SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

PUBLIC VERSION

The NRC staff determined that additional information was required (Reference 1) to enable the continued review of the SHINE Medical Technologies, Inc. (SHINE) application for a construction permit to construct a medical isotope facility (References 2 and 3). The following information is provided by SHINE in response to the remaining NRC staff's requests.

CHAPTER 9 – AUXILIARY SYSTEMS

Section 9a2.1 – Heating, Ventilation, and Air Conditioning Systems

RAI 9a2.1-3

NUREG-1537, Part 2, Section 9.1, "Heating, Ventilation, and Air Conditioning Systems," Acceptance Criteria, states, in part: "The design and operating features of the system should ensure that no uncontrolled release of airborne radioactive material to the unrestricted environment could occur."

a. *While SHINE provided information on the source of air supply for Radiological Controlled Area (RCA) Ventilation System Zone 1 (RVZ1), in response to RAI 9a2.1-1(a), PSAR Figures 9a2.1-1, "RVZ1 Ventilation Flow Diagram," and 9a2.1-2, "RVZ2SA and RVZ2 Ventilation Flow Diagram" were not revised. SHINE's response also did not clarify what areas/enclosures/rooms are considered RVZ1, RCA Ventilation System Zone 2 (RVZ2), and RCA Ventilation System Zone 3 (RVZ3). Additionally, a revised RVZ3 flow diagram was not provided as requested in RAI 9a2.1-1(b).*

   Additionally, while the text in SHINE PSAR Section 9a2.1.1, "Radiologically Controlled Area Ventilation System," describes RVZ1, RVZ2, and RVZ3, Figure 9a2.1-2 indicates the existence of a "Zone 4."

   SHINE PSAR Section 9a2.1.1 also describes a negative pressure differential between RVZ2 and RVZ3. However, there is insufficient information describing air flow and pressure differentials between other zones.

   In response to RAI 3.5-3 SHINE states, "…the RVZ3 fans are not operating…" while Figure 9a2.1-2 shows no fans associated with RVZ3. Figure 9a2.1-2 only depicts the Zone 3 airlocks. No other areas are shown to be part of RVZ3 and there is no discussion in the RAI response as to what RVZ3 encompasses.

   Therefore, additional information is needed for NRC staff to assess the adequacy of the design of SHINE RCA System Zones to ensure that no uncontrolled release of airborne radioactive material to the unrestricted environment could occur.

i. Provide additional information stating what areas/enclosures/rooms are considered RVZ1, RVZ2, and RVZ3, as well as revised flow diagrams and descriptions for RVZ1, RVZ2, and RVZ3. Ensure consistency between figures and descriptions in the text of SHINE PSAR Section 9a2.1, "Heating Ventilation, and Air Conditioning Systems." Include a description and flow diagram for "Zone 4," as applicable.

ii. Clarify whether a negative pressure differential is maintained to keep air flowing from low contamination areas towards high contamination areas, both in rooms and between zones. Include information describing whether a negative pressure differential is maintained between the RCA and outside the RCA.

b. SHINE's response to RAI 9a2.1-1 discusses "RPF Airlocks" and an "IF Airlock" supplied by RVZ2 Supply Air. The response also states that "RVZ3 areas include the RCA airlocks." Additionally, Figure 9a2.1-2 shows two "Zone 3 Airlocks" and Figure 9a2.1-2-1, "Facility Ventilation Zone 4 Flow Diagram," shows an arrow to the "RPF Airlocks" and an arrow to the "Irradiation Facility Airlock." However, SHINE PSAR Figure 1.3-2, "SHINE General Arrangement" depicts the following airlocks:

- *Receiving Airlock/Man Door Airlock (RCA NE corner)*
- *Airlock Emergency Exit (RCA NW corner)*
- *Two Airlocks by Shipping (RCA SE Corner)*
- *Airlock by Health Physics (RCA SW Corner)*

Additional information is needed relating the discussion of airlocks in response to RAI 9a2.1-1, the airlocks shown in Figures 9a2.1-2 and 9a2.1-2-1, and the airlocks shown in Figure 1.3-2 in order for NRC staff to assess the adequacy of the design of SHINE RCA System Zones to ensure that no uncontrolled release of airborne radioactive material to the unrestricted environment could occur.

Provide additional information relating the discussion of airlocks in response to RAI 9a2.1-1, the airlocks shown in Figures 9a2.1-2 and 9a2.1-2-1, and the airlocks shown in Figure 1.3-2.

SHINE Response

a. i. The SHINE production facility is designed with four ventilation zones, as described below. The Radiologically Controlled Area (RCA) Ventilation System (RV) consists of three ventilation zones and is ventilated such that airflow travels in the direction from areas of lower potential for contamination to areas of higher potential for contamination. The fourth ventilation zone, Facility Ventilation Zone 4 (FVZ4), consists of areas outside of the RCA where contamination is not expected to be present.

SHINE has revised Subsection 9a2.1.1 of the PSAR to provide a clear description of RCA Ventilation Zone 1 (RVZ1), RCA Ventilation Zone 2 (RVZ2), and RCA Ventilation Zone 3 (RVZ3). A mark-up of the PSAR changes is provided in Attachment 1. The non-public (proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 3. The public (non-proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 4.

A preliminary flow diagram of the RV is provided in Figure 9a2.1-3-1. SHINE has revised the PSAR to replace the RVZ1 flow diagram, provided in Figure 9a2.1-1 of the PSAR, and the RCA Zone 2 Supply Air (RVZ2SA) and RVZ2 flow diagram, provided in Figure 9a2.1-2 of the PSAR, with the preliminary flow diagram of the RV provided in Figure 9a2.1-3-1. A mark-up of the PSAR changes is provided in Attachment 1. The non-public (proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 3. The public (non-proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 4.

RCA Ventilation Zone 1 (RVZ1)

RVZ1, the primary confinement zone, includes those areas where high levels of airborne contamination are anticipated during normal operations. RVZ1 areas include the interior of hot cells, irradiation unit (IU) cells, enclosures, vessels, RVZ1 exhaust system ductwork, and high efficiency particulate air (HEPA) filter plenums.

RVZ1 areas draw ambient supply air from adjacent RVZ2 spaces. RVZ1 areas are maintained at negative pressure with respect to their surrounding RVZ2 spaces. RVZ1 area air inlets are equipped with automatic isolation dampers (fail closed), manual isolation dampers, and non-credited HEPA filters. These HEPA filters are not assumed to be present in accident analyses, and are present just to provide additional protection to workers and equipment.

The exhaust air from each RVZ1 area filters through local HEPA filters. In addition to the automatic isolation dampers on the air inlet, each RVZ1 area exhaust outlet includes automatic isolation dampers to enable confinement of the RVZ1 area. These automatic dampers are safety-related and isolate the RVZ1 areas upon a signal from the Engineered Safety Features Actuation System (ESFAS) or the Radiological Integrated Control System (RICS), and reduce the exhaust of released airborne material.

Negative space pressure in RVZ1 is controlled through modulation of local exhaust air flow control valves for each cell.

The RVZ1 exhaust system is equipped with redundant fans. During normal operation, one fan is operating while the other fan is on standby. If the operating fan fails, the standby fan will start automatically. The RVZ1 system exhaust fans draw air through the inlet filters, dampers, and piping, providing the pressure drop needed to maintain pressure negative within the RVZ1 area.

The speed of the RVZ1 exhaust fans is controlled to maintain a negative pressure set point in the RVZ1 exhaust duct header. RVZ1 exhaust also receives treated output from the Noble Gas Removal System (NGRS) through the Process Vessel Vent System (PVVS). The exhaust from RVZ1 areas collects in the RVZ1 system duct header and then draws through final, testable, HEPA filters and carbon adsorbers prior to discharge into the exhaust stack. Testing of the HEPA filters and carbon adsorbers is performed in accordance with vendor recommendations and applicable regulatory guidance, as described in the SHINE Response to RAI 11.3-2, below.

RVZ1 exhaust discharges to the nominally 56 inch diameter exhaust stack with a radiation monitoring system. The discharge point of the stack is approximately 10 feet above the roof line.

The RVZ1 exhaust heating, ventilation, and air conditioning (HVAC) control components operate through the Facility Integrated Control System (FICS) and are nonsafety-related, except for the isolation dampers noted above, and the automatic isolation dampers located in the RVZ1 exhaust ductwork downstream of the final filters. These isolation dampers are controlled by ESFAS and RICS, which are safety-related. The isolation dampers located in the RVZ1 exhaust ductwork downstream of the final filters perform a safety function and close when required to provide confinement at the RCA boundary.

The following areas/enclosures/rooms, as shown in Figure 9a2.1-3-2, are considered RVZ1:

- IU cells
- Target Solution Vessel (TSV) Off-Gas System (TOGS) shielded cells
- Hot cells
  - Supercells (including extraction, purification, and packaging segments)
  - Uranium extraction (UREX)
  - Solid waste packaging
  - Pump transfer
  - Waste evaporation
  - Liquid waste solidification
- Noble gas storage cell
- Thermal denitration area
- Tritium Purification System (TPS) gloveboxes

Tank atmospheres containing radioactive gases are vented by the PVVS, which ultimately discharges to RVZ1.

The two uranyl sulfate preparation tanks have an attached glovebox for the purposes of handling uranium oxide powder to prepare uranyl sulfate. These gloveboxes will share an atmosphere with the uranyl sulfate preparation tank. It is planned to connect this shared atmosphere to PVVS, which ultimately discharges to RVZ1. Therefore, these gloveboxes will be ventilated by RVZ1, but via the PVVS connection to RVZ1, rather than a direct connection.

The SHINE Response to RAI 9a2.1-1 (Reference 4) and Subsections 4b.2.1, 13a2.1.1, 13b.2.1, and 13b.2.4.2 of the PSAR contain an administrative error, referencing the thermal denitration process taking place in a hot cell. The thermal denitration process will take place within the thermal denitration area of the Radioisotope Production Facility (RPF), and not within a hot cell, due to the low activity of the material handled in this process. SHINE has revised Subsections 4b.2.1, 13a2.1.1, 13b.2.1, and 13b.2.4.2 to correct the administrative error. A mark-up of the PSAR changes is provided in Attachment 1. The non-public (proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 3. The public (non-proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 4.

