# ENCLOSURE 5

## SHINE MEDICAL TECHNOLOGIES, LLC

## SHINE MEDICAL TECHNOLOGIES, LLC OPERATING LICENSE APPLICATION RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION AND SUPPLEMENT NO. 3

## FINAL SAFETY ANALYSIS REPORT
PUBLIC VERSION

# CHAPTER 1

# THE FACILITY

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ACRONYMS AND ABBREVIATIONS

| **Acronym/Abbreviation** | **Definition** |
|---|---|
| 10 CFR | Title 10 of the Code of Federal Regulations |
| ac. | acre |
| ALARA | as low as reasonably achievable |
| ANL | Argonne National Laboratory |
| CAMS | continuous air monitoring system |
| DBA | design basis accident |
| DOE | U.S. Department of Energy |
| ESF | engineered safety feature |
| ESFAS | engineered safety features actuation system |
| FDWS | facility demineralized water system |
| FSAR | Final Safety Analysis Report |
| ha | hectare |
| HEU | highly enriched uranium |
| HIPS | highly integrated protection system |
| I-39 | Interstate-39 |
| I-90 | Interstate-90 |

ACRONYMS AND ABBREVIATIONS

| **Acronym/Abbreviation** | **Definition** |
|---|---|
| IE | initiating event |
| IF | irradiation facility |
| ISG | Interim Staff Guidance |
| IU | irradiation unit |
| km | kilometer |
| LEU | low enriched uranium |
| LWPS | light water pool system |
| MEPS | molybdenum extraction and purification system |
| MeV | million electron volt |
| MHA | maximum hypothetical accident |
| mi. | miles |
| MIPS | molybdenum isotope product packaging system |
| Mo | molybdenum |
| Mo-99 | molybdenum-99 |
| N2PS | nitrogen purge system |
| NDAS | neutron driver assembly system |

## ACRONYMS AND ABBREVIATIONS

| **Acronym/Abbreviation** | **Definition** |
|---|---|
| OL | operating license |
| ORNL | Oak Ridge National Laboratory |
| PCLS | primary closed loop cooling system |
| PICS | process integrated control system |
| PSB | primary system boundary |
| PVVS | process vessel vent system |
| RAMS | radiation area monitoring system |
| RCA | radiologically controlled area |
| RDS | radioactive drain system |
| RLWI | radioactive liquid waste immobilization system |
| RLWS | radioactive liquid waste storage system |
| RPCS | radioisotope process facility cooling system |
| RPF | radioisotope production facility |
| RV | radiological ventilation system |
| SASS | subcritical assembly support structure |
| SCAS | subcritical assembly system |

## ACRONYMS AND ABBREVIATIONS

| **Acronym/Abbreviation** | **Definition** |
|---|---|
| SGS | standby generator system |
| SNM | special nuclear material |
| SRWP | solid radioactive waste packaging |
| SSC | structure, system, and component |
| Tc-99m | technetium-99m |
| TCAP | thermal cycling absorption process |
| TPS | tritium purification system |
| TOGS | TSV off-gas system |
| TRPS | TSV reactivity protection system |
| TSPS | target solution preparation system |
| TSV | target solution vessel |
| U-235 | uranium-235 |
| UPSS | uninterruptible electrical power supply system |
| VDC | volts - direct current |

# CHAPTER 1 – THE FACILITY

## 1.1 INTRODUCTION

This Final Safety Analysis Report (FSAR) is submitted in accordance with the provisions of Title 10 of the Code of Federal Regulations (10 CFR) Part 50 “Domestic Licensing of Production and Utilization Facilities,” in support of the application by SHINE Medical Technologies, LLC (SHINE) to operate a medical isotope production facility.

This FSAR generally follows the content and organization of NUREG-1537, Part 1, Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content, as augmented by the Final Interim Staff Guidance (ISG) Augmenting NUREG-1537, Part 1, Guidelines for Preparing and Reviewing Applications for Licensing Non-Power Reactors: Format and Content for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors, October 17, 2012.

The applicant for this operating license (OL) and owner of the medical isotope production facility is SHINE Medical Technologies, LLC, a Delaware company. SHINE is a private organization that was created for the purpose of designing, constructing, and operating the facility described herein. The purpose of the facility is to produce molybdenum-99 (Mo-99) and other medical isotopes. Additional information about the SHINE organization and key personnel is provided in Section 12.1.

The facility is located on previously-undeveloped property in the City of Janesville, Rock County, Wisconsin. The SHINE site and details regarding the geographical location and the surrounding areas are presented in Chapter 2, including site features that address the basic attributes of the site such as geography, demography, nearby facilities, meteorology, hydrology, and geology.

SHINE has developed a new method for the manufacture of medical isotopes, primarily Mo-99. Mo-99 is the precursor of the diagnostic imaging isotope, technetium-99m (Tc-99m), which is used in diagnostic imaging procedures worldwide. Technetium becomes a “light source” within the body to provide a high-quality view of internal organs. It is primarily used in cancer screening and in stress tests to detect heart disease.

SHINE’s technology involves the use of a non-reactor based, subcritical fission process. The process includes the combination of a high-output deuterium-tritium gas-target neutron source with a low enriched uranium (LEU) target in a target solution vessel (TSV). Neutrons created by an accelerator-driven neutron source induce fission in the LEU, creating Mo-99 as a byproduct. Together the neutron driver, subcritical assembly, light water pool, TSV off-gas system (TOGS), and other supporting systems comprise an irradiation unit (IU). Eight IUs and their supporting systems comprise the irradiation facility (IF).

The main production facility also includes the radioisotope production facility (RPF). The RPF is where the irradiated material is processed to separate medical isotopes, and includes packaging of the resulting materials for shipment to customers.

