ENCLOSURE 2

SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL TECHNOLOGIES, LLC OPERATING LICENSE APPLICATION RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

PUBLIC VERSION

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The U.S. Nuclear Regulatory Commission (NRC) staff determined that additional information was required (Reference 1) to enable the continued review of the SHINE Medical Technologies, LLC (SHINE) operating license application (Reference 2). The following information is provided by SHINE in response to the NRC staff's request.

Chapter 1 – The Facility

RAI 1-1

NUREG-1537, Part 1, Appendix A, describes the applicability of 10 CFR 50.9, "Completeness and accuracy of information." As required by 10 CFR 50.9, information provided by an applicant must be complete and accurate.

Throughout the SHINE operating license application, SHINE uses various terms to refer to the complete SHINE Medical Isotope Production Facility. Some of the terms used throughout the application include:

- Main production facility
- Radioisotope production facility
- Irradiation facility
- SHINE facility
- Medical isotope production facility

It is unclear to the NRC staff how SHINE differentiates between these terms. For example, it is unclear whether the terms "main production facility," "SHINE facility," and "medical isotope production facility" are equivalent terms that may be used interchangeably or if the "main production facility" and "radioisotope production facility" are intended to be equivalent terms.

As authorized by Construction Permit No. CPMIF-001 (ADAMS Accession No. ML16041A473), the NRC staff understands that the proposed facility would comprise an irradiation facility and radioisotope production facility. The irradiation facility would consist of eight subcritical operating assemblies (or irradiation units), which would each be licensed as a utilization facility, as defined in 10 CFR 50.2, "Definitions," and supporting structures, systems, and components (SSCs) for the irradiation of low enriched uranium. The radioisotope production facility would consist of hot cell structures, licensed collectively as a production facility, as defined in 10 CFR 50.2, and associated SSCs for the processing of irradiated material and extraction and purification of Mo-99. The irradiation facility and radioisotope production facility are collectively referred to as the SHINE Medical Isotope Production Facility in Construction Permit No. CPMIF-001.

Clarification on SHINE's use of terminology is necessary for the NRC staff to clearly understand when SHINE is referencing portions of its facility to be licensed as either a utilization facility or production facility, as defined in the NRC's regulations and authorized by Construction Permit No. CPMIF-001. This information is necessary to ensure that SHINE has included complete and accurate information describing its facility and proposed operational activities.

Provide clear definitions of all terms used to refer to the SHINE Medical Isotope Production Facility, the irradiation facility, and radioisotope production facility, updating the FSAR as necessary.

SHINE Response

SHINE uses various terms throughout the operating license application to refer to the SHINE site, structures which make up the SHINE site, and areas within those structures. The terms used in the operating license application are "medical isotope production facility," "SHINE facility," "main production facility," "SHINE production facility," "irradiation facility (IF)," "radioisotope production facility (RPF)," "the facility," and "the plant." These terms are defined as follows:

- The term "medical isotope production facility" is used to identify the purpose of the facility for which the operating license is being sought.

- The term "SHINE facility" is used to describe the entirety of the site. Figure 1.3-3 of the Final Safety Analysis Report (FSAR) provides an overview of the site, identifying the structures and features which constitute the "SHINE facility." Section 1.4 of the FSAR lists the structures which constitute the "SHINE facility." SHINE uses of the terms "the plant" and "the facility" interchangeably with the term "SHINE facility" in the operating license application.

- The term "main production facility" specifically describes the SHINE building which contains both the "irradiation facility" and the "radioisotope production facility." Figure 1.3-1 of the FSAR provides a plan view of the "main production facility."

- The term "irradiation facility" describes the portion of the "main production facility" that contains the accelerator-driven subcritical operating assemblies. The "irradiation facility" contains supporting systems for the irradiation units such as tritium purification, cooling loops, and off-gas handling. Figure 1.3-1 of the FSAR identifies the areas of the "main production facility" that are part of the "irradiation facility."

- The term "radioisotope production facility" describes the portion of the "main production facility" that contains the equipment used to separate and purify the medical isotopes, including molybdenum-99, from target solution such that they are acceptable for sale and shipment. The "radioisotope production facility" also contains supporting systems for target solution preparation and the disposal/treatment of byproduct waste liquids and off-gases. Figure 1.3-1 of the FSAR identifies the areas of the "main production facility" that are part of the "radioisotope production facility."

SHINE has revised the FSAR to ensure consistent use of these defined terms, to remove use of the term "SHINE production facility," and to correct the name of the material staging building. A mark-up of the FSAR incorporating these changes is provided as Attachment 1.

Chapter 4 – Irradiation Unit and Radioisotope Production Facility Description

RAI 4a-1

Section 50.9 of 10 CFR Part 50 requires information provided by an applicant be complete and accurate.

SHINE FSAR Section 4a2.2.1.2, “Chemical Properties,” provides the optimum uranium concentration predicted by the SHINE neutronics model in units of grams of uranium per liter; however, it is not clear to the NRC staff whether these units of concentration refer to grams of uranium per liter of target solution or per liter of solvent.

Clarify whether the uranium concentration provided in the FSAR is given in grams of uranium per liter of target solution or per liter of solvent.

SHINE Response

The uranium concentration in the FSAR is given in grams of uranium per liter (gU/L) of target solution.

The following regulatory requirement is applicable to RAIs 4a-2 through 4a-17:

> Section 50.34(b)(2) of 10 CFR Part 50 requires, in part, that an FSAR include a description and analysis of the structures, systems, and components of the facility, with emphasis upon performance requirements, the bases, and the evaluations required to show that safety functions will be accomplished. The description shall be sufficient to permit understanding of the system designs and their relationship to safety evaluations.

RAI 4a-2

The ISG Augmenting NUREG-1537, Part 2, Section 4a2.2.1, “Reactor Fuel,” states that information provided in the FSAR should include various phenomena that results in changes to the initial fuel composition, such as radiolytic gas formation.

SHINE FSAR Section 4a2.2.1.5, “Off-Gas Formation,” states that radiolysis rates for uranyl sulfate undergoing fission were determined using published experimental data. SHINE stated that the formation rate is 71 standard cubic feet per hour (scfh) (33 standard liters per minute [slpm]) consisting of 67 percent hydrogen and 33 percent oxygen. Additionally, SHINE states that the target solution vessel (TSV) off-gas system (TOGS) is designed to accommodate a hydrogen generation rate of at least 53 scfh (25 slpm). SHINE FSAR Section 4a2.8.2, “System Process and Safety Functions,” states that a safety function of the TOGS is to maintain hydrogen concentrations below values which could result in a hydrogen explosion overpressure capable of rupturing the primary system boundary (PSB), preventing release of radioactive material that could result in undue risk to health and safety of workers and the public. However, SHINE does not specify the basis for the formation rates related to fission power, uranium concentration, and power of hydrogen (pH). Further, SHINE has not provided the reference conditions (e.g., temperature and pressure) that support the basis of its standard volumetric flow rates This information is necessary for the NRC staff to understand whether the operation of TOGS can maintain a safe concentration level of hydrogen and oxygen during Mode 2 operation of the SHINE irradiation units.

