
cm	centimeter
ft	feet
ft^2	square feet
ha	hectare
hr	hour
km	kilometer
m	meter
m^2	square meter
mi	mile
mrem	millirem
rem	roentgen equivalent in man

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CERTIFICATION AND DECLARATION OF WITNESS

I certify that this testimony was prepared by me or under my direction; that the written testimony is true and correct to the best of my information, knowledge and belief; and that I adopt these responses as part of my sworn testimony in this proceeding.

I declare under penalty of perjury that the foregoing written testimony is true and correct to the best of my information, knowledge, and belief.

Executed on January 1, 2018.

Respectfully submitted,

Executed in Accord with 10 C.F.R. § 2.304(d)

Carolyn C Haass

Digitally signed by Carolyn C Haass
Date: 2018.01.01 11:14:56 -07'00'

Signed (electronically) by Carolyn C. Haass

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