RCA Ventilation Zone 2 (RVZ2)

RVZ2, the secondary confinement zone, includes those areas where airborne contamination could be (but is not routinely) generated during normal operations, or as a result of a breach of an RVZ1 confinement area. RVZ2 areas are transient spaces prone to fluctuations in pressure because of changing airflows based on door

movements and fume hood activity. RVZ2 areas are established by walls, floors, ceilings, and associated ventilation systems that confine any potential release of hazardous materials from an RVZ1 confinement area.

RVZ2 areas are directly supplied air via the RCA supply air handling units (AHUs). The AHUs supply 100 percent outside air to the RVZ2 areas. Each AHU contains filters, pre-heat and cooling coils, and supply fans. The supply system includes three AHUs, each sized for 50 percent of total system capacity. If a single AHU fails, the standby AHU will start automatically. The AHUs normally supply a constant volume of conditioned air to RVZ2 and RVZ3 areas. In addition to the outside air supplied directly to RVZ2 areas, RVZ3 air is cascaded into RVZ2 areas through engineered airlock door leakage pathways by a negative pressure differential, maintaining the desired pressure drop between the zones. RVZ2 areas are maintained at negative pressure with respect to RVZ3 areas.

Terminal unit components in the supply duct system include air flow control valves and reheat coils. The terminal reheat coils provide final tempering of supply air to maintain the RVZ2 temperature set point. RVZ2 supply airflow control valves operate in conjunction with exhaust valves to control the negative pressure differential in each zone by maintaining a fixed offset between the total supply and exhaust air flows for each RVZ2 areas.

RCA supply air controls operate through the FICS and are nonsafety-related, except for the automatic isolation dampers (bubble-tight dampers) in the supply duct system at the RCA boundary. These dampers are operated by the safety-related RICS, and perform a safety function, closing when required to provide confinement at the RCA boundary.

RVZ2 areas exhaust through general room exhausts and fume hood enclosures (where present). A portion of the air in RVZ2 areas is also transferred to RVZ1 areas through RVZ1 area air inlets, which contain automatic isolation dampers (fail closed), manual isolation dampers, and non-credited HEPA filters. As described above, the RVZ2 supply and exhaust systems will have airflow control valves, reacting to maintain the design differential pressure and ensuring the zone pressures are negative with respect to atmosphere and RVZ3. Flow control valves in fume hood exhaust ducts (where present) maintain a constant volume through each fume hood. The control valves automatically modulate to compensate for changes in pressure drop due to loading of local filters.

The RVZ2 exhaust system is equipped with redundant fans. During normal operation, one fan is operating while the other fan is on standby. If the operating fan fails, the standby fan will start automatically. Exhaust from RVZ2 areas collects in an RVZ2 exhaust header, and then draws through final, testable, HEPA filters and carbon adsorbers, prior to discharge into the exhaust stack. The RVZ2 exhaust fan speed is controlled to maintain the desired negative pressure in the RVZ2 exhaust header, and local automatic control valves adjust to maintain the negative pressure in the zone.

Along with RVZ1, RVZ2 exhaust discharges to the nominally 56 inch diameter exhaust stack, which contains a stack monitoring system. The discharge point of the stack is approximately 10 feet above the roof line.

The RVZ2 controls operate through the FICS and are nonsafety-related, except for the automatic isolation dampers in the supply duct at the RCA boundary and in the RVZ2 exhaust duct system located downstream of the final filters. These perform a safety function and close when required to provide confinement at the RCA boundary.

SHINE has revised Subsection 9a2.1.1 to remove the reference to safety-related backdraft dampers in the supply duct system at the RCA boundary. SHINE does not credit the backdraft dampers in the accident analysis. A mark-up of the PSAR changes is provided in Attachment 1. The non-public (proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 3. The public (non-proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 4.

The following areas/enclosures/rooms, as shown in Figure 9a2.1-3-2, are considered RVZ2:

- Irradiation Facility (IF) general area
- Primary cooling rooms
- Tritium Purification System (TPS) room
- RPF hot cell operating and service access areas
- RCA exhaust filter room (mezzanine)
- Uranyl sulfate preparation area and fume hood
- Uranyl sulfate storage room
- U.S. Food and Drug Administration (FDA) Laboratory and fume hood
- Hot Laboratory and fume hood
- Decon room
- Health Physics room
- Tool crib

RCA Ventilation Zone 3 (RVZ3)

RVZ3, the tertiary confinement zone, includes those areas where airborne contamination is not expected during normal facility operations. RVZ3 areas are bounded by walls, doors, floors, and ceilings.

RVZ3 areas are directly supplied air via the RCA supply AHUs described above. A small amount of air is also transferred from FVZ4 to RVZ3 via the use of airlock doors. The SHINE Response to RAI 3.5-3 (Reference 4) contains an administrative error, describing RVZ3 areas as being supplied by RVZ3 fans. There are no RVZ3 fans in the design of the SHINE facility. An Issues Management Report (IMR) has been initiated to address the error.

RVZ3 areas have airflow control valves on the supply side delivering air balanced to the design values. Forced air supplied to RVZ3 is then transferred to RVZ2 spaces through engineered airlock door leakage pathways. RVZ3 areas are maintained at an elevated pressure relative to RVZ2 areas, and a negative pressure relative to FVZ4 spaces. No RVZ3 exhaust system is anticipated, as the air from RVZ3 areas is transferred to RVZ2 areas.

The following areas, as shown in Figure 9a2.1-3-2, are considered RVZ3:

- IF airlock (includes doors for personnel access and equipment access)
- RPF freight airlock (equipped with overhead doors, adjacent to the RPF shipping personnel airlock)
- RPF shipping personnel airlock (intended for personnel access)
- RPF main personnel airlock (located adjacent to the Health Physics room)
- RPF mezzanine airlock
- RPF emergency exit airlock

Facility Ventilation Zone 4 (FVZ4)

A description of FVZ4, including a flow diagram, is provided in the SHINE Response to RAI 9a2.1-2 (Reference 4) and Subsection 9a2.1.2 of the PSAR. Areas of the SHINE facility designated as FVZ4 are provided in Figure 9a2.1-3-2.

ii. SHINE maintains a negative pressure differential between the confinement zones of the SHINE facility (i.e., $P_{RVZ1} < P_{RVZ2} < P_{RVZ3} < P_{ambient}$), ensuring airflow travels in the direction from zones of lower potential for contamination to zones of higher potential for contamination. A pressure differential is not specifically maintained between rooms within the same confinement zone. FVZ4, outside of the RCA, is slightly positively pressurized with respect to the atmosphere, while RV zones have a negative pressure differential with respect to atmosphere. Preliminary differential pressures for each confinement zone of the SHINE facility are provided in Table 9a2.1-3-1, below.

Table 9a2.1-3-1: Confinement Zone Differential Pressures

Confinement Zone	Differential Pressure[(a)]
FVZ4	Slightly positive with respect to atmosphere
RVZ3	-0.01 to -0.15 in.
RVZ2	-0.3 to -0.6 in.
RVZ1	-1.0 to -1.2 in.

a) With respect to the reference gage pressure (atmosphere) of 0.00 in.

b. Part a(i) of this response, above, describes the airlock servicing the IF and the five airlocks servicing the RPF. Figure 9a2.1-3-2 provides the locations of the IF airlock and the five RPF airlocks, specifically labeling each of the airlocks shown on Figure 1.3-2 of the PSAR.

The SHINE Response to RAI 9a2.1-1 and Figure 9a2.1-2-1 (Reference 4) reference the IF airlock and group the five RPF airlocks into a single reference, “RPF airlocks.”

Figure 9a2.1-2 of the PSAR provided a typical configuration for an RVZ3 airlock, including supply air directly from the RCA supply AHUs and offset airflow from FVZ4, and the transfer of air from RVZ3 airlocks to RVZ2. The two typical airlock configurations provided in Figure 9a2.1-2 were representative of the actual configuration of the airlocks in the SHINE facility.

The preliminary RV flow diagram, provided as Figure 9a2.1-3-1, includes the IF airlock and the five RPF airlocks. SHINE has replaced Figure 9a2.1-2 of the PSAR with Figure 9a2.1-3-1, as described in Part a(i) of this response.

Figure 9a2.1-3-1: Preliminary RCA Ventilation System Flow Diagram
(Sheet 1 of 2)