Detailed descriptions of the IF and the RPF, including IU power level, are provided in Chapter 4. A summary of the principal safety considerations is provided in Section 1.2, including inherent and passive safety features as well as design features that address the basic safety concerns such as functional, radiological, and criticality safety.

## 1.2 SUMMARY AND CONCLUSIONS ON PRINCIPAL SAFETY CONSIDERATIONS

This section identifies safety criteria, principal safety considerations and conclusions for the SHINE facility structures, systems, and components (SSCs). The purpose of the safety criteria for the SHINE facility is to limit adverse effects on the public and workers due to operation of the facility. These criteria are assured by designing, constructing, and operating the plant such that safety-related SSCs remain functional during normal conditions and during and following design basis events.

The accident analysis uses the most conservative operational condition or operating mode to determine potential radiological consequences. See Chapter 13 for a description of the accident analysis for the SHINE facility. Section 4a2.6 and Section 7.3 provide a description of operating modes of the irradiation unit.

### 1.2.1 CONSEQUENCES FROM THE OPERATION AND USE OF THE FACILITY

The primary consequences resulting from the operation of the SHINE facility are radiological. The SHINE facility produces molybdenum-99 (Mo-99) and other medical isotopes from irradiation of low enriched uranium (LEU). Within the irradiation facility (IF), the LEU in the target solution is in the form of a uranyl sulfate. In the irradiation units (IUs), the target solution is irradiated in a subcritical assembly by neutrons produced by a fusion neutron source. The irradiated target solution is then processed in the radioisotope production facility (RPF) to extract and purify the Mo-99 and other medical isotopes. Radioactive waste materials are processed and/or converted to solid wastes for shipment to off-site disposal facilities. The main production facility is designed to be a zero radioactive liquid effluent discharge facility as described in Section 11.1.

The IF and RPF within the main production facility constitute the radiologically controlled area (RCA) (see Figure 1.3-1). Radioactive materials are primarily present in the following locations within the SHINE facility buildings:

- Main production facility - IF
    - IU cells
    - Target solution vessel (TSV) off-gas shielded cells
    - Tritium purification system (TPS) area
    - RCA ventilation equipment areas

- Main production facility - RPF
    - Target solution preparation and storage areas
    - Supercell
    - Target solution hold tanks
    - Carbon delay beds
    - Radioactive liquid waste storage tanks
    - Radioactive liquid waste immobilization (RLWI) shielded cell
    - Labs and storage rooms

- Main production facility - other areas
    - Shipping and receiving area

- Material staging building

Doses to workers and the public during normal operation are within the limits of 10 CFR 20.1201 and 20.1301, respectively. In addition, there are potential exposures to the public from postulated accidents as described in the Chapter 13 accident analysis.

### 1.2.2 SAFETY CONSIDERATIONS

Within the IF, medical isotopes are produced in a subcritical assembly. The subcritical assembly is different from a nuclear reactor because it is designed to remain subcritical in all operating modes. Processes in the RPF are maintained subcritical with approved margins of subcriticality.

The subcritical assembly uses target solution consisting of LEU in the form of uranyl sulfate solution. The use of LEU as the source material meets U.S. government non-proliferation objectives related to elimination of the use of highly enriched uranium (HEU) for the production of medical isotopes.

The main production facility building, which contains the IF and RPF, is designed to withstand severe natural phenomena, including seismic events and tornados, as described in Chapter 3. The building structure is robust enough to remain intact following an aircraft impact as described in Section 3.4.

Primary functions of the IUs, including the power level within the TSV, are described in Chapter 4a2. Primary functions of the RPF are described in Chapter 4b. Major processes performed at the SHINE facility are summarized in Sections 1.3 and 1.6.

Safety considerations that influenced the selection of the specific site for the SHINE facility include:

- The size and shape of the proposed parcel,
- Proximity to an airport,
- Proximity to an interstate highway, and
- Seismic characteristics.

Consideration of the size and shape of the proposed parcel includes distance to the boundaries (e.g., greater distance from the facility to the site boundary decreases potential radiological impacts on the public). Of the parcels considered, the Janesville site had the largest minimum distance to the site boundary. Considering seismic characteristics, each potential site was comparably attractive because there are no major fault lines in Wisconsin.

The close proximity to the Southern Wisconsin Regional Airport increases safety because the medical isotope product spends less time and travels less distance being transported to the airport than it would if the airport were farther away. Although the close proximity to an airport increases the probability of an aircraft crash impact, the IF and RPF are designed to withstand an aircraft crash impact in order to mitigate this risk. The transportation safety improvement offsets the risk related to the increased probability of an aircraft crash impact.

The close proximity to Interstate-39/Interstate-90 (I-39/I-90) increases safety because of the need to spend less time and distance transporting radioactive cargo, such as waste or product, through populated areas. Although the close proximity to I-39/I-90 reduces the distance to hazardous chemicals that are transported on interstate highways, an analysis, described in Section 2.2, has been performed to ensure that these chemicals will not pose a threat to SHINE safety-related structures or to personnel from either explosions or hazardous levels of vapor. The need to spend less time and distance transporting radioactive materials through populated areas offsets the risk related to the reduced distance to hazardous chemicals transported on interstate highways.