(1) Provide the target solution fission power, uranium concentration, and pH that were used to determine the hydrogen and oxygen formation rates provided in Section 4a2.2.1.5. of the SHINE FSAR.

(2) Provide the reference conditions, such as temperature and pressure, used to calculate standard volumetric flow rates.

(3) Clarify the published experimental data SHINE used to determine the radiolysis rates for uranyl sulfate undergoing fission.

(4) Provide an explanation on the maximum hydrogen generation rate in the TSV, considering conservatism and uncertainty.

(5) Provide an explanation on the maximum hydrogen generation rate that the TOGS is designed to process, considering conservatism and uncertainty.

SHINE Response

(1) Subsection 4a2.2.1.5 of the FSAR describes the formation rate of hydrogen and oxygen up to approximately 71 standard cubic feet per hour (scfh) (33 standard liters per minute [slpm]). This gas generation rate is based on a bounding analysis of nominal target solution vessel (TSV) conditions (i.e., target solution fission power of 125 kilowatts [kW] and uranium concentration of [ ]$^{PROP/ECI}$).

Subsection 4a2.2.1.5 of the FSAR also describes that the TSV off-gas system (TOGS) is designed to accommodate a hydrogen generation rate of at least 53 scfh (25 slpm), corresponding to a 80 scfh formation rate of hydrogen and oxygen. The TOGS design hydrogen handling rate is based on a bounding analysis of limiting TSV conditions for radiolysis rates (i.e., target solution fission power of 137.5 kW and uranium concentration of [ ]$^{PROP/ECI}$).

The target solution pH was not used to determine the hydrogen and oxygen formation rates within the TSV at full power.

(2) Standard conditions for the calculation of hydrogen radiolysis flow rates were 273.15 K and 101,325 Pascal (Pa).

(3) Radiolysis rates for uranyl sulfate undergoing fission were determined from data in published experiments (Reference 3). The 0.995 fission energy fraction values were used since they are higher (i.e., more conservative).

(4) The maximum hydrogen generation rate in the TSV was calculated by determining the G-value (formation rate per unit energy) for the target solution based upon the uranium concentration. For conservatism and margin, because lower concentrations yield higher G-values, the minimum target solution uranium concentration was reduced to account for measurement uncertainty. Fission G-values were calculated by fitting a 2nd order polynomial to the data (Reference 3) versus uranium concentration. Error was calculated for each data point compared to the result of the polynomial and standard deviation was calculated. A one-sided 95/95 confidence interval was calculated, which gave 12.6 percent uncertainty on the G-value as calculated from the second order polynomial fit; the total gas production was increased by 12.6 percent to account for this uncertainty. A target solution fission power of

137.5 kW was used, which corresponded to 127 kW of fission power absorbed in the target solution (i.e., based on calculations, 10.5 kW of power contained in radiation escapes the solution). Neutrons produced within the accelerator were considered as an additional source of hydrogen production. A total of 53 scfh of hydrogen (3.8E-02 grams per second [g/s]) was calculated.

(5) TOGS is rated to process a steady-state hydrogen generation rate of 53 scfh of hydrogen (3.8E-02 g/s), which includes the conservatism and uncertainty described above. The TOGS components affecting hydrogen processing rate are the recombiner and recombiner condenser. The recombiner is designed with not less than [ ]PROP/ECI margin for conservatism. The recombiner condenser is designed with not less than [ ]PROP/ECI heat transfer area margin for conservatism. Therefore, the TOGS is capable of processing roughly [ ]PROP/ECI grams per second of hydrogen, which is a [ ]PROP/ECI greater hydrogen processing rate than the rated rate. At this hydrogen processing rate, the TOGS sweep gas hydrogen concentration would be higher than normal because the sweep gas flowrate is not intentionally varied during irradiation.

RAI 4a-3

The ISG Augmenting NUREG-1537, Part 2, Section 4a2.7, “Gas Management System,” states that radiolytic gas recombiner must be capable of preventing a hydrogen deflagration or dentation anywhere within the gas confinement boundary.

SHINE FSAR Section 4a2.2.6, “Neutron Multiplier,” states that the neutron multiplier is an annulus of aluminum-clad uranium metal that serves to moderate and multiply the fast neutrons coming from the reactions initiated by the neutron driver. The NRC staff needs more information to understand the potential of hydrogen generation to ensure hydrogen concentrations are maintained below acceptable limits to prevent ignition and deflagration conditions within the as confinement boundary.

Clarify whether SHINE considered the potential of hydrogen generation within the gas confinement boundary. If hydrogen is generated, explain where this hydrogen may accumulate and what system or systems mitigate the hydrogen generated by a potential event.

SHINE Response

SHINE has considered the potential of hydrogen generation within the irradiation unit (IU) cell. The primary source of hydrogen generation is within the TSV due to radiolysis as discussed in Section 4a2.2 of the FSAR. Mitigation of the hydrogen generated within the TSV and TSV dump tank is discussed in Section 4a2.8 of the FSAR. Hydrogen will also be generated in the primary closed loop cooling system (PCLS) cooling water and in the light water pool system (LWPS) pool water due to radiolysis. Hydrogen generation and mitigation of hydrogen in the PCLS and LWPS is discussed in Section 5a2.2.7 of the FSAR.

SHINE has also considered the potential for hydrogen generation within the IU cell during off-normal conditions. If target solution were to leak out of the TSV, hydrogen generation resulting from target solution contacting the aluminum neutron multiplier cladding is minimized by PCLS cooling water. The annular space between the inner shell of the TSV and the outer surface of the aluminum-clad neutron multiplier is a PCLS cooling water channel of the subcritical assembly system (SCAS). In a scenario where target solution leaked out of the TSV, the target solution would be diluted by the water in the cooling channel and mixed with the bulk of the

PCLS cooling water. The amount of hydrogen produced within the PCLS cooling water due to interaction of the heavily diluted target solution and the aluminum cladding would be negligible compared to the amount of hydrogen produced within the PCLS cooling water during normal operation due to radiolysis.

Another potential source of hydrogen generation in the IU cell during off-normal conditions is within the natural uranium core of the neutron multiplier. In a scenario where the neutron multiplier aluminum cladding failed, the natural uranium core could be exposed to water. The reaction between the natural uranium and the water would release hydrogen, [

]PROP/ECI Any hydrogen escaping the neutron multiplier cladding would enter the PCLS cooling water, where it would be mitigated by the PCLS. The amount of hydrogen produced would be small compared to the amount of hydrogen produced within the PCLS cooling water during normal operation due to radiolysis.

RAI 4a-4

The ISG Augmenting NUREG-1537, Part 2, Section 4a2.2.1, “Reactor Fuel,” states that information provided should include various phenomena that results in potential fuel precipitation.