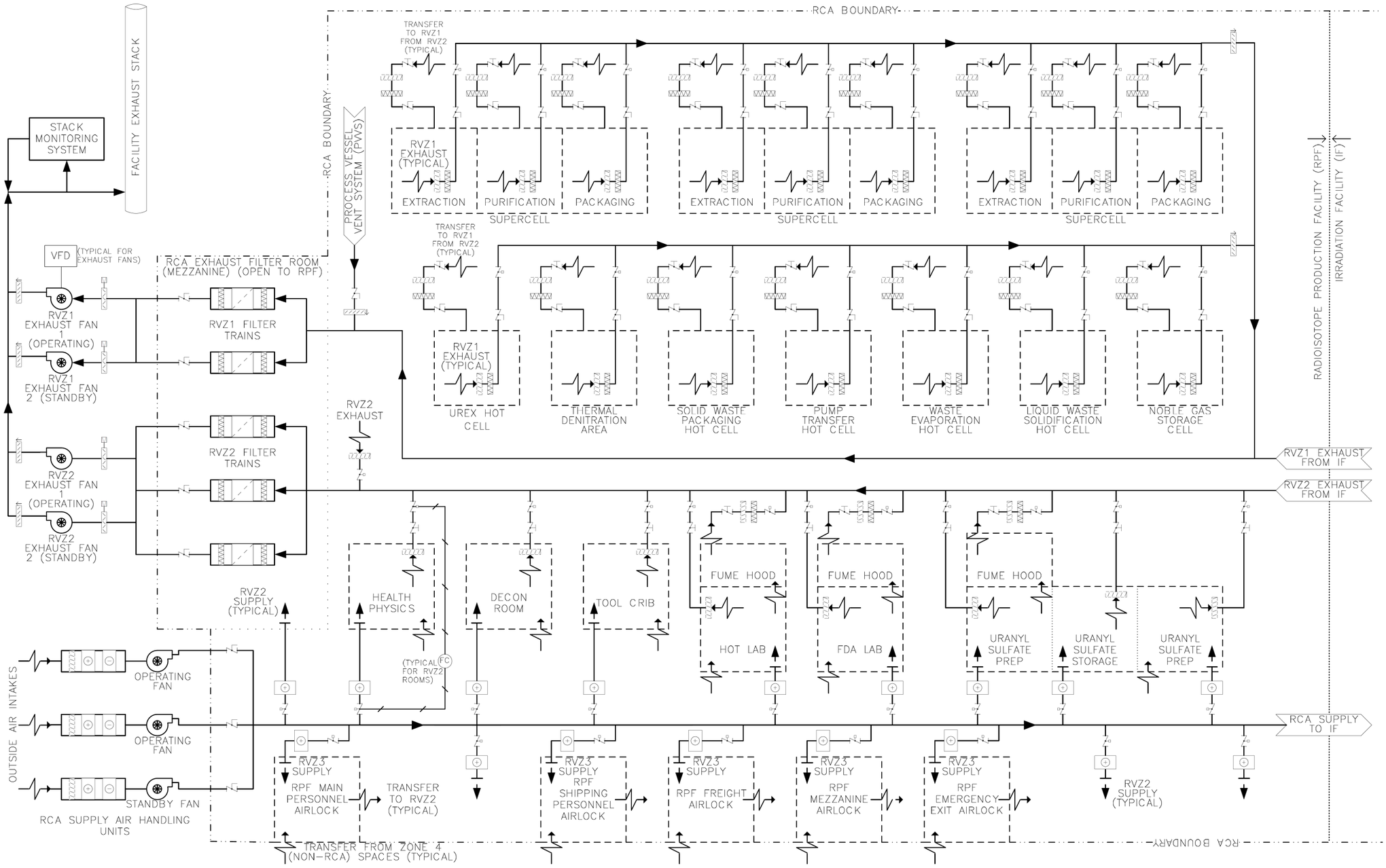

Figure 9a2.1-3-1: Preliminary RCA Ventilation System Flow Diagram
(Sheet 2 of 2)

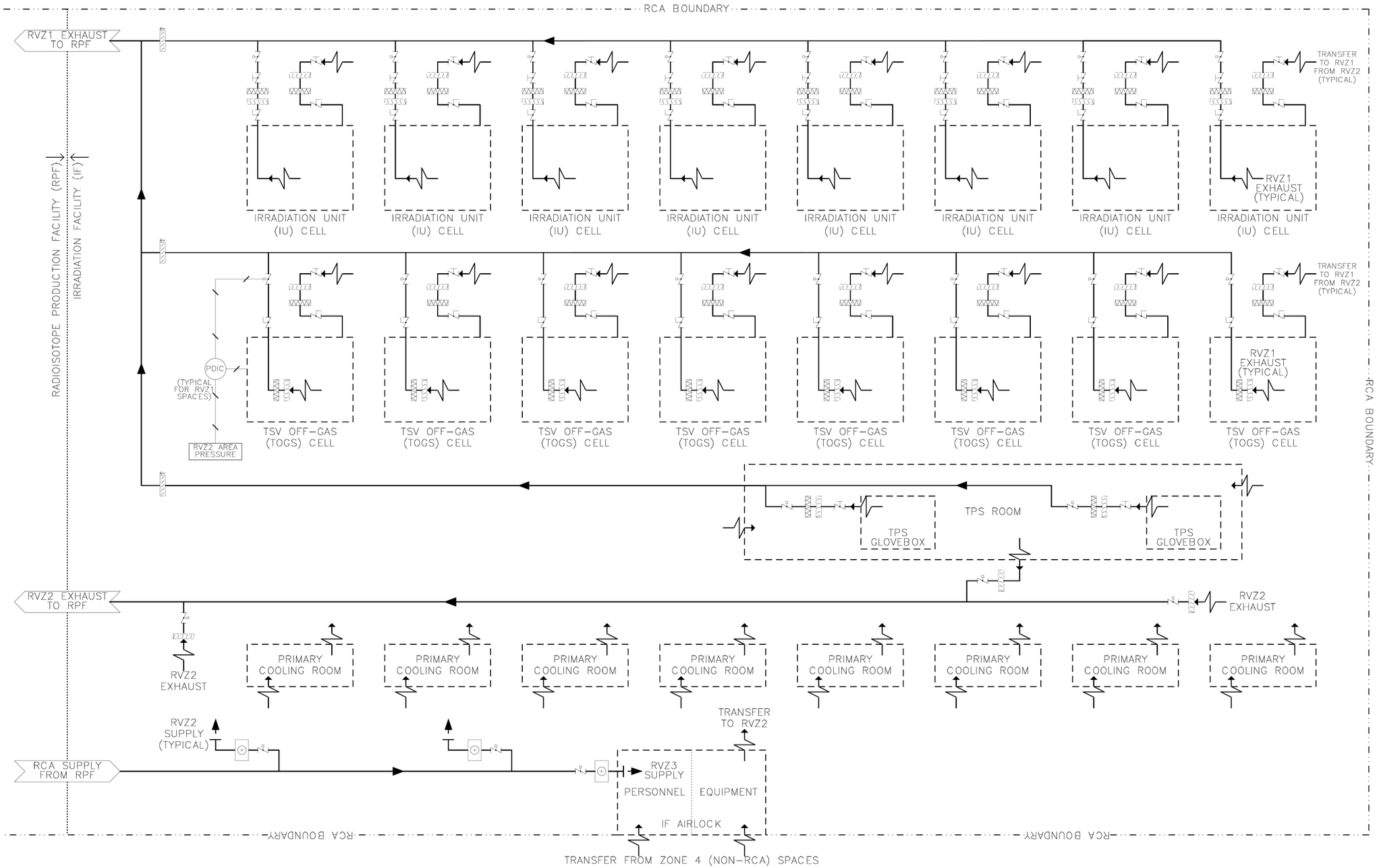

Figure 9a2.1-3-2: Preliminary Ventilation System Zone Designations Within the SHINE Facility

Security-Related Information

CHAPTER 11 – RADIATION PROTECTION PROGRAM AND WASTE MANAGEMENT

Section 11.1 – Radiation Protection

RAI 11.1-10

NUREG-1537, Part 2, Section 11.1.1 states in part, "All sources of radiation should be discussed by the applicant. This discussion should include the … exposure rates, energy level, encapsulation (sealed or unsealed), use, storage conditions and locations…"

SHINE PSAR Section 11.1.1, (page 11-2) "Radiation Sources," indicates that radiation shielding is designed to ensure that the use and storage conditions for the radiation sources have the appropriate controls and shielding. In addition, the shielding will ensure that the exposure rates assure conformance with ALARA practices as required by 10 CFR 20.1101.

Additional information is needed for the NRC staff to evaluate the consistency of SHINE's shielding design based on the types and locations of radiation sources.

a. *Specify the sections of 10 CFR Parts 20 (e.g., ALARA, occupational dose limits, public dose limits) and the exposure rates that will be implemented by shielding.*

b. *Provide additional information on the type(s) and location(s) of shielding used at the SHINE facility to ensure compliance with ALARA practices, the administrative dose limits, and the occupational dose limits.*

SHINE Response

a. Biological shielding within the SHINE facility is designed to ensure that occupational dose limits, public dose limits, and the as low as reasonably achievable (ALARA) requirements of 10 CFR 20 are met. Specifically, shielding helps to implement the occupational limits in 10 CFR 20.1201, 20.1207, and 20.1208, and the public dose limits of 10 CFR 20.1301. The SHINE Radiation Protection (RP) Program and the facility shielding will maintain occupational exposure and exposure to the public ALARA, in accordance with 10 CFR 20.1101. As described in Table 11.1-7 of the PSAR, SHINE administratively restricts whole body total effective dose equivalent (TEDE) to adult workers to 0.5 rem/year, which is a factor of 10 below the regulatory limit.

   Shielding calculations are performed using conservative assumptions to obtain conservative estimates of the dose rates in the facility. The exposure rates that will be achieved by shielding for normally-occupied areas are 0.25 mrem/hr or less at 12 inches from the surface of the shielding. Tables 11.1-4 and 11.1-5 of the PSAR provide specific dose rates to be achieved by shielding.

b. Radiation sources that have significant dose rates associated with them are evaluated to determine shielding requirements. The primary materials for biological shielding include an engineered concrete mix and steel reinforcing bars. Shielding in specific areas may consist of other materials, as well, such as steel, lead, and leaded glass. Shield thicknesses are designed to reduce dose rates to 0.25 mrem/hr or less at 12 inches from the surface for normally occupied areas. Penetrations through biological shields are designed with well demonstrated techniques of non-linear paths, supplemental shielding, location in areas of

low incident radiation, and other methods to reduce streaming and leakage. Temporary shielding in the form of personal protective equipment and movable shielding will also be used when necessary during maintenance activities to maintain exposures ALARA.

Specific details on the biological shielding within the IF and RPF are provided in Sections 4a2.5 and 4b.2 of the PSAR, respectively. Tables 11.1-4 and 11.1-5 of the PSAR provide specific dose rates to be implemented by shielding. Based on the above, the shielding used at the SHINE facility will ensure compliance with ALARA practices, the administrative dose limits, and the occupational dose limits.

(Applies to RAIs 11.1-11 through 13)

> *10 CFR 20.1101, "Radiation protection programs," Item (b) requires licensees to "…use, to the extent practical, procedures and engineering controls…to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)."*

RAI 11.1-11

NUREG-1537, Part 2, Section 11.1.1 states, in part, that maximum annual dose and collective doses for major radiological activities shall be shown to be within the applicable limits of 10 CFR Part 20.

SHINE PSAR Section 11.1.1.1 (page 11-3), "Airborne Radioactive Sources," states that "[t]he tritium purification system and neutron driver are designed such that the estimated annual doses to the [maximally exposed individual] and the nearest resident are below the regulatory limits specified in 10 CFR 20.1101(d)."

Additional information is needed for the NRC staff to determine the adequacy of SHINE's implementation of the applicable limits of 10 CFR Part 20.

Clarify that all the activities in the SHINE Radioisotope Production Facility are designed to meet the requirements of 10 CFR 20.1101(d), as the current statement in the SHINE PSAR only applies to the tritium purification system and neutron driver.