## 1.2.3 INHERENT AND PASSIVE SAFETY FEATURES, DESIGN FEATURES, AND DESIGN BASES

### 1.2.3.1 Safety Features of Structures, Systems, and Components

The SHINE facility utilizes a number of inherent safety features that represent good engineering practice for nuclear facilities.

a. The RCA of the main production facility is located within seismic Category I structures, as described in Chapter 3, that are designed to survive the design basis earthquake and other design basis events.
b. Tanks and piping that are expected to contain significant concentrations of fissile material are designed and controlled to be geometrically favorable for criticality safety as described in Section 6b.3.
c. Confinement is used to prevent or minimize the spread of radioactive materials as described in Sections 6a2.2 and 6b.2.
d. Shielding is used to minimize occupational exposures in normally-occupied areas of the facility as described in Sections 4a2.5 and 4b.2.
e. Ventilation systems for normally-occupied areas are separate from ventilation systems for areas containing radioactive materials. The ventilation system in the RCA is designed to pull air from the least contaminated areas to the most contaminated areas as described in Section 9a2.1.
f. Areas, tanks, equipment, and piping that contain radioactive materials drain to favorable geometry sump tanks that are provided with leak detection as described in Section 9b.7.

Those SSCs whose intended functions are to prevent accidents that could cause undue risk to health and safety of workers and the public, and to control or mitigate the consequences of such accidents, are classified as safety-related SSCs. SSCs are designed, constructed, and operated such that safety-related SSCs remain functional during normal conditions and during and following design basis events. Principal design criteria for the facility are described in Section 3.1. SSCs that perform an engineered safety feature (ESF) function are classified as safety-related. ESFs for the IF and RPF are described in Chapters 6a2 and 6b, respectively.

### 1.2.3.2 Radiological Safety

The Radiation Protection Program is provided to protect the radiological health and safety of workers and members of the public in compliance with the regulatory requirements in 10 CFR 19 and 10 CFR 20. This program includes an as low as reasonably achievable (ALARA) program, radiation monitoring and surveying, exposure control, dosimetry, contamination control, and environmental monitoring. The Radiation Protection Program is described in Section 11.1. The Radioactive Waste Management Program is described in Section 11.2. The Respiratory Protection Program is described in Section 11.3.

Shielding is used extensively to minimize personnel exposures. The IU cell walls and the light water pool provide neutron and gamma shielding. The IU cells and light water pool are described in Chapter 4a2. IF biological shielding is described in Section 4a2.5. RPF biological shielding is described in Section 4b.2. Confinement is used in both the IF and the RPF to minimize the release and spread of contamination.

Control of gaseous, liquid, and solid radioactive wastes is provided by the process vessel vent system (PVVS) (Section 9b.6), the radioactive liquid waste storage system (RLWS) (Section 9b.7), the radioactive liquid waste immobilization system (RLWI) (Section 9b.7), and the solid radioactive waste packaging system (SRWP) (Section 9b.7). Potentially radioactive drains are part of the radioactive drain system (RDS) as described in Section 9b.7. Radiation Protection Program equipment and procedures are described in Section 11.1, including the use of area radiation monitors, continuous air monitors, the detection and monitoring of gaseous and liquid effluent release streams, control point monitoring, and the use of radiation surveys within the SHINE facility.

### 1.2.3.3 Reactivity Control in the IF

The subcritical assembly is designed to remain subcritical in all operating modes. To maintain this subcritical state, reactivity control is provided in the TSV through passive, active, and administrative controls. The IUs, which include the subcritical assembly, are identified as utilization facilities as defined in 10 CFR 50.2. Operating limits applicable to the TSV are described in Section 4a2.6. During TSV filling, neutron flux detectors combined with a fixed neutron source are used for reactivity increase measurements during the 1/M fill process and approach to critical. The fill process is normally stopped at approximately 5 percent by volume below critical. The 1/M fill process is described in Subsection 4a2.6.1. During TSV irradiation, the neutron flux detectors are used to determine fission power and reactivity. During both filling and irradiation, if neutron flux exceeds predetermined magnitudes, the TSV reactivity protection system (TRPS) initiates an IU Cell Safety Actuation. The TRPS is discussed in Section 7.4. Insertion of excess reactivity scenarios have been analyzed as described in Chapter 13a2, including inadvertent target solution fill scenarios (see Subsection 13a2.1.2).

### 1.2.3.4 Criticality Control in the RPF

The nuclear criticality safety program for operations in the RPF is described in Section 6b.3.

Nuclear criticality safety evaluations are conducted for each fissile material operation within the RPF to ensure that under normal and credible abnormal conditions, all nuclear processes remain subcritical with an approved margin of subcriticality. A fissile material operation is any process or system that has the potential to contain more than 250 g of non-exempt fissile material. For the purposes of application of this limit, all fissionable isotopes in the process or system are considered to be fissile.

In systems where the equipment is not safe-by-design, the double contingency principle is used ensuring at least two unlikely, independent, and concurrent changes in process conditions are required before a criticality accident is possible. The preferred hierarchy of nuclear criticality safety controls is (1) passive engineered, (2) active engineered, (3) enhanced administrative, and (4) administrative. Use of explicit nuclear criticality safety controls is preferred to reliance on the natural and credible course of events. Generally, control on two independent criticality parameters is preferred over multiple controls on a single parameter. If redundant controls on a single parameter are used, a preference is given to diverse means of control on that parameter.

### 1.2.4 POTENTIAL ACCIDENTS AT THE FACILITY

Potential design basis accidents (DBAs) at the SHINE facility were identified by the application of hazard analysis methodologies to evaluate the design of the facility and processes for potential hazards, initiating events (IEs), scenarios, and associated controls. As described in Chapter 13, these methodologies were applied to both the IF and the RPF. The list of accident categories and IEs that were the basis for the identification of potential DBAs are described in Chapter 13. The following accident categories and IEs are addressed for the SHINE facility. Some are applicable to the IF, some are applicable to the RPF, and some are applicable to both.