SHINE FSAR Section 4a2.6.3.5, “Limiting Core Configuration,” states that uranyl peroxide is known to precipitate out of uranyl sulfate solution under certain conditions of irradiation due to the presence of hydrogen peroxide formed from radiolysis effects. The formation of uranium precipitates is dependent on the rates of hydrogen peroxide production, the peroxide solubility, and the rate of decomposition. The key factors influencing these parameters include the solution chemistry (including pH and catalysts), temperature, and power density. The NRC staff needs more information to understand how these parameters associated with solubility are monitored and maintained to prevent uranium precipitation from the target solution.

Explain how solubility, temperature, pH, power density, and any other target solution parameters are measured, monitored, and maintained within acceptable limits at zero power with cold conditions to prevent precipitation of uranium from the target solution.

SHINE Response

The SHINE Response to RAI 4a-4 will be provided by July 31, 2020.

RAI 4a-5

The ISG Augmenting NUREG-1537, Part 2, Section 4a2.3, “Reactor Vessel,” states that all penetrations and attachments to the vessel below the fuel solution level should be designed to avoid loss of fuel solution.

SHINE FSAR Section 4a2.4.1.4, “Location of Penetrations,” describes TSV penetrations. However, it is not clear to the NRC staff which penetrations are only into the TSV or through the TSV. It is also not clear whether penetrations are voided or filled with target solution to ensure that the design avoids loss of fuel solution.

For each TSV penetration described in FSAR Section 4a2.4.1.4, clarify whether the penetration is into the TSV (i.e., open to TSV) or only transitions through the TSV (i.e., closed to TSV). Additionally, provide dimensions of each penetration, and clarify whether each penetration is voided or filled with target solution during Mode 2 operation of the irradiation units.

SHINE Response

Additional information for each of the TSV penetrations described in Subsection 4a2.4.1.4 of the FSAR is provided below:

- [

  ]PROP/ECI During Mode 2 operation, [ ]PROP/ECI are filled with PCLS cooling water.

- The TSV contains two nominal pipe size (NPS) [ ]PROP/ECI drain lines for interconnection to the TSV dump tank. The drain lines penetrate the bottom head of the TSV and are open to the TSV. During Mode 2 operation, these drain lines are filled with target solution up to the TSV dump valve.

- The TSV contains two connections to solution overflow lines. Internal to the TSV, the overflow lines consist of two NPS [ ]PROP/ECI standpipes approximately [ ]PROP/ECI tall. During Mode 2 operation, the solution overflow lines contain TSV off-gas (i.e., voided).

- The TSV contains four TOGS supply/return connections. The TOGS supply/return connections penetrate the top head of the TSV and are open to the TSV. The two TOGS supply connections are NPS [ ]PROP/ECI pipe and the two TOGS return connections are NPS [ ]PROP/ECI pipe. During Mode 2 operation, the TOGS supply/return connections contain TSV off-gas (i.e., voided).

- There are three vertical thermowells that pass through the TSV. The thermowells transition through the TSV and are closed to the TSV. Each thermowell is NPS [ ]PROP/ECI pipe. During Mode 2 operation, the thermowells are filled with temperature instrumentation and water.

- The TSV contains two inspection openings. The inspection openings penetrate the top head of the TSV and are open to the TSV. Each inspection opening is an NPS [ ]PROP/ECI pipe. During Mode 2 operation, the inspection openings contain TSV off-gas (i.e., voided).

- The TSV contains two condensate return connections. The condensate return connections penetrate the side of the TSV and are open to the TSV. Each condensate return connection is an NPS [ ]PROP/ECI pipe. During Mode 2 operation, the condensate return connections contain TSV off-gas and condensate (i.e., partially voided).

- The TSV contains two spare irradiation sleeves. The spare irradiation sleeves transition through the TSV and are closed to the TSV. Each spare irradiation sleeve is a [ ]PROP/ECI. During Mode 2 operation, the spare irradiation sleeves contain air (i.e., voided).

RAI 4a-6

The ISG Augmenting NUREG-1537, Part 2, Section 4a2.2.1, “Reactor Fuel,” states that the various phenomena that result in changes to the initial fuel composition and properties should be considered. Application submittals should include information on radiolytic gas formation, transport, and changes in void fraction, along with the reactivity implications of these items.

SHINE FSAR Section 4a2.2.1.6, “TSV Operating Conditions,” states that the bulk void fraction within the target solution is expected to be less than five percent. Further, Table 4a2.6-10, “Limiting Core Configuration Calculated Parameters,” of the SHINE FSAR states the average void fraction. SHINE FSAR Section 4a2.6.1.2, “TSV Operating Characteristics,” states the estimated nominal average void fraction during Mode 2 operation of the irradiation units. However, it is unclear to the NRC staff how the void fraction within the target solution was determined.

Explain how the average void fraction in SHINE FSAR Table 4a2.6-10 was determined, including the basis for expecting the bulk void fraction within the target solution to be less than five percent.

SHINE Response

Chapter 4a2 of the FSAR discusses void fractions within the target solution volume considering different TSV core configurations. The limiting core configuration is the core configuration that yields the highest power densities, as described in Subsection 4a2.6.3.5 of the FSAR. The nominal core configuration is the typical core configuration expected during normal operations and is described in Section 4a2.6 of the FSAR. Throughout the FSAR, the terms “average void fraction” and “bulk void fraction” are used interchangeably; these terms both mean the void fraction averaged throughout the target solution volume.

The methodologies for determining the nominal core configuration average void fraction in Subsection 4a2.6.1.2 of the FSAR, the limiting core configuration average void fraction in Table 4a2.6-10 of the FSAR, and the maximum average void fraction in Subsection 4a2.2.1.6 of the FSAR are the same. A literature review was performed on bubble formation in sulfate solutions under irradiation. The results of this literature review were applied to conditions in the TSV under irradiation to determine both an expected and a bounding range of bubble sizes as well as a void fraction distribution.

The analysis calculates the average void fraction using a model based on an idealized evolution of an average bubble traveling through solution. Output from the single-bubble analysis is applied to an estimated radiolytic gas generation distribution to estimate the developed void fraction throughout the solution. The treatment of bubble evolution is idealized in that dissolved gas concentrations are assumed to remain constant at the critical concentration necessary for bubble nucleation in the solution. This neglects how dissolved gas concentrations dynamically evolve due to changing bubble populations and gas generation rates. It is expected that the dissolved gas concentration will oscillate about the critical concentration due to the interplay between continuous radiolytic gas generation and the periodic depletion of dissolved gas from bubble growth. The assumption simplifies the situation by averaging the dissolved gas concentrations with respect to time, but still yields accurate results because it simulates the macro steady state behavior of the dissolved gas concentrations.

The model considers only volumetric bubble formation within the target solution. This is where fission fragments deposit energy along short tracks within the liquid, thereby radiolyzing solution and nucleating bubbles. Surface formation was not considered, since historic experience with aqueous homogenous reactors suggests volumetric formation dominates due to the slow diffusion of radiolytic gases from the solution bulk to the container interface.