SHINE Response

In addition to the design of the Tritium Purification System (TPS) and the neutron driver, all activities in the IF and RPF are designed to meet the dose constraint specified in 10 CFR 20.1101(d)

SHINE has revised Subsection 11.1.1.1 of the PSAR to clarify that activities in the IF and RPF are designed such that the estimated annual doses to the maximally exposed individual (MEI) and the nearest resident are below the dose constraint specified in 10 CFR 20.1101(d). A mark-up of the PSAR changes is provided in Attachment 1. The non-public (proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 3. The public (non-proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 4.

RAI 11.1-12

NUREG-1537, Part 2, Section 11.1.3, "ALARA Program," states, in part that "[f]acility management should ensure that sufficient emphasis is placed on and sufficient resources are given to ALARA considerations during design, construction, and operation of facilities…"

SHINE PSAR Section 11.1.3.2.1, "General Design Considerations for ALARA Exposures," indicates that ALARA is applied to the general design considerations and methods without any explanation.

Additional information is needed for the NRC staff to determine that sufficient emphasis is placed on ALARA considerations for the design of the SHINE facility.

Describe how ALARA is applied to the general design considerations and methods.

SHINE Response

General design considerations and methods to maintain in-plant radiation exposures ALARA at the SHINE facility are consistent with the recommendations of Regulatory Guide 8.8 (Reference 5). ALARA design considerations are described in Subsection 11.1.3.2.1 of the PSAR, in a bulleted list entitled, "Examples of features that assist in maintaining exposures ALARA." Additional ALARA design considerations are described in Subsections 11.1.3.2.2 and 11.1.3.2.3 of the PSAR.

RAI 11.1-13

SHINE PSAR Section 11.1.3.2, "ALARA Program Design Considerations," states in part, that "[t]he basic management philosophy guiding the SHINE facility design effort so that radiation exposures are ALARA can be expressed as: [d]esign structures, systems and components to reduce the radiation fields and control streaming, thereby reducing radiation exposure during operation, maintenance, and inspection activities."

Additional information is needed for the NRC staff to determine whether the design of structures, systems, and components to reduce radiation fields and control streaming are designed to meet ALARA requirements.

Describe how the ALARA concepts of time, distance and shielding are incorporated into the design of structures, system and components for employee work stations.

SHINE Response

Employee work stations within the RCA will be designed using the ALARA concepts of time, distance, and shielding to minimize employee exposures.

The work stations will be designed to minimize the time that operators need to be in radiation fields in order to perform their tasks. This is accomplished by locating equipment, instruments, and sampling sites that require routine maintenance, calibration, operation, or inspection in areas that promote ease of access to minimize task durations. The design provides for the movement of equipment or components requiring service to lower radiation areas, where practicable. Also, when components in elevated radiation fields have planned periodic replacements, quick disconnects or similar means are provided where practicable in order to reduce evolution time.

The work stations will be designed to maximize distance from radiation sources in order to reduce radiation fields. Radiation sources and occupied areas are separated, where practicable. Equipment, instruments, and sampling sites are located in the lowest practicable radiation zone. Control panels to permit remote operation of essential instrumentation and controls are located in the lowest radiation zone practicable. Also, plant layout is designed so that access to work stations does not require passing through higher radiation zones.

The work station designs also incorporate shielding, where appropriate, to keep radiation doses as low as reasonable achievable. Substantial shielding is provided between the radiation sources and the work stations for the hot cells, such as the Mo-99 extraction, purification, and packaging supercells. Shielding design includes consideration of wall thickness requirements, shielded window designs, and shielding around penetrations. As described in Subsections 3.5a.10.2.2 and 3.5b.1.9.2.2 of the PSAR, the design for the biological shielding, which includes the shielding for the operator work stations in the RCA, is to provide dose rates at 12 in. (30.48 cm) from the surface of the shielding of 0.25 mrem/hr or less for normally occupied areas.

Subsection 11.1.1 of the PSAR states that the goal for the normal operations dose rate for normally occupied locations in the facility is 0.25 mrem/hr at the surface, which is inconsistent with Subsections 3.5a.10.2.2 and 3.5b.1.9.2.2 with respect to the design dose rate of 0.25 mrem/hr at 12 in. from the surface. An IMR has been initiated to address the inconsistency.

SHINE has revised Subsection 11.1.1 to state that the goal for the normal operations dose rate for normally occupied locations in the facility is 0.25 mrem/hr at 12 in. from the surface of the shielding. A mark-up of the PSAR changes is provided in Attachment 1. The non-public (proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 3. The public (non-proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 4.

RAI 11.1-14

NUREG-1537, Part 2, Section 11.1.1, "Radiation Sources," states, in part, that "[a]ll sources of radiation should be discussed by the applicant, [including] the physical and chemical form…"

SHINE PSAR Section 11.1.1 (page 11-2), states that special nuclear material inventories are tabulated in Tables 4b.4-1 and 4b.4-13 for the SHINE Radioisotope Production Facility (RPF).

The amount of U-235 represented in Table 4b.4-1 (based on the inventory of special nuclear material and the level of enrichment) does not seem to agree with the amount of U-235 process inventory specified in Table 4b.4-13.

Specify the quantity of special nuclear material and U-235 processed at one time in the RPF, ensuring that the values in Tables 4b.4-1 and 4b4-13 are consistent.

SHINE Response

The RPF inventory of special nuclear material (SNM) includes:

- Material that is in storage (i.e., in the uranium metal, oxide storage racks, uranium in shipping containers awaiting processing);
- Material that is in the preparation process (i.e., in the uranyl sulfate preparation tanks and in the uranium metal dissolution tanks);
- Material that is awaiting reuse in the TSV or other processing/adjustment (i.e., in the target solution hold tanks and in the recycle target solution tanks);
- Material that is actively undergoing extraction (i.e., being processed in the extraction hot cell);
- Material that is being processed through the Uranyl Nitrate Conversion System (UNCS) (i.e., in the uranyl nitrate conversion tanks, UREX feed tanks, UREX processing equipment, thermal denitration equipment, and interconnecting piping and vessels); and
- Small quantities in waste streams and packaged waste.

The masses for the uranium oxide, uranyl nitrate, and uranyl sulfate quantities provided in Table 4b.4-1 of the PSAR are based on the total masses of the chemical form assumed (e.g., UO_3, $UO_2(NO_3)_2$, and UO_2SO_4). The uranium mass is obtained by determining the mass fraction of uranium in the chemical formula and multiplying it by the mass in the table. For uranyl nitrate in Table 4b.4-1, this results in a uranium mass of approximately [Security-Related Information]. For uranyl sulfate in Table 4b.4-1, this results in a uranium mass of approximately [Security-Related Information].

SHINE considers the SNM in processing to be the SNM that is not in storage or packaged waste. The quantity of SNM in processing in the RPF at one time is up to approximately [Security-Related Information], which is the sum of the uranium mass derived from the uranyl nitrate and uranyl sulfate masses in Table 4b.4-1, as described above. Given SHINE's enrichment, this quantity is equivalent to approximately [Security-Related Information] of uranium-235.

Table 4b.4-1 is an estimate of the total SNM inventory within the RPF at one time. Note that the inventory for the uranyl sulfate is a bounding inventory based on the bounding uranium concentration and batch volume, and conservative assumptions regarding the number of target solution hold tanks, target solution recycle tanks, uranyl sulfate preparation tanks, and uranyl nitrate conversion tanks holding uranyl sulfate solution at one time.

The values in Table 4b.4-13 of the PSAR specify only a per batch quantity of the fissile isotopes uranium-233, uranium-235, and plutonium-239, rather than a total inventory (e.g., eight batches of recycled target solution can be contained within the eight target solution hold tanks). Also, the values in Table 4b.4-13 are based on nominal batch quantities (i.e., nominal uranium concentration and solution volume) rather than bounding values.

Therefore, the values in Table 4b.4-1 and Table 4b.4-13 provide alternate means to estimate the quantity of SNM in the RPF, and are not inconsistent.

RAI 11.1-15

NUREG-1537, Part 2, Section 11.1.1, "Radiation Sources," states in part that, "The applicant should present the best estimates of the maximum annual dose and the collective doses for major radiological activities during the full range of normal operations for facility staff and members of the public. The doses shall be shown to be within the applicable limits of 10 CFR Part 20." SHINE PSAR Section 11.1.1, (page 11-2) contains a commitment to implement sufficient shielding to ensure direct exposure rates do not exceed 0.25 mrem/hr, except during tank transfers.

Additional information is needed on the dose rates that will occur during the tank transfers to ensure consistency with ALARA and the dose limits.

Explain why dose rates during tank transfers that exceed 0.25 mrem/hr are acceptable and consistent with ALARA principles. Explain why shielding will not be used for the tank transfers.

a. *SHINE PSAR section 11.1.1.1, (page 11-3) provides annual dose estimates for the maximum exposed member of the public, but does not state whether the dose rate limit in 10 CFR 20.1301 will also be met.*

   Demonstrate that in addition to meeting the annual dose limit, the dose rate limit in 10 CFR 20.1301 will also be met.

SHINE Response

a. SHINE is committed to an operating philosophy that maintains occupational exposures to radiation consistent with ALARA principles. These ALARA principles include limiting exposure through temporary and permanent shielding of radioactive material, providing sufficient distance between personnel and radioactive material, and limiting the time personnel are exposed to radioactive material. ALARA principles are maintained through commitment by SHINE management to maintain exposures ALARA, as well as through vigilance of means to reduce exposures by RP staff.

   Shielding is used for tank transfers as part of SHINE's ALARA operating philosophy. Target solution transfer piping is contained within shielded trenches with thick (at least three feet) concrete shield plugs.

   The SHINE facility will be designed to the goal of 0.25 mrem/hr for normally occupied locations during normal operations, which includes routine, planned tank transfers. For example, the shielding requirements for the operator workstation of the Mo-99 extraction Supercell have been evaluated assuming target solution is being transferred through the cell for the extraction process. Shielding thickness was set to meet the goal of 0.25 mrem/hr during this process.

   Some areas in the SHINE facility, such as areas where target solution piping transitions into a hot cell, may have dose rates that locally exceed 0.25 mrem/hr during some solution transfers. However, these local increases are not expected to significantly affect doses in the normally occupied areas. The increased dose rates will be monitored by Radiation Protection (RP) staff and the areas will be posted appropriately.