- Maximum hypothetical accident (MHA)
- Insertion of excess reactivity
- Reduction in cooling
- Mishandling or malfunction of target solution
- Loss of off-site power
- External events
- Mishandling or malfunction of equipment
- Large undamped power oscillations
- Detonation and deflagration in the primary system boundary
- Unintended exothermic chemical reactions other than detonation
- System interaction events
- Facility-specific events
- Critical equipment malfunction
- Inadvertent nuclear criticality in the RPF
- RPF fire
- Hazardous chemical accidents

## 1.3 GENERAL DESCRIPTION OF THE FACILITY

The SHINE main production facility consists of an irradiation facility (IF), radioisotope production facility (RPF), shipping and receiving area, and other areas that contain various support systems and equipment. General arrangement floor plan and section drawings of the facility showing the layout of major structures are provided in Figures 1.3-1 and 1.3-2. The SHINE facility site overview is provided in Figure 1.3-3. The radiologically controlled area (RCA) of the main production facility consists of the IF and the RPF (see Figure 1.3-1).

### 1.3.1 GEOGRAPHICAL LOCATION

The SHINE facility is located on the south side of the City of Janesville corporate boundaries, in Rock County, Wisconsin. Geographical coordinates of the SHINE site are provided in Section 2.1.

### 1.3.2 PRINCIPAL CHARACTERISTICS OF THE SITE

The SHINE site consists of a previously undeveloped, approximately 91-acre (ac.) (36.8-hectare [ha]) parcel that has been historically farmed. Safety-related structures are located within a rectangular area located near the center of the property. The region of the SHINE site is entirely contained within Rock County, Wisconsin. The dominant land use in the region is agricultural/cultivated crops. The northern limits of the City of Beloit are located approximately 3.7 miles (mi.) (6.0 kilometers [km]) to the south. Principal characteristics of the site are further described in Chapter 2.

### 1.3.3 PRINCIPAL DESIGN CRITERIA, OPERATING CHARACTERISTICS, AND SAFETY SYSTEMS

The SHINE facility is licensed under 10 CFR 50. Classifications of systems, structure, and components (SSCs) of the SHINE facility are described in Section 3.1.

#### 1.3.3.1 Principal Design Criteria

Principal design criteria for the facility are described in Section 3.1.

#### 1.3.3.2 Operating Characteristics

The irradiation units (IUs) are operated in a batch mode with an approximate week-long operating cycle. An operating cycle includes the following steps:

- target solution transfer from the RPF to the target solution vessel (TSV),
- irradiation in the subcritical assembly for approximately 5.5 days,
- shut down, and
- transfer of the irradiated target solution to the RPF for isotope extraction.

During the irradiation in the subcritical assembly system, the target solution is maintained in a subcritical state. Operating characteristics of the IUs, including power level, are discussed in more detail in Chapter 4a2.

The RPF also operates in a batch mode. The major operating steps include the following:

- preparation of uranyl sulfate solution from raw feed materials,
- extraction of molybdenum-99 (Mo-99) from processed target solution,
- purification of extracted Mo-99, and
- packaging of Mo-99 for shipment to customers.

Operating characteristics of the RPF are discussed in more detail in Chapter 4b.

### 1.3.3.3 Facility Systems

The IF consists of eight IUs. Each IU consists of a neutron driver assembly system (NDAS), a subcritical assembly system (SCAS), a primary closed loop cooling system (PCLS), a light water pool, a TSV off-gas system (TOGS), and related support systems.

The NDAS is an accelerator-based assembly that accelerates a deuterium ion beam into a tritium gas target chamber. The resulting fusion reaction produces 14 million electron volt (MeV) neutrons, which move outward from the tritium target chamber in all directions. The NDAS is described in Section 4a2.3. Potential upsets in the neutron driver system that would otherwise result in higher unplanned fission rates are prevented by systems that cause the IU to trip. The following actions occur on an IU Cell Safety Actuation:

- the neutron driver is de-energized by opening the safety-related circuit breaker for its high voltage power supply;
- the TSV dump valves are opened to drain the target solution to the geometrically favorable TSV dump tank; and
- the primary system boundary is isolated.

The neutron driver is located directly above the subcritical assembly. Most of the neutrons enter the SCAS, where they are slowed down to thermal energies. The resulting thermal neutron flux interacts with the uranium-235 (U-235) atoms in the target solution, causing the atoms to fission. Each SCAS includes a TSV, a neutron multiplier, a subcritical assembly support structure (SASS), and a TSV dump tank. The SCAS and its subcomponents are described in Section 4a2.2. The PCLS provides cooling to the SCAS and is described in Section 5a2.2. The SCAS is located inside of the light water pool. The light water pool is described in Section 4a2.4. The TOGS removes the off-gas from the TSV and is described in Section 4a2.8.

The function of the RPF is to extract, purify, and package Mo-99 and other medical isotopes for the end users. Additionally, the RPF prepares feed target solution for the IU. The RPF includes facility features and systems where the processes that support the IUs are performed and where processing of the irradiated target solution occurs. The major systems and processes are described below.

The target solution preparation system (TSPS) prepares fresh target solution from either uranium metal or uranium oxide. Recycled target solution is adjusted between cycles, as needed, by the addition of small volumes of acid or uranyl sulfate solution through TSPS. The TSPS is described in Section 4b.1.

The molybdenum extraction and purification system (MEPS) receives irradiated target solution, processes the target solution to extract the Mo-99, then purifies the product into its final form prior to packaging and shipping. The MEPS is described in Section 4b.1.

The process vessel vent system (PVVS) collects and processes radioactive gases from the vents of process vessels that handle the main process fluids. This system is briefly discussed in Section 4b.1 and described in detail in Section 9b.6.

The molybdenum isotope product packaging system (MIPS) receives the Mo-99 from MEPS and packages it for shipment to the customers. This system is briefly discussed in Section 4b.1 and described in detail in Section 9b.7.

Other systems located in the RPF are briefly discussed in Section 4b.1 and are described in more detail in the following chapters of this report.