The model tracks the idealized evolution of a characteristic bubble by incrementally calculating its size and ascended height. Bubble diameters were calculated by numerically integrating a differential equation for the diameter growth rate using a fourth-order Runge-Kutta method. This equation was derived from a bubble stability pressure condition, the ideal gas law, and Fick's second law of diffusion. The bubble stability pressure condition is itself based on the dissolved gas concentration in the target solution, the corresponding Henry's law constants, the bubble diameter, the surface tension of the solution, and the liquid pressure. Bubble ascent was calculated by numerically integrating the effective bubble speed following Euler's method. Bubbles rise relative to target solution at approximately their terminal velocity, so their effective ascent speed was the sum of this and the estimated average upward speed of target solution convection currents.

To estimate the average void fraction within the TSV, the target solution was modeled as a mesh of voxels arrayed by depth and radial position within the TSV. The void fraction in a given voxel is the ratio of the gas volume it contains to its total volume. The gas volume depends on the amount of gas generated in it via radiolysis and the net flow of gas through it. The fission rate used to calculate the radiolysis rate was based on a fission distribution determined in an MCNP analysis of the TSV. The net flow of gas into and out of the voxel depends on the number, size, and absolute speed of bubbles traveling through it.

When using the characteristics of the nominal core configuration in the analysis, the result is the nominal average void fraction of [ ]$^{PROP/ECI}$ as described in Subsection 4a2.6.1.2 of the FSAR. When using the characteristics of the limiting core configuration in the analysis, the result is the limiting core configuration average void fraction of [ ]$^{PROP/ECI}$ as stated in Table 4a2.6-10 of the FSAR. When using the limiting steady-state TSV power of 137.5 kW, the result is the maximum average void fraction of less than 5 percent. This leads to expecting the bulk (i.e., average) void fraction within the target solution to be less than 5 percent, as described in Subsection 4a2.2.1.6 of the FSAR, because the TSV power analyzed bounds normal operating power.

RAI 4a-7

The ISG Augmenting NUREG-1537, Part 2, Section 4a2.4, "Biological Shield," states that the shield design should address damage from induced radioactivity in reactor components.

SHINE FSAR Section 4a2.3.3, "Operation Overview," states that each deuterium-tritium fusion reaction produces a single high energy neutron of approximately 14.1 million electron volt [MeV] and a single high energy alpha particle of approximately 3.5 MeV. The neutrons produced radiate outward, with most entering the subcritical assembly system. However, it is unclear to the NRC staff what the potential is for radiation damage to safety-related SSCs caused by these high-energy neutrons.

(1) Discuss the potential for neutron streaming paths during Mode 2 operation of the irradiation units, including penetrations into the light water pool, that may allow high-energy neutrons to bypass the shielding provided by the light water.

(2) Explain any methods or materials used to prevent high-energy neutron radiation damage to safety-related SSCs within the irradiation unit cell, TOGS shielded cell, primary cooling room, and radioisotope production facility (RPF) valve pit.

SHINE Response

(1) Water covers most of the equipment in the light water pool, minimizing neutron streaming paths. Items exiting the pool, such as pipes and conduits, do not present continuous neutron streaming paths from the subcritical assembly or tritium target chamber to the pool surface. The one potentially significant neutron streaming path out of the light water pool is through the neutron driver assembly system (NDAS) target stage. Neutrons are generated roughly isotropically in the target chamber. Therefore, some of the neutrons will exit the target chamber through the same tube by which the beam from the neutron driver enters the target chamber. Some of these neutrons leaving the target chamber will enter into the IU cell air space above the light water pool. The IU cell is surrounded by a thick concrete enclosure which is part of the irradiation facility biological shield (ICBS).This concrete enclosure is designed to provide adequate shielding from high energy neutrons streaming from the target chamber, as well as those generated in the portions of the neutron driver above the pool. Additional description of the ICBS design is provided in Section 4a2.5 of the FSAR.

(2) High-energy neutron radiation damage will not occur to systems within the TOGS shielded cell, primary cooling room, or RPF valve pit because there are no significant neutron sources in these locations. The ICBS provides shielding between these locations and the IU cell, which minimizes the entry of neutrons into these areas from the IU cell.

Within the IU cell, the structural materials used, which are principally austenitic stainless steels, have been shown to retain sufficient strength, ductility, and fracture toughness when exposed to neutron fluences corresponding to the service lifetime of the SCAS components. The light water pool surrounds the SCAS and the NDAS target stage, thereby partially shielding other systems within the IU cell from high-energy neutrons generated within the target chamber. Supplemental shielding and/or radiation hardened equipment are used as necessary.

RAI 4a-8

The ISG Augmenting NUREG-1537, Part 2, Section 4a2.3, “Reactor Vessels,” states that the outer and inner surfaces of the vessel are designed and treated to avoid corrosion in locations that are inaccessible for the life of the vessel.

SHINE FSAR Section 4a2.4.1.3, “Design Description of Materials and Supporting Structures,” states that the TSV is constructed of 347 stainless steel, which has been shown to have high corrosion resistance in SHINE target solution environments and offer acceptable nuclear performance. However, it is unclear to the NRC staff what potential mechanisms contribute to the corrosion and embrittlement of the TSV over its lifetime. For example, tellurium, which is a fission product in nuclear reactor fuels, can embrittle the surface of grain boundaries of nickel-based structural materials. This information is necessary to ensure integrity of the TSV.

Explain the corrosive impact of trace fission products, such as tellurium, on the TSV and associated welds to ensure the integrity of the TSV and TSV dump tank. Additionally, explain any mitigation actions or monitoring SHINE plans to conduct related to corrosion of the TSV and TSV dump tank.

SHINE Response

The acceptability of the welded 347 stainless steel construction for the TSV and TSV dump tank is supported by historic operating experience with aqueous homogeneous reactors and the results from reactor test loop and benchtop experiments. The uranyl sulfate fuel solution used in these reactors and test loop contained the same fission products that will be present in the target solution within the TSV and TSV dump tank. Specifically, tellurium is not a concern given the low operating temperatures of the TSV and the lack of intergranular cracking observed in iron-based stainless steel at tellurium concentrations that produce intergranular cracking in nickel-based alloys.

Corrosion within the TSV and TSV dump tank is mitigated by fabricating the vessels out of welded 347 stainless steel and by incorporating conservative corrosion allowances within their respective designs. Welded 347 stainless steel is corrosion resistant, so SHINE does not plan on adding corrosion inhibiting chemicals in the target solution. The utilized corrosion allowances were calculated using a bounding treatment of historic data from reactor test loop and benchtop experiments. The conservative nature of the corrosion allowances protect against the impacts of trace fission products and other phenomena. Monitoring planned by SHINE to ensure corrosion allowances are not exceeded includes internal visual inspection of the TSV and TSV dump tank and by the placement of corrosion coupons within the TSV, as described in Subsection 4a2.4.1.5 of the FSAR.

RAI 4a-9

The ISG Section 4a2.3, Part 2, “Reactor Vessel,” states that a plan should be in place to assess irradiation of and chemical damage to vessel materials. Remedies for damage or a replacement plan should be discussed.