Given that sufficient shielding is used for tank transfers and the dose rate goal for shielding in normally occupied areas is 0.25 mrem/hr, including during routine, planned tank transfers, the design is acceptable and consistent with ALARA principles.

b. Annual doses to the public were calculated and were determined to be below the annual dose limit from airborne effluents in 10 CFR 20.1301 of 0.1 rem/yr and below the 10 CFR 20.1101 ALARA air emissions annual dose constraint of 0.01 rem/yr. Exposures are due to the periodic release of decayed noble gases in the Noble Gas Removal System (NGRS) to the PVVS and normal continuous releases of Ar-41 from IU cells.

   PVVS and the IU cells are connected to RVZ1, which exhausts to the atmosphere through the facility exhaust stack. The radioactive gases are held in NGRS at least 40 days before being released to the stack. Releases from NGRS will occur throughout the year, with the activity expected to be distributed among at least 10 small quantity releases per year. Additionally, the releases from the NGRS tanks are expected to occur in a slow, controlled manner over a significant period of time (e.g., several hours). The Ar-41 releases are continuous during operation and were calculated to result in less than 1 mrem TEDE to the MEI over the course of a year.

   Total dose to the MEI is estimated at 9.0 mrem over an entire year (which includes dose due to long-term ingestion pathways, as well). By conservatively assuming that all of the releases are due to NGRS gas releases, and given the information above, the unrestricted area dose rate will be less than 0.0009 rem in any one hour. Therefore, the dose in any unrestricted area from external sources will be well below the 10 CFR 20.1301 dose rate limit of 0.002 rem in any one hour.

RAI 11.1-16

NUREG-1537, Part 2, Section 11.1.1 states, in part, that "[l]iquid effluent volumes and radionuclide concentrations should be shown to be within the requirements of 10 CFR Part 20."

SHINE PSAR Section 11.1.1.2, (page 11-3 and 11-4) "Liquid Radioactive Sources," describes liquid radioactive sources at the SHINE facility.

Additional information is needed for the NRC staff to determine the adequacy of the design of the SHINE facility to protect workers and the public from radiation exposures due to liquid radioactive sources.

Provide a description of the safety features in place to prevent exposures to liquid radioactive sources, (e.g., regular maintenance, shielding, berms).

SHINE Response

SHINE has safety features in place to prevent exposures to liquid radioactive sources. The primary barriers to preventing worker exposure to liquid radioactive sources are prevention of leakage and shielding.

The systems that contain radioactive liquids will be made from corrosion resistant materials, based on the chemical composition of the materials they contain, to minimize the potential for leaks. Piping, tanks, and valves that contain radioactive liquids at SHINE will be of robust construction, and will be made of appropriate grades of stainless steel (e.g., 316L) and other corrosion-resistant materials, which will greatly reduce the potential for leakage of liquid

radioactive sources. SHINE will have a Preventive Maintenance Program for components such as valves to identify, prevent, and correct leakage.

Significant radioactive liquid sources (e.g., the irradiated target solution material, UREX process, and raffinate waste liquid from UREX) are located in shielded cells, underground vaults, and trenches. These cells, vaults, and trenches have significant amounts of shielding to decrease exposure to liquid radioactive sources. The exterior dose rates from these shielded cells are provided in Table 11.1-5 of the PSAR.

Furthermore, should a leakage occur, SHINE has a Radioactive Drain System (RDS), which has drains and a collection tank to divert and collect leakage of vessels, pipes, and valves containing significant quantities of fissile material. The floors are sloped towards the drains, and the RDS has the capability to detect leakage and initiate alarms to alert the operators. The RDS is also located within substantial (e.g., three feet thick) concrete shielding.

Berms will be used as needed in conjunction with other leak collection safety features to direct and contain radioactive liquid leak flows and reduce potential for personnel exposure should a leak occur.

RAI 11.1-17

NUREG-1537, Part 2, Section 11.1.2, "Radiation Protection Program," states, in part, that "[p]rocedures should be organized and presented for convenient use by operators and technicians at the appropriate locations, and should be free of extraneous material."

SHINE PSAR Section 11.1.2.1.5, (pg 11-8) "Commitment to Written Radiation Protection Procedures," states that radiation work permits (RWPs) will be used for both routine and non-routine activities.

Additional information is needed for NRC staff to determine the adequacy of the organization of SHINE's radiation protection program procedures. The description of RWPs appears contradictory because it requires RWPs for routine activities which should already be covered by existing operating procedures.

Clarify the conditions under which RWPs will be used. Clarify under what conditions routine activities, typically covered by existing operating procedures, would also require RWPs.

SHINE Response

SHINE will perform all work in the RCA under a radiation work permit (RWP), including any activity in the RCA covered by an existing operating procedure.

SHINE has revised Subsection 11.1.2.1.5 of the PSAR to clarify that all work performed in the RCA is performed in accordance with an RWP. A mark-up of the PSAR changes is provided in Attachment 1. The non-public (proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 3. The public (non-proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 4.

RAI 11.1-18

NUREG-1537, Part 2, Section 11.1.4, "Radiation Monitoring and Surveying," states, in part, that the "procedures and equipment should be designed to ensure that air, liquids, solids, and reactor radiation beams and effluents are monitored and sampled as necessary."

a. *SHINE PSAR Section 11.1.4.1, "Radiation Monitoring," indicates that radiation area monitors (RAMs) will be used at the SHINE facility. However, there is no information on the location or conditions that will be present for these monitors to be installed.*

   Additional information is needed for NRC staff to determine the adequacy of the design of the SHINE facility ensure that air, liquids, solids, and reactor radiation beams and effluents are monitored and sampled as necessary.

   Provide additional information on the location and conditions that will result in the instillation of RAMs. Provide sufficient information to determine if RAMs will be used in locations where exposures may exceed administrative limits under normal operations or credible accident conditions, as determined by the Integrated Safety Analysis or equivalent means.

b. *SHINE PSAR Section 11.1.4, provides a general overview of the survey and monitoring program. However, there is no indication of the facility function/program responsible for overseeing and implementing this program or the plan to use written procedures.*

   Additional information is needed for NRC staff to determine that the radiation protection program will oversee the adequacy of the design of the SHINE facility to ensure that air, liquids, solids, and reactor radiation beams and effluents are monitored and sampled as necessary.

   Describe the function or program (e.g., radiation protection program) that is responsible for implementing the radiation survey and monitoring program. Also, establish that the program will have written procedures that specify the types, times, and methods for radiation sampling and monitoring.

c. *SHINE PSAR Section 7a2.7.4.3, (page 7a2-45), "Audible and Visual Alarm Devices," states that radiation alarms have present activation levels.*

   Additional information is needed for NRC staff to determine that radiation alarms have the appropriate oversight to ensure that air, liquids, solids, and reactor radiation beams and effluents are monitored and sampled as necessary.

   Specify the alarm levels or identify the function or program (e.g., radiation protection program) responsible for setting these limits and the methodology to be used to establish these values (e.g., administrative limits).

d. *SHINE PSAR section 11.1.4.1(g), (page 11-18), "Control Point Monitoring," states the radiological monitoring equipment will be calibrated and maintained.*

Additional information is needed for NRC staff to determine that radiation monitoring equipment will have the appropriate calibration and maintenance to ensure that air, liquids, solids, and reactor radiation beams and effluents are monitored and sampled as necessary.

Provide additional information to clarify which group (e.g., the radiation protection program) is responsible for maintaining and checking the radiological monitoring equipment.

SHINE Response

a. SHINE will provide the following information in the RP Program and in the Final Safety Analysis Report (FSAR), as part of detailed design:

    1. Information on the location and conditions which will result in the installation of radiation area monitors (RAMs); and
    2. Sufficient information showing that the RAMs will be used in locations where exposures may exceed administrative limits under normal operations or credible accident conditions, as determined by the accident analysis.

    An IMR has been initiated to track the inclusion of this information in the RP Program and in the FSAR.

b. The requirements for radiation surveying and monitoring will be specified in the RP Program. Implementing procedures for the RP Program will specify the types, times, and methods for radiation sampling and monitoring.

    An IMR has been initiated to track the inclusion of this information in the RP Program.

c. Settings for alarm level limits and the methodology to be used to establish these values (e.g., administrative limits) will be specified in the RP Program.

    An IMR has been initiated to track the inclusion of this information in the RP Program.

d. The maintenance and calibration requirements for radiological monitoring equipment will be specified in the RP Program.

    An IMR has been initiated to track the inclusion of this information in the RP Program.

RAI 11.1-19

NUREG-1537, Part 2, Section 11.1.4, "Radiation Monitoring and Surveying," states, in part, that "[i]n coordination with the information presented in Chapter 6, 'Engineered Safety Features,' the applicant should describe the interface between the radiation monitoring system and the engineered safety features."

SHINE PSAR Section 6b.2.1.2, (page 6b-5) "Confinement System and Components," and Table 6b.1-1, "Summary of RPF Design Basis Events and ESF Provided for Mitigation," indicate that the confinement systems for the hot cell and the radiological integrated control system (RICS) are considered safety-related systems, structures and components (SSCs).

Additional information is needed for the NRC staff to determine that the radiation monitoring systems are adequate to remain available and reliable to support the engineered safety features.

Since RICS depends in part on the automatic notification from the continuous air monitoring system (CAMS) and radiation area monitoring system (RAMS), clarify whether these items used to support the RICS for the hot cells and other potentially high radiation areas are safety-related systems, structures and components (SSCs). Demonstrate that radiation monitors (e.g., CAMS and RAMS) used as SSCs or to support SSCs have appropriate controls (e.g., management measures) to ensure they remain available and reliable.

SHINE Response

The RICS initiates engineered safety features (ESF) actuation for RPF hot cells and other isolable areas (e.g., noble gas shielded cell, RVZ2 isolation) that require isolation upon measured parameters exceeding setpoints as determined in the safety analysis.

Safety-related confinement isolation actuation by RICS is described in Subsection 6b.2.1 of the PSAR. The Radiation Area Monitoring System (RAMS) supplies information to RICS to determine if confinement isolation is required due to high radiation levels. RICS compares the measured values provided by RAMS with the isolation actuation setpoints. Should actuation setpoints be exceeded due to high radiation levels, RICS generates a confinement isolation signal, which closes the corresponding bubble-tight isolation dampers and isolation valves on piping systems.