### 1.3.4 ENGINEERED SAFETY FEATURES

SSCs that perform an engineered safety feature (ESF) function are classified as safety-related. ESFs for the IF are described in Section 6a2.2 and include ESFs related to confinement of radiological material. The SHINE facility does not have a containment feature but uses confinement to minimize the release and spread of radioactive contamination. Confinement is used to describe the low-leakage boundary that surrounds radioactive materials and the associated radiological ventilation (RV) system. Confinement systems are designed to localize release of radioactive material to controlled areas in normal operational states and mitigate the consequences of design basis accidents (DBAs). Radiation protection control features such as shielding and the RV minimize hazards normally associated with radioactive materials. The principal design and safety objective of the confinement systems is to protect on-site personnel, the public, and the environment. The second design objective is to minimize reliance on administrative or complex active engineering controls to provide a confinement system that is as simple and as fail-safe as reasonably possible.

The TSV, TSV dump tank, TOGS, and associated components act as the primary system boundary (PSB). These components act as the primary fission product boundary. The confinement boundary of the IU cell and TOGS shielded cell encloses the PSB. Confinement is achieved through the RV, the TSV reactivity protection system (TRPS), and the passive confinement structures provided by the steel and concrete comprising the walls, roofs, and penetrations of the IU cell and TOGS shielded cell. The tritium confinement boundary provides confinement for portions of the tritium purification system (TPS). Isolation of the tritium confinement boundary is actuated by the engineered safety features actuation system (ESFAS).

ESFs outside the IF are described in Section 6b.2 and include confinement of radiological material and hazardous material in the RPF. The RPF confinement areas include hot cell enclosures and gloveboxes for process operations and trench and vault enclosures for process tanks and piping. Confinement is achieved through RV, ESFAS, and passive confinement structures provided by the steel and concrete comprising the walls, roofs, and penetrations of the confinement areas.

### 1.3.5 INSTRUMENTATION, CONTROL, AND ELECTRICAL SYSTEMS

The process integrated control system (PICS) monitors and controls various operations throughout the IF and RPF as described in Section 7.3. The TSV is protected by the TSV reactivity protection system (TRPS) as described in Section 7.4. Various ESF functions are monitored and controlled within the ESFAS as described in Section 7.5. The highly integrated protection system (HIPS) design is used for both the TRPS and ESFAS as described in Chapter 7.

Design features of the control consoles and display instrumentation, and the radiation monitoring systems for both the IU and the RPF, are described in Chapter 7. Radiation monitoring systems include process radiation monitoring, the radiation area monitoring system (RAMS), the continuous air monitoring system (CAMS), and effluent monitoring.

The SHINE facility has a common normal electrical power system which provides power to the IF, the RPF, and other support buildings. Power service is provided by the local utility via offsite feeds. The normal electrical power system is described in Section 8a2.1.

Emergency electrical power for the SHINE facility is provided by a common safety-related uninterruptible electrical power supply system (UPSS) and a common nonsafety-related standby generator system (SGS). The UPSS consists of two independent trains, each consisting of a 125 volts-direct current (VDC) battery subsystem with associated charger, inverter, and distribution system. The SGS includes a natural gas-fired generator and provides power for asset protection purposes to selected loads in the event of a loss of offsite power. These emergency electrical power systems are described in Section 8a2.2.

### 1.3.6 TSV COOLING AND OTHER AUXILIARY SYSTEMS

Primary cooling for the TSV and related components is provided by the PCLS as described in Section 5a2.2. The TSV and related components are submerged in the light water pool. The light water pool is described in Section 4a2.4. Make-up to the light water pool and the PCLS is provided by the facility demineralized water system (FDWS) as described in Section 5a2.6. Cooling for various IF and RPF systems is provided by the radioisotope process facility cooling system (RPCS) as described in Section 5a2.3.

Ventilation for both the IF and the RPF is provided by the RV as described in Section 9a2.1. Equipment and processes related to handling and storage of target solution are described in Section 9a2.2. The tritium purification system (TPS) processes gas from the tritium target of the NDAS, including separating the deuterium from the tritium and returning the purified gases to the NDAS, as described in Section 9a2.7. The facility fire protection systems and fire protection program are described in Section 9a2.3. Communications systems are described in Section 9a2.4. Other auxiliary systems are also described in Chapters 9a2 and 9b.

### 1.3.7 RADIOACTIVE WASTE MANAGEMENT AND RADIATION PROTECTION

The SHINE facility has a radiation protection program to protect the radiological health and safety of its workers. This program includes an as low as reasonably achievable (ALARA) program, radiation monitoring and surveying, exposure control, dosimetry, contamination control, and environmental monitoring. The radiation protection program is described in Section 11.1. The

SHINE facility has a respiratory protection program to protect its workers from airborne contamination as described in Section 11.3.

The SHINE facility has a radioactive waste management program. This program is described in Section 11.2. Control of gaseous, liquid, and solid radioactive wastes is provided by the PVVS, the radioactive liquid waste storage system (RLWS), the radioactive liquid waste immobilization system (RLWI), and the solid radioactive waste packaging system (SRWP). Drains from vaults, trenches, and other areas where uranium-bearing solutions may be present are part of the radioactive drain system (RDS), described in Chapter 9b.

### 1.3.8 EXPERIMENTAL FACILITIES AND CAPABILITIES

The SHINE facility does not include experimental facilities or capabilities.