While SHINE FSAR Section 4a2.4.1.5, “Chemical Interactions and Neutron Damage,” provides SHINE’s plan to assess irradiation of and chemical damage to the TSV, SHINE doesn’t provide a discussion of any remedies for damage or a replacement plan for the TSV, TSV dump tank, and TOGS in the event of an adverse finding of damage.

Discuss remedies for damage to the PSB, a replacement plan, or an alternate approach to addressing an adverse finding of damage upon inspection of these components.

SHINE Response

The robust construction of the major components within the primary system boundary (PSB), including the TSV, TSV dump tank, TOGS vessels, and PSB piping, are expected to withstand bounding lifetime irradiation and chemical damage without the need for replacement. As a confirmatory measure, corrosion rates and material properties will be tracked during operation using test coupons installed within the PSB. Specialized components interfacing with the PSB that may have an increased probability of degradation over time are designed to be replaceable by means of long handled tools and shield casks. Such components include the powered

valves, blowers, instrumentation, demister pads, heat exchangers, recombiners, and zeolite beds. These components are fitted with flanges to permit removal and replacement.

RAI 4a-10

The ISG Augmenting NUREG-1537, Part 2, Section 4a2.5.2, “Reactor Core Physics Parameters,” states that calculation methods should be justified and traceable to their development and validation.

SHINE FSAR Section 4a2.6.2.1, “Analysis Method and Code Validation,” states that transient analyses are performed using the SHINE Transient Reactivity Integration Accelerator Driven Multiphysics (TRIAD) computer code, which is an extension of the Los Alamos National Laboratory (LANL)-developed dynamic system simulation tool. The TRIAD code calculates the integrated system response of the subcritical assembly system (SCAS), TOGS, neutron driver, and primary closed loop cooling system (PCLS). From the LANL code, SHINE added capability to the code, adjusted it to match SHINE subcritical assembly system parameters, and performed in-house verification and validation of the completed code. However, SHINE has not sufficiently described in the FSAR how it modified the LANL code and performed its validation and verification of the TRIAD computer code to justify its calculation methods.

Describe how SHINE modified the TRIAD code and why it is an acceptable model for analyzing SCAS, TOGS, neutron driver, and PCLS.

SHINE Response

Los Alamos National Laboratory (LANL) created a time-dependent model to calculate aqueous homogeneous reactors or subcritical accelerator-driven solution fueled assemblies, which is described in Reference 4. SHINE modified the code and renamed it Transient Reactivity Integration Accelerator Driven Multiphysics Simulation Software (TRIAD). The theory behind TRIAD (including the equations used) is identical to the theory presented in Reference 4, except that pressures in the plenum model are not used (i.e., pressure is not calculated in the plenum and is not required for the rest of the code to function properly). This is appropriate because SHINE does not use TRIAD for the direct calculation of pressure. For void collapse cases where a pressurization causes a reduction or removal of void, pressure effects are applied to the model by controlling how much void collapses.

The original LANL code contained multiple models, including a Super Power (SUPO) reactor to compare the system of equations to the SUPO reactor operated at LANL and a SHINE-like accelerator driven system. The SUPO part of the code was used in early LANL validation to show that the general methodology was appropriate. The SUPO code was a completely separate section of code from the accelerator driven part (i.e. all equations were written specifically for SUPO in one section and equations were written again specifically for the accelerator driven system in an independent section of code).. TRIAD deactivated the SUPO reactor parts of the code, because they were separate and because SHINE did not validate the SUPO reactor parts of the code. Additionally, the hard-coded geometry of the accelerator driven system was updated to the current SHINE model in TRIAD.

There were several bugs that were fixed in the original LANL code in creating TRIAD. These bugs include an incorrect call to a variable by number, hard-coded inputs that should have been linked to the input variable, and calls to similar but incorrect variables (either calling the right variable from the wrong cooling loop or using the properties of water rather than solution).

In addition, TRIAD incorporated the following functional changes to the original LANL code:

1. An additional class, InputFile, was added to the code to allow the user to make an input file. The InputFile allowed the user to change the accelerator source strength (neutrons/second), select the natural convection correlation used, oscillate the neutron source (sine wave), select the frequency of output data written, calibrate the power, put a multiplier on heat transfer coefficients, add/remove reactivity to simulate a calculated event, oscillate reactivity (sine wave), input a table of reactivity loss to temperature/void, recover a saved state, set input conditions, control coolant flow, set solution property correlations, and partially/fully collapse void.

    a. Unit test functionality was built into the InputFile class to quickly verify that TRIAD was properly reading and interpreting the input. This functionality had a set of standard tests and expected responses that were compared. A test report was automatically generated from the unit test and this was used in verification/validation.

2. The natural convection correlation described in Subsection 4a2.7.5.1 of the FSAR was added into TRIAD and used for all transient analyses.

In addition to the functional changes described above, additional natural convection correlations were added into TRIAD for comparison of results; however, these correlations were not used in the transient analyses.

TRIAD was verified and validated in accordance with the SHINE Software Test Plan (STP), implemented in accordance with the SHINE Quality Assurance Program Description (QAPD). The STP includes unit tests of input file functionality, system tests where output was verified against the input, a code review for requirements that could not be verified via unit and system tests, and validation against Silene and Kinetics Experiments on Water Boilers (KEWB) data, as described in Subsection 4a2.6.2.1 of the FSAR.

For validation, the effects of bubbles forming from radiation are difficult to predict since it is unknown when they will come out of solution and how fast they will move through the solution. In general, the less reactivity added to the system, the less need there is for void in the solution to shut the reaction down (i.e., Silene and KEWB cases are typically large reactivity insertions that are shut down by negative reactivity). The purpose of the validation was to assure that TRIAD is properly using the data input and that it has reasonable results.

For Silene models, reactivity insertions were compared; peak powers, change in temperature, and total fissions were compared to literature (Reference 5). For KEWB, experimental results for peak power were compared to experimental data (Reference 6).

All verification and validation criteria set out in the STP passed; therefore, it is appropriate for modeling of the TSV and its relation to the neutron driver source strength and cooling from PCLS. TOGS effects on the TSV were modeled using reactivity insertion that was calculated outside of TRIAD.

RAI 4a-11

The ISG Augmenting NUREG-1537, Part 2, Section 4a2.5.3, “Operating Limits,” states that an applicant should justify the minimum negative reactivity that will ensure the safe shutdown of the reactor. This discussion should address the methods and the accuracy with which this negative reactivity can be determined to ensure its availability.

SHINE FSAR Section 4a2.6.3.4, “Negative Reactivity,” states that the TSV must drain within 183 seconds with a minimum TSV target solution volume, which is the limiting core configuration. However, it is unclear to the NRC staff why the SHINE FSAR does not address the maximum drain time of the TSV with a maximum TSV target solution volume.