RAMS is a safety-related system. The components of RAMS necessary to support the RICS safety-related confinement isolation function are safety-related. Safety-related structures, systems, and components (SSCs), including RAMS, have the appropriate controls through the Technical Specifications (TS) to ensure that they remain available and reliable. Proposed parameters for TS for the radiation monitoring systems are provided in Item 3.7 of Table 14a2-1 of the PSAR.

While the Continuous Air Monitoring System (CAMS) is expected to provide radiation level information to RICS, it is not credited with providing safety-related information for confinement isolation actuation. Therefore, CAMS is not required to be safety-related, and is a nonsafety-related system in the SHINE facility.

SHINE has revised Subsections 7a2.7.4.3 and 7b.1.3 of the PSAR to remove the reference to CAMS providing input to RICS for ESF functions. A mark-up of the PSAR changes is provided in Attachment 1. The non-public (proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 3. The public (non-proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 4.

RAI 11.1-20

NUREG-1537, Part 2, Section 11.1.5, "Radiation Exposure Control and Dosimetry," states, in part, that the "[d]esign of the facility…should prevent uncontrolled radiation releases to the environment or to the work areas during normal operations."

SHINE PSAR 11.1.5.1.1, (page 11-19) "Radiological Zones," describes radiation zones that have varied definitions and span of control.

Additional information is needed for the NRC staff to understand how these radiological zones operate and are used to (1) control the spread of contamination, (2) control personnel access to avoid unnecessary exposure of personnel to radiation, and (3) control access to radioactive sources present in the facility.

Provide additional information describing how the radiological zones are defined, how they work, how each zone is physically separated from other zones, and how the zones are maintained.

SHINE Response

The SHINE Response to RAI 9a2.1-3, above, provides additional information describing how the RCA ventilation zones are defined, how they work, how each zone is physically separated from other zones, and how the zones are maintained.

Subsection 11.1.5.1.1 of the PSAR describes radiation areas in the RCA with respect to varying radiation levels and varying contamination levels. Anticipated radiation areas in the SHINE facility are described in the SHINE Response to RAI 11.1-4 (Reference 4). Anticipated airborne radioactive material concentration zones are described in the SHINE Response to RAI 11.1-1 (Reference 4).

RAI 11.1-21

NUREG-1537, Part 2, Section 11.1.5, states, in part, that the "design of entry control devices…should alert workers to, or prevent unauthorized entry into, high radiation areas and very high radiation areas, as appropriate."

SHINE PSAR 11.1.5.2, (page 11-21) "Access and Egress Control," refers to active and passive engineered safeguards to control access to high radiation areas.

Additional information is needed for NRC staff to determine the adequacy of the design of entry control devices to alert workers to, or prevent unauthorized entry to specified radiation areas, as appropriate.

a. *Provide a description of the active and passive safety systems that are used to control access to high radiation areas.*

b. *Clarify whether the "engineered safeguards" discussed in PSAR Section 11.1.5.2, (page 11-21) are security-related, consistent with the guidance in NUREG-1537, Section 12.8, "Security Planning."*

SHINE Response

a. SHINE will provide active and passive safety features to control access to high radiation areas in accordance with 10 CFR 20.1601. These safety features include:

   - Neutron driver personnel access door interlocks de--energize the accelerator to reduce the level of radiation upon personnel entry, and accelerator key switches prevent the activation of the accelerator while personnel are present.
   - Based on the hazards analysis during final design, hot cells requiring periodic/routine entry where there is potential for excessive personnel exposures are equipped with door interlocks to prevent the hot cell door from being opened when the evaluated hazard exists (e.g., excessive radiation field, target solution transfer occurring in cell).
   - The neutron driver and hot cells are equipped with audible and visual warnings so that an individual attempting to enter the high radiation area and the supervisor of the activity are made aware of the entry, consistent with 10 CFR 20.1601(a)(2).

- High radiation areas are radiologically shielded and isolated from access to individuals by the use of engineered physical barriers, as described in Subsection 11.1.5.1.1 of the PSAR. These include structural shield blocks and/or locked shield doors, consistent with 10 CFR 20.1601(a)(3).

SHINE has revised Subsection 11.1.5.2 of the PSAR to include the safety features used to control access to high radiation areas described above. A mark-up of the PSAR changes is provided in Attachment 1. The non-public (proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 3. The public (non-proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 4.

b. Subsection 11.1.5.2 of the PSAR states:

"Because there are high radiation areas in the facility, access to those areas is physically prevented due to radiation level. Access control is by a combination of administrative methods and active as well as passive engineered safeguards."

The term "engineered safeguards" discussed above is not security-related. This is consistent with the guidance provided in Section 12.8 of NUREG-1537 (References 6 and 7), Regulatory Guide 5.59 (Reference 8), and Regulatory Issue Summary 2005-31 (Reference 9).

The SHINE access control program, described in Subsection 11.1.5.2, ensures that: (a) signs, labels, and other access controls are properly posted and operative; (b) restricted areas are established to prevent the spread of contamination and are identified with appropriate signs; and (c) step-off pads, change facilities, protective clothing facilities, and personnel monitoring instruments are provided in sufficient quantities and locations.

RAI 11.1-22

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

a. SHINE PSAR Section 9a2.1.1, (page 9a2-2) "Radiologically Controlled Area Ventilation System," indicates the automatic cell ventilation dampers are safety-related.

Additional information is needed for the NRC staff to determine the adequacy of the design basis for the SHINE automatic cell ventilation dampers to ensure ALARA considerations are maintained.

Since these items are safety-related, identify the management measures required to ensure the dampers remain available and reliable to ensure radiation doses are maintained ALARA and within regulatory limits.

b. SHINE PSAR section 9a2.1.1, (page 9a2-3) "Radiologically Controlled Area Ventilation System," indicates flow control valves will maintain constant pressure for the fume hoods.

Additional information is needed for the NRC staff to determine that appropriate minimum pressure gradient will be maintained across the fume hood threshold.

Demonstrate that a minimum pressure gradient will be maintained across the fume hood threshold consistent with guidance in Regulatory Guide 8.24, "Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication." Show that, if the gradient drops below this level, the pressure drop will be identified and corrected.

SHINE Response

a. Isolation damper operability will be controlled by TS, as specified by Item 3.5 of Table 14a2-1 of the PSAR. The SHINE Quality Assurance Program, Preventive Maintenance Program, and TS surveillance activities will ensure the dampers remain available and reliable to ensure radiation doses are maintained ALARA and within regulatory limits.

b. SHINE will follow the guidance provided in Regulatory Guide 8.24 (Reference 10) for fume hood operations and maintenance involving uranium-235 processing. Issues identified during fume hood surveys, operations, and maintenance will be placed in the SHINE Corrective Action Program. Fume hood work will be terminated if parameters are found to be below acceptable levels, as specified in Regulatory Guide 8.24.

(Applies to RAIs 11.1-23 through 25)

The ISG Augmenting NUREG-1537, Part 2, Section 11.1, "Radiation Protection," states, in part:

"[I]ndividuals who are not workers, as defined in 10 CFR 70.4, may be permitted to perform ongoing activities…in the controlled areas if the licensee…[p]rovides training that satisfies 10 CFR 19.12(a)(1)-(5) to these individuals and ensures that they are aware of the risks associated with accidents involving the licensed activities as determined by the ISA…"

Additional information is needed for the NRC staff to determine whether SHINE has ensured that individuals are aware of the risks associated with accidents involving licensed activities.

RAI 11.1-23

While SHINE PSAR Section 13b.2.1.2, "Identification of Initiating Events and Causes," discusses a rupture of five noble gas storage tanks, it does not identify the credible accident events that could initiate this accident sequence.

Identify the potential credible accident sequences that could result in the radiological maximum hypothetical accident (MHA). Provide sufficient information to describe the initiating events and demonstrate that the consequences are calculated for both the credible unmitigated conditions (without SSCs) and mitigated conditions (with SSCs).

SHINE Response

SHINE has identified a Maximum Hypothetical Accident (MHA) consistent with the guidance provided in Parts 1 and 2 of NUREG-1537 (References 6 and 7), and Parts 1 and 2 of the Interim Staff Guidance (ISG) augmenting NUREG-1537 (References 11 and 12). The guidance on the MHA is primarily described in Chapter 13 of NUREG-1537 and Sections 13a2 and 13b of the ISG.

In Section 13a2 of Part 1 of the ISG, it is stated that the MHA selected should bound all credible potential accidents at the facility and that the MHA may be a non-mechanistic failure assumed to establish outer limit consequence, but the scenario need not be entirely credible. In Section 13b.1.2 of Part 2 of the ISG, under the evaluation findings for the MHA, it is stated that the MHA is not considered a credible event for the facility.

SHINE considers the rupture of five noble gas storage tanks simultaneously to not be an entirely credible event and is a means to establish an outer limit consequence. Therefore, SHINE did not identify potential credible accident sequences that could result in the radiological MHA.

Choosing an event that bounds the other identified credible events at the facility and demonstrating acceptable consequences from this event helps to demonstrate that the facility is designed in an acceptable manner.

Mitigated dose consequences calculated for the MHA are provided in Subsection 13b.2.1.7 of the PSAR. The availability of mitigators is discussed in Part b of the SHINE Response to RAI 11.1-24, below.

SHINE did not calculate the MHA dose consequences for both the worker and the off-site public excluding mitigation because there is no regulatory requirement. In addition, the SHINE Response to RAI 13b.1-3 (Reference 13) provides a detailed accident sequence description for the MHA, from the initiating event through the sequence's mitigated consequences.

(Applies to RAIs 11.1-24 through 25)

> *As required by 10 CFR 50.34(a)(4), the preliminary safety analysis report shall include "[a] preliminary analysis and evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility…, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents."*
>
> *As set forth in ISG Augmenting NUREG-1537, Part 1, Section 13b, "Radioisotope Production Facility Accident Analyses," the NRC staff has determined that the "use of ISA methodologies, as described in 10 CFR Part 70, ["Domestic Licensing of Special Nuclear Material,"] and NUREG-1520, ["Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility,"] application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, designation of IROFS [items relied on for safety], and establishment of management measures are acceptable ways of demonstrating an adequate margin of safety for the medical isotopes production facility. 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 the safety features. As used in the ISG, the term "performance requirements," when referencing 10 CFR Part 70, subpart H, is not intended to mean that the performance requirements of subpart H are required for a radioisotope production facility license, only that their use as accident consequence and likelihood criteria may be found acceptable by NRC staff.*

RAI 11.1-24

SHINE PSAR section 13b.2.1.4, page 13b-5 identifies mitigating structures, systems, and components that should not be included in the unmitigated accident analysis. The mitigating structures, systems, and components cannot be credited during the unmitigated portion of the accident analysis. The MHA, under unmitigated conditions, could be bound by a 100 percent release of the contents of the five noble gas storage tanks to the environment.

a. Recalculate the MHA for both the worker and the public excluding mitigation, assuming credible accident conditions consistent with the rupture of the five noble gas storage tanks.