### 1.3.9 RESEARCH AND DEVELOPMENT

The following research and development activities were identified as ongoing in NUREG-2189, Safety Evaluation Report Related to SHINE Medical Technologies, Inc. Construction Permit Application for a Medical Radioisotope Production Facility (USNRC, 2016), and have since been resolved:

(1) Irradiation and corrosion testing at Oak Ridge National Laboratory (ORNL) to study the mechanical performance of materials
(2) Precipitation studies at Argonne National Laboratory (ANL) to ensure precipitation of uranyl peroxide in the target solution will not occur

The testing of materials included zirconium alloy for the TSV as well as the stainless steel for the SASS and the process piping and vessels around the facility. As the material of construction for the target solution vessel has been changed to stainless steel, as described in Section 4a2.4, the data for the zirconium alloy is no longer needed. The stainless steel testing results from ORNL were used along with data from Los Alamos National Laboratory, ANL, and literature to define bounding corrosion allowances for the materials of construction in the process conditions they will be exposed to. The data included extensive testing of stainless steel in uranyl sulfate solution as part of historical aqueous homogeneous reactor experiments at ORNL. Given the corrosion and irradiation data that has been obtained, no further research and development is required.

Precipitation studies at ANL were conducted using uranyl sulfate solution encompassing the SHINE target solution operating parameters. These studies included a range of temperatures, uranium concentrations, catalyst materials, and power densities. This data was combined with data from historical operation of aqueous homogeneous reactors including HRE, KEWB, L-8, L-54, and Argus to define power density limits for the SHINE target solution. Section 4a2.6 defines the operating limits to ensure that no significant uranyl peroxide precipitation occurs. Given that SHINE will operate within these limits, no further research and development is required.

**Figure 1.3-1 – Main Production Facility Building General Arrangement**

Figure 1.3-2 – Main Production Facility Building General Arrangement Section “A-A”

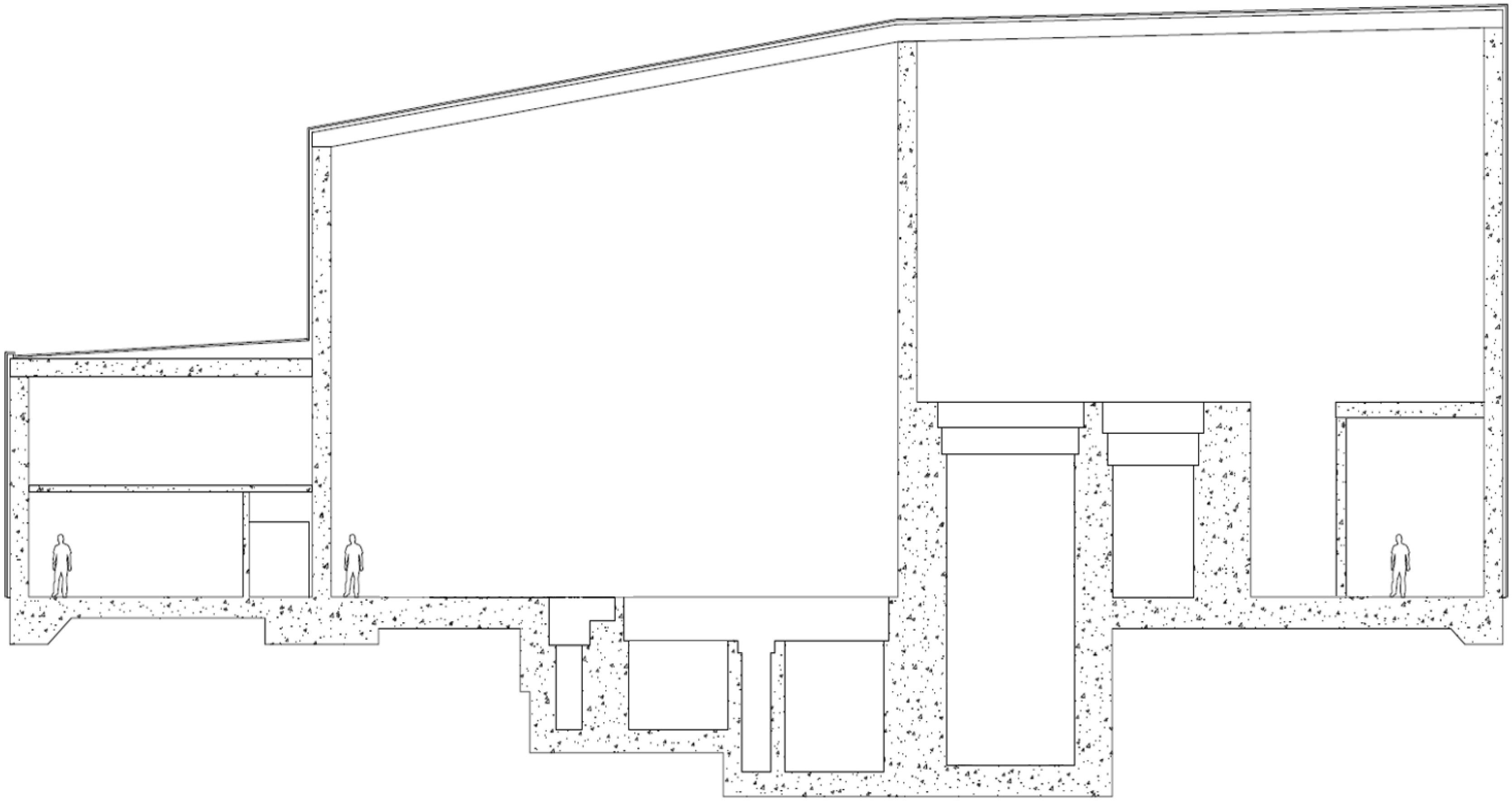
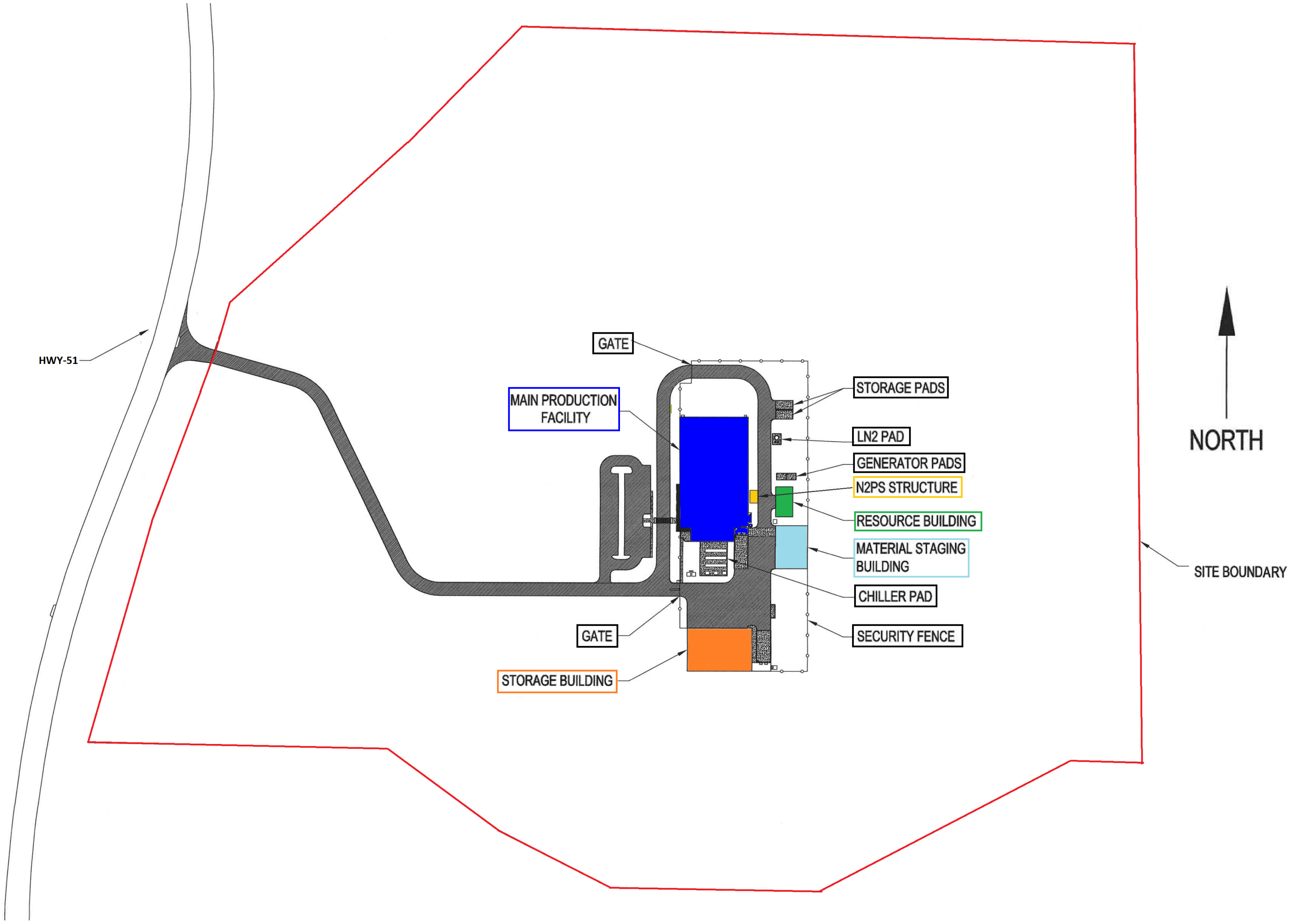