Provide the maximum drain times for the TSV with the maximum solution volume or explain why maximum drain times are not needed for the maximum solution volume in the TSV to support transient or accident sequence analyses involving the shutdown of the TSV.

SHINE Response

The limiting scenarios involving shutdown of the TSV that rely upon a maximum drain time are based on thermal hydraulics. Although the TSV drains completely more quickly for the minimum TSV target solution volume (i.e., limiting core configuration) than the maximum TSV target solution volume (i.e., nominal core configuration), the reduced heat transfer area and increased power density of the minimum TSV fill volume case results in higher target solution temperatures than the maximum TSV fill volume case. Therefore, the drain time for the minimum TSV fill volume case is more limiting.

SHINE considered a scenario involving shutdown of the TSV that relies upon a maximum drain time for the maximum TSV fill volume. Based on the thermal hydraulics (e.g., increased heat transfer area and decreased power density resulting in lower target solution temperatures) this case is less limiting than the minimum TSV volume case described in Subsection 4a2.6.3.4 of the FSAR.

RAI 4a-12

The ISG Augmenting NUREG-1537, Part 2, Section 4a2.5, “Nuclear Design,” states, in part, that the FSAR should include information on the anticipated core evolution, accounting for changes in the fuel solution chemical stability caused by radiolysis.

SHINE FSAR Section 4a2.6.1.1, “Gas Management System Effects,” states that the radiolysis of water in the in the system and constant evaporation of target solution causes an anticipated increase in the reactivity during operation due to the holdup of water within the TOGS condensers and piping. However, it is unclear to the NRC staff whether there are other system paths for potential water loss due evaporation of the target solution. This information is necessary to ensure that there are not changes in the fuel solution that could affect the chemical stability or result in inadvertent criticality.

Clarify whether water vapor can condense in the TSV overflow lines or TSV dump tank and collect in the TSV dump tank and discuss whether this potential path for water loss was considered in the volume margin to criticality due to the increase in uranium concentration, providing updates to the FSAR as necessary.

SHINE Response

Water vapor condensation in the TSV overflow lines or TSV dump tank during Mode 1 or Mode 2 is prevented by the TOGS returning sweep gas to the dump tank at a temperature below the light water pool temperature. After passing through the TSV dump tank, this sweep gas flows up the overflow lines into the TSV headspace. This constant updraft of sweep gas in the overflow lines prevents the moist air in the TSV headspace from entering the TSV overflow lines or TSV dump tank. Therefore, condensation cannot occur on the interior walls of the TSV overflow lines or in the TSV dump tank. Because condensation in these areas does not occur in Mode 1 or Mode 2, water loss to the TSV dump tank via condensation is not a factor in the volume margin to criticality. During Modes 3 and 4, the target solution is located in the TSV dump tank, so condensation in the TSV overflow lines or TSV dump tank is inconsequential. During Mode 0 there is no target solution in the SCAS.

RAI 4a-13

The ISG Augmenting NUREG-1537, Part 2, Section 4a2.2.1, “Reactor Fuel,” states that the fuel operating parameters should consider characteristics that could limit fuel barrier integrity, such as physical stresses from mechanical or hydraulic forces (internal pressures).

SHINE FSAR Section 4a2.6.3.3, “Credible Inadvertent Insertion of Reactivity,” states that relief valves on the TSV maintain the TSV headspace pressure within the range of -4.5 to 15 psig (-31.0 to 103 kPa) should the TOGS pressure regulation fail. The NRC staff needs more information to understand the design bases of the vacuum and pressure relief valves to maintain TSV headspace pressure.

Provide the following information:

(1) The design basis for relief valve setpoint and flow capacity.

(2) The design basis for vacuum relief valve setpoint and flow capacity.

(3) The relief valve flow capacity at the setpoint pressure.

(4) The vacuum relief valve flow capacity at the setpoint pressure.

(5) An explanation on how much reactivity would need to be inserted to reach the high-pressure relief valve setpoint.

SHINE Response

(1) The design basis for the pressure relief valve setpoint is to protect the function of the TOGS blowers. While the PSB has a design pressure of 100 pounds per square inch (psi) to protect against credible hydrogen deflagrations, the steady-state pressure in the PSB must be limited to a lower value to maintain TOGS sweep gas density within a range that can be effectively pumped by the TOGS blowers. The pressure relief valves are not intended to protect the PSB from hydrogen deflagrations because relief valves are ineffective against brief duration pressure pulses such as those resulting from deflagrations.

The design basis for the pressure relief valve flow capacity is to maintain the PSB pressure within the allowable range for the limiting gas addition scenario. The limiting gas addition scenario involves a control system failure that results in the uncontrolled addition of nitrogen or oxygen gas into the PSB from an external source. The pressure relief valves are sized to relieve the bounding gas flowrate resulting from this scenario while maintaining PSB pressure within allowable limits.

The pressure relief valves are sized in accordance with the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code (BPVC), Section VIII, Division 1.

(2) The design basis for the vacuum relief valve setpoint is to prevent boiling of the target solution at the limiting target solution temperature in the TSV and TSV dump tank.

The design basis for the vacuum relief valve flow capacity is to maintain the PSB pressure within the allowable range for the limiting gas removal scenario. The limiting gas removal scenario involves a control system failure that results in the uncontrolled suction of TOGS sweep gas into the TOGS vacuum tank from the rest of the PSB. The vacuum relief valves are sized to relieve the bounding gas flowrate resulting from this scenario while maintaining PSB pressure within allowable limits.

The vacuum relief valves are sized in accordance with the ASME BPVC, Section VIII, Division 1.

(3) The pressure relief valve flow capacity at the setpoint pressure is a minimum of 20 standard cubic feet per minute (scfm).

(4) The vacuum relief valve flow capacity at the setpoint pressure is a minimum of 23 scfm.

(5) Prompt criticality in the TSV would be required to potentially reach the high pressure relief valve setpoint via a reactivity insertion. Because the TSV reactivity protection system (TRPS) prevents the TSV from going prompt critical, a reactivity insertion that causes conditions to reach the high pressure relief valve setpoint is not credible. Therefore, the pressure relief valve is not relied upon to protect the PSB from the pressure pulse that could result from a prompt criticality.

RAI 4a-14

The ISG Augmenting NUREG-1537, Part 2, Section 4a2.5.1, “Normal Operating Conditions,” states that information should include calculated core reactivities for the possible and planned configurations. The reactivity impacts of radiolytic gas and void formation, and condensate return to the core should be provided.

SHINE FSAR Section 4a2.8.2, “System Process and Safety Functions,” states that the TOGS condenses water vapor generated by the target solution in the TSV and returns the condensate to the TSV to limit water holdup in TOGS to less than three liters. Further, SHINE FSAR Section 4a2.2.2, “Reactivity Control Mechanisms,” states that water holdup by TOGS affects reactivity but is not a controlled variable. The NRC staff needs more information to understand the TOGS water holdup basis to ensure the margin to criticality is adequately maintained for possible and planned core configurations.

(1) Provide the basis, using bounding evaporation and condensation rates, for determining that the maximum water holdup for the TOGS is three liters.