In addition, safety systems used to prevent or mitigate a credible event must remain available and reliable under the credible accident conditions. For example, a credible accident (e.g., seismic event, fire, explosion, airplane crash) that can result in rupture of the five noble gas storage tanks may also result in failure of the fail-safe bubble-tight isolation dampers, etc.

b. Provide justification for the assumptions in PSAR Section 13b.2.1.7, (page 13b-7) "Radiological Consequence Analysis," used to mitigate the MHA. Provide justification that the safety related systems, structures, and components relied on to mitigate the MHA will remain available and reliable under credible accident conditions.

SHINE Response

a. The basis for the selection of the MHA is described in the SHINE Response to RAI 11.1-23, above.

   SHINE did not calculate the MHA dose consequences for both the worker and the off-site public excluding mitigation because there is no regulatory requirement. In addition, the SHINE Response to RAI 13b.1-3 (Reference 13) provides a detailed accident sequence description for the MHA, from the initiating event through the sequence's mitigated consequences.

b. Safety-related SSCs that mitigate the event include RVZ1 (including isolation dampers), RVZ2, the structure and confinement seals of the noble gas shielded cell (as part of the confinement boundary), and the RAMS. Subsection 13b.2.1.7 of the PSAR describes specific assumptions with regards to mitigating the event, including: the NGRS storage cell confines the release; RVZ1 confines and directs releases through the exhaust filter housings; radiation detectors (i.e., RAMS) detect the high radiation levels; and RVZ1 limits the release through the closing of the isolation dampers.

   SHINE did not identify potential credible accident sequences that could result in the MHA. However, the mitigators described above are also used as mitigators for the rupture of a single NGRS tank, which is considered credible and is described in Subsection 13b.2.4 of the PSAR.

   The portions of the SSCs described above that are necessary in order for the SSC to perform its safety function are safety-related, and will be designed, procured, installed, and maintained in accordance with Quality Level 1 (QL-1) requirements, as required by the SHINE Quality Assurance Program Description (QAPD). These safety-related components will be controlled under a configuration management program, and periodically tested in accordance with TS surveillance requirements. These components will be Seismic Category I components, and will be protected from credible external events. Furthermore,

these components will be qualified to perform their function in the post-accident environment, as described in Subsection 3.5a.4 of the PSAR, and will be designed to meet the single failure criterion, as described in Section 3.5 of the PSAR. Therefore, the mitigating SSCs will remain available and reliable to perform their safety function, and the assumptions presented in Subsection 13b.2.1.7 are correct.

RAI 11.1-25

SHINE PSAR Section 13b.2.1.1, (page 13b-5) "Initial Conditions and Assumptions," identifies systems that are mitigative without designating them as IROFS or safety-related structures, systems, and components.

Designate all mitigative or preventive systems relied on to meet the performance requirements of 10 CFR 70.61 (or equivalent) as safety-related structures, systems, and components or IROFS, as applicable, and designate appropriate management measures. Provide a commitment to evaluate all credible accidents under unmitigated conditions and implement safety-related structures, systems, and components or IROFS, as applicable, and management measures to ensure intermediate and high consequence events comply with the performance requirements of 10 CFR 70.61 (or equivalent).

SHINE Response

The SSCs which are required to mitigate the MHA described in Subsection 13b.2.1 of the PSAR to meet the dose requirements specified in 10 CFR 20 include RVZ1 (including isolation dampers), RVZ2, the structure and confinement seals of the noble gas shielded cell (as part of the confinement boundary), and the RAMS. As described in the SHINE Response to RAI 13b.1-3 (Reference 13), the SSCs credited to perform a preventative function are the process tanks and piping (i.e., the integrity of the NGRS storage tanks and interconnecting piping), and the administrative control credited with helping to prevent this event (i.e., Conduct of Operations Program).

The portions of the SSCs described above that are necessary in order for the SSCs to perform their safety functions are safety-related, and will be designed, procured, installed, and maintained in accordance with QL-1 requirements, as required by the SHINE QAPD.

The basis for the selection of the MHA with respect to credibility is described in the SHINE Response to RAI 11.1-23, above. Evaluated unmitigated consequences for this event are described in the SHINE Response to RAI 11.1-23, and unmitigated consequences for other accident sequences are described in the SHINE Response to RAI 13b.1-3. Safety-related SSCs and administrative controls required to prevent and mitigate the events are described in the SHINE Response to RAI 13b.1-1 (Reference 4).

Section 11.2 – Radioactive Waste Management

(Applies to RAIs 11.2-6 through 8)

> *NUREG-1537, Part 2, Section 11.2.1, "Radioactive Waste Management Program," states, in part, that the "SAR should contain a commitment to comply with applicable regulations for managing radioactive wastes."*
>
> *Additional information is needed for NRC staff to determine the adequacy of SHINE's commitment to comply with applicable regulations for managing radioactive wastes.*

RAI 11.2-6

SHINE PSAR Section 11.2, "Radioactive Waste Management," states that SHINE is committed to comply with all applicable local and national regulations for managing radioactive wastes.

Provide a summary list of the regulations and any standards or guidance that SHINE intends to follow to demonstrate its commitment to complying with applicable regulations for managing radioactive wastes.

SHINE Response

SHINE will comply with the following federal regulations related to radioactive wastes:

- 10 CFR 20, "Standards for Protection Against Radiation"
- 10 CFR 61, "Licensing Requirements for Land Disposal of Radioactive Waste"
- 10 CFR 71, "Packaging and Transportation of Radioactive Material"
- 40 CFR, Chapter I, Subchapter F, "Radiation Protection Programs"
- 40 CFR, Chapter I, Subchapter I, "Solid Wastes"
- 49 CFR, Chapter I, Subchapter C, "Hazardous Materials Regulations"

SHINE is regulated by the NRC. The SHINE facility is not regulated by the State of Wisconsin pertaining to matters involving the management of radioactive wastes per Wisconsin Statutes Chapter 254.365(1) and Wisconsin Administrative Code Chapter DHS 157.02(1).

SHINE will comply with Wisconsin regulations relating to the transportation and disposal of hazardous waste per Wisconsin Administrative Code Chapter NR 662.

The State of Wisconsin will regulate radioactive waste once it leaves the SHINE facility and is transported. The State of Wisconsin implements the Department of Transportation (DOT) radioactive waste transportation regulations. As stated above, SHINE will meet the DOT regulations contained in 49 CFR, Chapter I, Subchapter C, and therefore, will comply with the State of Wisconsin radioactive waste transportation requirements.

SHINE will also comply with the waste acceptance criteria of the selected disposal facilities, including any local or state regulations specified in those criteria.

SHINE will use the following standards as guidance related to managing radioactive wastes:

- ANSI/ANS-55.1-1992 (R2009), "Solid Radioactive Waste Processing System for Light-Water-Cooled Reactor Plants" (Reference 14)
- ANSI/ANS-55.4-1993 (R2007), "Gaseous Radioactive Waste Processing Systems for Light Water Reactor Plants" (Reference 15)
- ANSI/ANS-55.6-1993 (R2007), "Liquid Radioactive Waste Processing System for Light Water Reactor Plants" (Reference 16)

SHINE will use the following regulatory guidance related to managing radioactive wastes:

- Regulatory Guide 1.143, "Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants" (Reference 17)
- Regulatory Guide 4.20, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees other than Power Reactors" (Reference 18)
- Regulatory Guide 8.8, "Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Stations will be As Low As Reasonably Achievable" (Reference 5)
- Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Reasonably Achievable" (Reference 19)
- NUREG/BR-0204, "Instructions for Completing NRC's Uniform Low-Level Radioactive Waste Manifest" (Reference 20)
- Information Notice No. 90-09, "Extended Interim Storage of Low Level Radioactive Waste by Fuel Cycle and Materials Licensees" (Reference 21)
- Regulatory Issue Summary 2008-12, "Considerations for Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees" (Reference 22)
- Regulatory Issue Summary 2011-09, "Available Resources Associated with Extended Storage of Low-Level Radioactive Waste" (Reference 23)

RAI 11.2-7

SHINE PSAR Section 11.1.1.2, (page 11-4) "Liquid Radioactive Sources" indicates that solid waste will be sent to disposal facilities.

Provide additional information indicating that these disposal facilities will have appropriate licenses for managing radioactive wastes (i.e., licensed disposal facilities).

SHINE Response

The disposal facilities referred to in Subsection 11.1.1.2 of the PSAR will have appropriate licenses for managing radioactive waste (i.e., licensed disposal facilities).

RAI 11.2-8

SHINE PSAR Sections 11.2.3.1, 11.2.3.2, and 11.2.3.3, (pages 11-49 through 11-49) describe the control of solid, liquid and gaseous waste streams.

Provide a description of the survey or monitoring equipment [e.g., continuous air monitoring system (CAMS) and radiation area monitoring system (RAMS)] and program that will be used to ensure wastes remain in these designated controls/processes and identify any loss of control or unplanned releases.

SHINE Response

The CAMS equipment is described in Subsection 7a2.7.4.1 of the PSAR, and the RAMS equipment is described in Subsection 7a2.7.4.2 of the PSAR.

The RP Program will ensure wastes remain in these designated controls/processes, and identify any loss of control or unplanned releases.