**Figure 1.3-3 – Site Overview**



## 1.4 SHARED FACILITIES AND EQUIPMENT

The SHINE facility does not share any systems or equipment with facilities not covered by this report.

The SHINE main production facility includes the irradiation facility (IF), the radioisotope production facility (RPF), the non-radiologically controlled seismic area, and a non-safety related area. The SHINE facility includes the following structures:

- Main production facility
- Resource building
- Material staging building
- Storage building
- N2PS structure

## 1.5 COMPARISON WITH SIMILAR FACILITIES

### 1.5.1 COMPARISON OF PHYSICAL PLANT AND EQUIPMENT

As stated in Section 1.1, the SHINE facility uses new technology for the manufacture of medical isotopes. The irradiation unit (IU), consisting of the neutron driver, subcritical assembly, light water pool, target solution vessel (TSV) off-gas system (TOGS), and other supporting systems, represents new technology. As such, there are no similar facilities that compare to the IUs. These systems and components are discussed in Chapter 4a2.

The neutron driver in particular has specifically been developed for use in the SHINE facility. The subcritical assembly, consisting of the TSV, neutron multiplier, subcritical assembly support structure (SASS), and subcritical multiplication source, is also a new design. The neutron driver is discussed in Section 4a2.3. The subcritical assembly is discussed in Section 4a2.2.

In the radioisotope production facility (RPF), the irradiated target solution is processed in hot cells to separate and purify the medical isotopes that are produced. The hot cell design is conventional and is similar to the design used in many other facilities. The RPF is discussed in Chapter 4b.

As stated in Section 11.1, the objective of the as low as reasonably achievable (ALARA) program is to make every reasonable effort to maintain exposure to radiation as far below the dose limits of 10 CFR 20.1201 and 10 CFR 20.1301 as is practical. The design and implementation of the ALARA program is consistent with the NRC guidance as described in Section 11.1. This compares favorably to other facilities that are required to have an ALARA program.

### 1.5.2 COMPARISON OF CHEMICAL PROCESSES

#### 1.5.2.1 Molybdenum Extraction

The SHINE facility molybdenum (Mo) extraction system uses selective adsorption of Mo from the irradiated target solution as described in Chapter 4b. There are currently no NRC or U.S. Department of Energy (DOE) facilities that use this specific process. However, the use of solid sorbents to remove specific components from an aqueous solution has been widely researched and demonstrated on a commercial scale.