(2) Provide an explanation of the water holdup points and volume within TOGS components, considering the orientation and size of tanks, blowers, and piping in the system, which could contribute to a reactivity insertion.

SHINE Response

(1) The basis for the volume of water holdup in the TOGS is analysis of the identified mechanisms of water holdup. The four mechanisms considered in the analysis were:

1. film condensation on the interior surfaces of the TOGS;
2. water trapped in low points and demister pads of the TOGS;
3. water vapor in the TOGS; and
4. radiolytic decomposition products of water in the TOGS.

Full-power irradiation and nominal process conditions were assumed when evaluating the evaporation and condensation in the analysis:

1. TSV power of 125 kW;
2. TOGS condenser outlet temperature of [ ]PROP/ECI;
3. TSV headspace pressure of [ ]PROP/ECI;
4. TOGS Train A flow rate of [ ]PROP/ECI; and
5. TOGS Train B flow rate of [ ]PROP/ECI.

Conservative methods were used to estimate the water holdup at nominal conditions.

The volume of water held up as film condensation was estimated using a falling film equation and the surface area of TOGS components where condensation is expected to occur. This method is conservative, because it assumes a continuous film of water is coating these surfaces, while only intermittent coverage is expected.

The volume of water vapor held up in low points was estimated by inspection of the three-dimensional solid models of the TOGS equipment to identify low points, and calculation of the volume of the low points identified. This method is conservative, because the low points were assumed to be completely filled with water and because the low points are not expected to empty between irradiation cycles.

The volume of water held up as water vapor and decomposition products of water was calculated based on the calculated concentrations of these gases in the TOGS components and the gas volumes of the TOGS components. The amount of water held up by this mechanism was found to be insignificant.

TOGS water holdup will be measured during startup testing, as described in Subsection 12.11.2.2.5 of the FSAR. The target solution volume margin to critical at fill will be adjusted based on the expected TOGS water holdup, as described in Subsection 4a2.6.1 of the FSAR.

(2) The TOGS is designed to minimize water holdup by limiting the quantity and size of low point volumes. Tanks, blowers, and piping are typically oriented with the low points located at inlets or outlets to permit drainage and preclude liquid holdup volumes. The exception is the TOGS demister condensate drain traps. The TOGS demisters are equipped with the drain traps to prevent the backflow of sweep gas through the condensate drain lines, which could otherwise interfere with proper drainage. These drain traps are manufactured from small-bore piping to minimize holdup volume. The water holdup volume in these traps is calculated based on the inner diameter of the drain pipe and the length of pipe that would be filled with condensate during operation. The demister condensate drain trap holdup volume is included in the analysis discussed in Part (1) of this response as part of the second water holdup mechanism.

Chapter 7 – Instrumentation and Control Systems

The following regulatory requirements are applicable to RAIs 7-1 through 7-8:

> Section 50.34(b)(2) of 10 CFR Part 50 requires, in part, that an FSAR include a description and analysis of the structures, systems, and components of the facility, with emphasis upon performance requirements, the bases, and the evaluations required to show that safety functions will be accomplished. The description shall be sufficient to permit understanding of the system designs and their relationship to safety evaluations.
>
> Section 50.34(b)(2)(ii) of 10 CFR Part 50 states, in part, that for facilities other than nuclear reactors, such items as the instrumentation and control systems (I&C) shall be discussed insofar as they are pertinent.

The technical bases for RAIs 7-1 through 7-8 are drawn from the guidance contained in Chapter 7, "Instrumentation and Control Systems," of NUREG-1537, Parts 1 and 2. RAIs 7-1 through 7-8 request that SHINE provide sufficient information for the NRC staff to make the applicable safety findings described in Chapter 7 of NUREG-1537, Part 2. As described in Section 7.2.1, "Design Criteria," of NUREG-1537, Part 1, an applicant should discuss the criteria for developing the design bases for the I&C systems of the facility. The basis for evaluating the reliability and performance of the I&C systems should be included in the application. Consistent with Section 7.2, "Design of Instrumentation and Control Systems," of NUREG-1537, Part 2, the NRC staff review the following for each of the I&C systems and subsystems described in the application:

- Design criteria
- Design bases
- System descriptions
- System performance analysis
- Conclusion

With respect to design criteria, consistent with Section 3.1, "Design Criteria," of NUREG-1537, Part 1, design criteria should include applicable standards, guides, and codes; NRC regulatory guides; and national, State, and local building, plumbing and electrical codes, as applicable.

Sufficient information is to be included in the application for the NRC staff to determine how applicable design criteria have been established and satisfied by the design of the facility using appropriate guidance, including appropriate codes and standards. Further, an application should describe the relationship between the design criteria and design bases to explain how systems are designed.

The information requested below is necessary for the NRC staff to determine that the requirements of paragraphs (b)(2) and (b)(2)(ii) of 10 CFR 50.34 have been satisfied and that sufficient detail has been provided as described in Chapter 7 of NUREG-1537, Parts 1 and 2.

RAI 7-1

Section 3.1 of the SHINE FSAR identifies the design criteria for the instrumentation and control (I&C) systems in the SHINE facility. Consistent with the guidance in NUREG-1537, described above, the NRC staff expects that Chapter 7 of the SHINE FSAR include the descriptions of

how each I&C system meets the applicable design criteria. However, Chapter 7 of SHINE's FSAR does not describe how the I&C system designs implement SHINE's design criteria.

Further, Chapter 7, "Instrumentation and Control Systems," of the SHINE FSAR includes the design bases for each I&C system. However, Chapter 7 of SHINE's FSAR does not describe the relationship between the design bases to the applicable design criteria in Chapter 3 of the SHINE FSAR.

(1) Describe how each I&C system meets each applicable design criterion listed in Section 3.1 of the SHINE FSAR.

(2) Describe the relationship between the design bases to each of the applicable design criterion listed in Section 3.1 of the SHINE FSAR.

SHINE Response

The SHINE Response to RAI 7-1 will be provided by August 31, 2020.

RAI 7-2

Chapter 7 of the SHINE FSAR identifies additional system-specific design criteria for each I&C system (e.g., see: SHINE FSAR Section 7.4.2, "Design Criteria"). In addition, Chapter 7 of the SHINE FSAR describes the design bases (e.g., see: SHINE FSAR Section 7.4.3, "Design Basis") and design attributes (e.g., see: SHINE FSAR Section 7.4.4, "Design Attributes") for each I&C system. The descriptions provided in the design attributes sections of Chapter 7 of the SHINE FSAR do not describe the design of the SHINE I&C systems in sufficient detail to permit understanding of the system designs and their relationship to the safety analyses.

For each I&C system, describe how the design implements (or meets) each of the system-specific design criteria identified in the subsections of Chapter 7 of the SHINE FSAR.

SHINE Response

The SHINE Response to RAI 7-2 will be provided by August 31, 2020.