Section 11.3 – Respiratory Protection Program

(Applies to RAIs 11.3-1 through 3)

> *The ISG Augmenting NUREG-1537, Part 2, Section 11.3, "Respiratory Protection Program," states, in part, that the applicant should "[i]nstall appropriately sized ventilation and containment systems in areas of the plant identified as having potential airborne concentrations of radionuclides that could exceed occupational derived air concentration values in 10 CFR Part 20."*
>
> *Additional information is needed for NRC staff to determine the adequacy of the ventilation system at the SHINE facility.*

RAI 11.3-1

SHINE PSAR Section 9a2.1.1 indicates that air which passes from radiation controlled area ventilation Zone 2 (RVZ2) to radiation controlled ventilation Zone 1 (RVZ1) is first passed through HEPA filtration. This appears to imply that the zones are isolated from each other and that air is filtered between each zone.

Provide additional information to clarifying whether each zone can be isolated from the other zones automatically using the automatic isolation dampers and whether the air is filtered between each zone.

SHINE Response

RVZ1 areas draw supply air from adjacent RVZ2 spaces. RVZ1 area air inlets are equipped with automatic isolation dampers (fail closed), manual isolation dampers, and non-credited HEPA filters. The air inlet HEPA filter ensures that if an RVZ1 area were to see a flow reversal, the air stream would be filtered.

Should high radiation levels be detected within an RVZ1 area, ESFAS (IF) or RICS (RPF) generate a confinement isolation signal, which closes the corresponding bubble-tight isolation dampers on the air inlet and exhaust outlet for each affected RVZ1 area. This automatic isolation does provide isolation between the affected RVZ1 area and the adjacent RVZ2 space.

Confinement barrier penetrations are sealed, as necessary, to reduce leakage. However, some leakage between zones is expected to occur even after the isolation described above, and potential leakage is accounted for in safety analysis calculations, as described in Chapter 13 of the PSAR.

RVZ1 exhaust can also be isolated downstream of the filter trains on high radiation levels in RVZ1. This point of RVZ1 isolation does not isolate RVZ1 from the other zones; however, it provides an additional means to reduce releases to the environment.

Also, should high radiation levels be detected within RVZ2, RICS generates a signal for confinement isolation at the RCA boundary, which closes bubble-tight isolation dampers in the supply duct at the RCA boundary and in the RVZ2 exhaust duct downstream of the final filters. This automatic isolation does not isolate RVZ2 from other zones directly; however, it reduces the potential releases to the environment.

There are no automatic isolations necessary or provided for RVZ3 or FVZ4.

RAI 11.3-2

SHINE PSAR Section 9a2.1.1 (page 9a2-2) indicates that the ventilation air in the exhaust header is tested before being exhausted to the stack.

Provide additional information to demonstrate that the tests will verify some pre-defined differential pressure gradient across the filters and measure the level of contamination following the filters. Additionally, indicate the type of action that will be taken (e.g., a notification will be sent to the control room or other appropriate facility for action) if a specified differential pressure or contamination level is exceeded.

SHINE Response

Subsection 9a2.1.1 of the PSAR states:

> *"The exhaust from the cells collects in an RVZ1 system duct header and then draws through final, testable, HEPA filters and carbon adsorbers prior to discharge into the exhaust stack."*
>
> and
>
> *"The exhaust air from these spaces collects in an RVZ2 exhaust header and then draws through final, testable, HEPA filters and carbon adsorbers prior to discharge into the exhaust stack."*

Subsection 9a2.1.1 is stating that HEPA filters and carbon adsorbers are testable, not that ventilation air in the exhaust header is tested before being exhausted to the stack.

SHINE will test the pressure differential across HEPA filters and decontamination efficiencies of carbon adsorbers to ensure adequate operation and minimize the potential for contamination downstream of the exhaust filter housings. SHINE will test the HEPA filters and carbon adsorbers in accordance with vendor recommendations and applicable regulatory guidance.

SHINE will ensure differential pressure instruments are installed to allow for filter monitoring. Operators will periodically monitor differential pressure and compare the measurement to a pre-defined allowed pressure gradient. If monitoring or testing indicate filter or charcoal adsorber replacement is necessary, an IMR will be issued to ensure corrective actions are taken (e.g., filter replacement).

RAI 11.3-3

SHINE PSAR Section 9a2.1.1 (page 9a2-3) states that fume hood exhaust ducts are controlled automatically to compensate for changes in pressure drops for loading of filters.

Additional information is needed for NRC staff to determine the adequacy of the ventilation system at the SHINE facility.

Justify that an acceptable differential pressure will be maintained across facility air filters. Indicate whether this will be done through monitoring or some other process. Describe any notification that may be generated to change the filters if a set-point is exceeded.

SHINE Response

SHINE will monitor fume hood exhaust for adequate airflow in accordance with the ventilation survey guidance provided in Regulatory Guide 8.24 (Reference 10). If monitoring indicates deficient airflow, an IMR will be issued to initiate corrective actions (e.g. filter replacement). The requirements for monitoring will be included in the RP Program.

RAI 11.3-4

The ISG Augmenting NUREG-1537, Part 2, Section 11.3, (pages 11-57 through 11-59) states, in part, that the applicant should "[d]escribe the criteria for the ventilation and containment systems, including minimum flow velocity at openings in these systems, maximum differential pressure across filters, and types of filters to be used."

SHINE PSAR Sections 9a2.1.1 and 11.3, "Respiratory Protection Program," do not provide the minimum flow velocity at openings, maximum differential pressure across filters, or types of filters to be used.

Additional information is needed for NRC staff to determine the adequacy of SHINE design criteria for the ventilation and containment systems.

Describe the criteria for the ventilation and containment systems, including minimum flow velocity at openings in these systems, maximum differential pressure across filters, and types of filters to be used. In addition, state which safety function is responsible for maintaining the respiratory program (e.g., the radiation protection program).

SHINE Response

The SHINE facility does not have a containment feature, but uses confinement to minimize the release and spread of radioactive contamination. The design basis for confinement is described in Subsection 6a2.2.1 of the PSAR.

SHINE will follow the ventilation survey guidance in Regulatory Guide 8.24 (Reference 10) for fume hood and glovebox operations and maintenance involving uranium-235 processing. This guidance includes monthly surveys to determine that airflow velocities in hoods preclude the escape of airborne uranium and to minimize potential intake by workers, as well as surveys of negative pressure maintained in gloveboxes.

The specific criteria for the ventilation systems, including minimum flow velocity at openings in these systems, maximum differential pressure across filters, and types of filters to be used will be determined in detailed design and provided in the FSAR. An IMR has been issued to track inclusion of this information in the FSAR.

Respiratory protection programmatic requirements are included in the RP Program, and implemented through SHINE procedures.

References

(1) NRC letter to SHINE Medical Technologies, Inc., dated April 15, 2015, SHINE Medical Technologies, Inc. – Request for Additional Information Regarding Application for Construction Permit (TAC Nos. MF2305, MF2307, and MF2308) (ML15099A607)

(2) SHINE Medical Technologies, Inc. letter to NRC, dated March 26, 2013, Part One of the SHINE Medical Technologies, Inc. Application for Construction Permit (ML130880226)

(3) SHINE Medical Technologies, Inc. letter to NRC, dated May 31, 2013, Part Two of the SHINE Medical Technologies, Inc. Application for Construction Permit (ML13172A324)

(4) SHINE Medical Technologies, Inc. letter to NRC, dated December 3, 2014, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information (ML14356A528)

(5) U.S. Nuclear Regulatory Commission, “Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Stations will be As Low As Reasonably Achievable,” Regulatory Guide 8.8, Revision 3, June 1978 (ML003739549)

(6) U.S. Nuclear Regulatory Commission, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content," NUREG-1537, Part 1, February 1996 (ML042430055)

(7) U.S. Nuclear Regulatory Commission, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria," NUREG-1537, Part 2, February 1996 (ML042430048)

(8) U.S. Nuclear Regulatory Commission, “Standard Format and Content for a Licensee Physical Security Plan for the Protection of Special Nuclear Material of Moderate or Low Strategic Significance,” Regulatory Guide 5.59, Revision 1, February 1983 (ML100341301)

(9) U.S. Nuclear Regulatory Commission, “Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material,” Regulatory Issue Summary (RIS) 2005-31, December 22, 2005 (ML053480073)

(10) U.S. Nuclear Regulatory Commission, “Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication,” Regulatory Guide 8.24, Revision 2, June 2012 (ML110400305)

(11) U.S. Nuclear Regulatory Commission, "FINAL Interim Staff Guidance 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," October 17, 2012 (ML12156A069)

(12) U.S. Nuclear Regulatory Commission, "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," October 17, 2012 (ML12156A075)

(13) SHINE Medical Technologies, Inc. letter to NRC, dated May 1, 2015, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information

(14) American National Standards Institute/American Nuclear Society, “Solid Radioactive Waste Processing System for Light-Water-Cooled Reactor Plants,” ANSI/ANS-55.1-1992 (R2009), La Grange Park, IL

(15) American National Standards Institute/American Nuclear Society, “Gaseous Radioactive Waste Processing Systems for Light Water Reactor Plants,” ANSI/ANS-55.4-1993 (R2007), La Grange Park, IL

(16) American National Standards Institute/American Nuclear Society, “Liquid Radioactive Waste Processing System for Light Water Reactor Plants,” ANSI/ANS-55.6-1993 (R2007), La Grange Park, IL

(17) U.S. Nuclear Regulatory Commission, “Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants,” Regulatory Guide 1.143, Revision 2, November 2001 (ML013100305)

(18) U.S. Nuclear Regulatory Commission, “Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees other than Power Reactors,” Regulatory Guide 4.20, Revision 1, April 2012 (ML110120299)

(19) U.S. Nuclear Regulatory Commission, “Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Reasonably Achievable,” Regulatory Guide 8.10, Revision 1-R, September 1975 (ML003739563)

(20) U.S. Nuclear Regulatory Commission, “Instructions for Completing NRC’s Uniform Low-Level Radioactive Waste Manifest,” NUREG/BR-0204, Revision 2, July 1998 (ML071870172)

(21) U.S. Nuclear Regulatory Commission, “Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees,” Information Notice No. 90-09, February 5, 1990 (ML031130300)

(22) U.S. Nuclear Regulatory Commission, “Considerations for Extended Interim Storage of Low-Level Radioactive Waste by Fuel Cycle and Materials Licensees,” Regulatory Issue Summary 2008-12, May 9, 2008 (ML073330725)

(23) U.S. Nuclear Regulatory Commission, “Available Resources Associated with Extended Storage of Low-Level Radioactive Waste,” Regulatory Issue Summary 2011-09, August 16, 2011 (ML111520042)