In particular, cesium-137 and strontium-90 are typically isotopes that are removed from aqueous streams, due to their gamma emission driving worker and public dose rates. Cesium can be removed by crystalline silico-titanate, or sodium titanosilicate followed by alumina montmorillonite clay. Strontium is removed by sodium titanosilicate, followed by titanium silicate pharmacosiderites. These processes have been researched extensively; however, no facilities utilizing these technologies have been approved by DOE or NRC.

At Sellafield in the United Kingdom, the Site Ion Exchange Effluent Plant (SIXEP) uses clinoptilolite to remove cesium and strontium from aqueous process streams. Clinoptilolite is a naturally occurring clay-like material. The SIXEP facility has been in operation since 1985.

### 1.5.2.2 Molybdenum Purification

The SHINE Mo purification process is very similar to the Cintichem process developed in the 1950s and 1960s by Union Carbide. The special nuclear material (SNM) license was transferred from the Union Carbide Corporation to Cintichem, Inc. in 1984. Cintichem, Inc. operated the process until 1990 as a means to purify Mo-99 for use as a medical isotope. There are no NRC or DOE licensed facilities currently using this technology. The process used by Union Carbide and Cintichem, Inc. generated Mo-99 produced by fission in highly enriched uranium (HEU) solid targets. The SHINE process produces Mo-99 derived from irradiation of low enriched uranium (LEU) target solution. The chemistry of the process has been adjusted slightly to accommodate the change in chemical and isotopic composition due to the switch from HEU to LEU.

The purification process is a small scale, batch chemical procedure performed in laboratory glassware. This is unchanged between the previous deployment of the Cintichem process and the system employed at the SHINE facility.

### 1.5.2.3 Tritium Purification System

Tritium is purified using the thermal cycling absorption process (TCAP) technology. TCAP was developed at the Savannah River Site to separate tritium from deuterium and protium. Other process equipment is used to support the TCAP separation, including impurity removal and tritium storage. For SHINE, TCAP and its supporting process equipment is known as the tritium purification system (TPS). TPS is similar in design to the processes within the following facilities:

a. Savannah River Site, South Carolina.
b. Laboratory for Laser Energetics, Rochester, New York.

Due to the sensitive and confidential nature of information relating to tritium production and purification, the design and operational details of these systems are not published. A comparison of the SHINE system with existing facilities is therefore not possible. The same is true of other tritium facilities around the globe.

## 1.5.3 COMPARISON OF SUPPORT SYSTEMS

Supporting systems, including ventilation, cooling water, waste processing, and electrical power, are conventional in nature. In general, there are no unique features that warrant discussion here. These systems are discussed in the corresponding chapters of this report.

## 1.6 SUMMARY OF OPERATIONS

The major operations to be performed in the SHINE facility are as follows:

- Target solution preparation from raw feed material.
- Irradiation of target solution.
- Molybdenum (Mo) extraction from irradiated target solution.
- Mo purification.
- Target solution adjustments.
- Solidification of radioactive liquid waste.

Target solution preparation from raw feed material (uranium metal) starts with either uranium metal or uranium oxide. Either form of uranium is low enriched uranium (LEU). If uranium metal is used as the feed material, it is first converted to uranium oxide by a furnace within the uranium receipt and storage system (URSS) glovebox. Uranium oxide is then dissolved in sulfuric acid to produce the uranyl sulfate target solution. Hydrogen peroxide may be used as a catalyst to aid the conversion. After initial startup of the facility, receipt of uranium will be infrequent, occurring only as necessary to make up for losses or to generate fresh target solution batches as needed.

The irradiation facility (IF) consists of eight irradiation units (IUs). Each IU is operated for an approximately week-long cycle. The operating cycle includes the following steps:

- Prepared target solution is transferred to the target solution hold tank, and then into the target solution vessel (TSV). The volume of uranyl sulfate solution in the TSV is described in Chapter 4a2.
- The neutron driver is energized and ramped up to power.
- The subcritical assembly is operated at power for approximately 5.5 days.
- The unit is shut down and the target solution is allowed to decay.
- The target solution is transferred to the radioisotope production facility (RPF) for processing.

Molybdenum extraction is performed in a hot cell in the RPF. Mo extraction from irradiated target solution involves passing the irradiated target solution through an adsorbent. The Mo and other fission products are adsorbed Mo is eluted using a base. The eluate is dried and redissolved in nitric acid. The resulting Mo-99 product is transferred to the Mo-99 purification system. The adsorbent for the Mo extraction process is contained in a packed column configuration.

Molybdenum purification is performed in a hot cell in the RPF. The Mo-99 product is purified in a laboratory glassware system.

The fission product inventory from operation of the facility is discussed in Section 11.1. Normal effluent release pathways from the SHINE facility to the environment are discussed in Section 11.1.

## 1.7 COMPLIANCE WITH THE NUCLEAR WASTE POLICY ACT OF 1982

The SHINE facility does not produce either high-level nuclear wastes or spent nuclear fuel. Therefore, the Nuclear Waste Policy Act of 1982 is not applicable to this facility.

## 1.8 FACILITY MODIFICATIONS AND HISTORY

The SHINE facility described in this report is new construction. There are no existing facilities, there have been no modifications, and there is no history to report. Therefore, this section is not applicable to the SHINE facility.

## 1.9 REFERENCES

**USNRC, 2016.** Safety Evaluation Report Related to SHINE Medical Technologies, Inc. Construction Permit Application for a Medical Radioisotope Production Facility, NUREG-2189, U.S. Nuclear Regulatory Commission, August 2016.