RAI 7-3

Chapter 7 of the SHINE FSAR includes a list of codes and standards that SHINE applied to the design of each I&C system (e.g., For the target solution vessel reactivity protection system (TRPS) design, this list is provided in Section 7.4.4.15, "Quality," of the SHINE FSAR. Another list is provided in Section 7.9, "References," of the SHINE FSAR.). However, it is not clear to the NRC staff how SHINE has used the codes and standards identified in the FSAR in the design of its I&C systems.

Describe how each of the codes or standards listed in the FSAR are used to design each of the I&C systems. This discussion should address how SHINE intends to comply or take exception from the relevant codes or standards.

SHINE Response

The SHINE Response to RAI 7-3 will be provided by August 31, 2020.

RAI 7-4

Chapter 7 of the SHINE FSAR describes the highly integrated protection system (HIPS) platform for the TRPS and engineered safety features actuation system (ESFAS). However, the FSAR appears to contain inconsistent descriptions of the use of the HIPS platform and/or implies how the HIPS platform will be used to implement the design of the TRPS and ESFAS.

(1) Clarify how the TRPS and ESFAS use the generically approved HIPS platform. If the application intends to credit the NRC-approved HIPS platform, then:

    (a) Describe how the Application Specific Action Items identified for the HIPS platform are dispositioned, including those that are not applicable for the SHINE TRPS and ESFAS.

    (b) Describe the differences between the system architecture approved for HIPS platform and the architecture proposed for the TRPS and ESFAS and explain it is acceptability for the SHINE design.

(2) Provide a description of the SHINE system design, as well as the suitability and adequacy of the HIPS platform for performing SHINE design functions, including conformance with the SHINE design criteria and bases. This RAI is similar to RAI 7-1, but in this case, SHINE should indicate the specific design or attributes in the HIPS platform that will meet each of its applicable design criterion.

SHINE Response

The SHINE Response to RAI 7-4 will be provided by August 31, 2020.

RAI 7-5

The SHINE FSAR states that the process integrated control system (PICS) will monitor, control, and operate the SHINE I&C systems in the SHINE irradiation facility (IF) and the radioisotope production facility (RPF). However, the SHINE FSAR does not clearly identify all I&C systems controlled by PICS (i.e., Figure 7.3-1, “Process Integrated Control System Interfaces,” of the FSAR refers to “IF Process Systems,” “RPF Process Systems,” and “Other I&C Systems”). Further, the FSAR identifies systems in the IF that will interface with the PICS, but does not identify systems in the RPF that will interface with the PICS.

(1) Identify all I&C systems that the PICS will monitor, control, and operate in the SHINE facility.

(2) Describe how the PICS will operate the SHINE facility and, in case of its failure, the safety controls included to mitigate or prevent an accident.

(3) Provide the system architecture that shows all systems that interface or interact with the PICS, not only those installed in the IF.

SHINE Response

The SHINE Response to RAI 7-5 will be provided by August 31, 2020.

RAI 7-6

The SHINE FSAR uses the terms “channel” and “division.” However, the SHINE FSAR does not clearly define or distinguish what constitutes a channel or a division. For example, Section 7.2.5.3, “Access Control,” of the SHINE FSAR states, in part:

> Each division of TRPS and ESFAS systems has a nonsafety-related MWS for the purpose of online monitoring and offline maintenance and calibration. The HIPS platform MWS supports online monitoring through one-way isolated communication ports. The MWS is used to update setpoints and tunable parameters in the HIPS chassis when the safety function is out of service. Physical and logical controls are put in place to prevent modifications to a safety channel when it is being relied upon to perform a safety function. A temporary cable and OOS switch are required to be activated before any changes can be made to an SFM. When the safety function is removed from service, either in bypass or trip, an indication is provided by the HIPS platform that can be used to drive an alarm in the facility control room to inform the operator. Adjustments to parameters are performed in accordance with facility technical specifications, including any that establish the minimum number of redundant safety channels that must remain operable for the applicable operating mode and conditions. [emphasis added]

This paragraph seems to use the terms “channel” and “division” interchangeably.

Define what constitutes a channel and what constitutes a division.

SHINE Response

The SHINE Response to RAI 7-6 will be provided by August 31, 2020.

RAI 7-7

Section 50.36, “Technical Specifications,” of 10 CFR requires that each applicant for an operating license include proposed technical specifications (TSs). The proposed technical specifications (TSs) in the application should identify the safety systems necessary to protect the facility when a postulated accident occurs. The proposed TS should include: Limiting Conditions for Operation (LCOs), Limiting Safety System Settings (LSSSs), and surveillance requirements (SR). LCOs are the lowest functional capability or performance levels (e.g., LSSSs) of equipment required for safe operation of the facility. The SR should identify the tests performed on a predetermined periodicity to verify that required safety system is operating as assumed in the accident analyses and within the licensing basis or the facility is operating outside an LCOs. The TS should be based on the analysis provided in Chapter 13, “Accident Analysis,” of the FSAR.

The relationship between LCOs, LSSSs, and SRs are not clear and appears to be inconsistent in some cases for the respective descriptions in Chapters 7 and 13.

(1) Clarify inconsistencies among the instrument range, analytical limits, safety limits (SLs), and associated LSSSs in Chapters 7 and 13 of the application, as well as the TSs. The FSAR should include sufficient information to conclude that SLs are protected, and that LSSS and LCO settings were established through the analyses in Chapter 13.

(2) For the safety functions, verify and update the descriptions in the FSAR to be consistent with the description in the bases for TS for LSSSs.

SHINE Response

The SHINE Response to RAI 7-7 will be provided by August 31, 2020.

RAI 7-8

Section 50.36(c)(2) of 10 CFR states that the TSs will include LCOs. Section CFR 50.36(c)(2)(i) of 10 CFR defines LCOs as "the lowest functional capability or performance levels of equipment required for safe operation of the facility." Section 50.36(a)(1) of 10 CFR states, in part, that "[a] summary statement of the bases or reasons for such specifications, other than those covering administrative controls, shall also be included in the application, but shall not become part of the technical specifications."

Criterion 15 in Chapter 3 of the SHINE FSAR requires adequate reliability or redundancy to protect against the loss of a protection function when a component is removed from service. The design of the TRPS states that it meets the single failure criteria by having three independent channels of instrumentation (any two of which can initiate a protective action). In other words, any single failure in the TRPS would not prevent a protective action from being implemented. However, the TS LCOs only require two channels of instrumentation to be operable (see SHINE TS LCO 3.2.4); this means that SHINE would allow the TRPS to be operated indefinitely with one channel inoperable (an immediate shutdown is specified if only one is operable). The basis for SHINE TS LCO 3.2.4 states, in part:

> The NFDS provides indication of neutron flux and TSV power during IU operations, as described in FSAR Section 7.8. The NFDS signals provide input to TRPS functions, as described in FSAR Subsection 7.4.5. Three Channels of NFDS are provided for each of the variables in Table 3.2.4, one Channel for each of Divisions A, B, and C. Only two Channels are required to be Operable to provide redundancy to protect against a single failure. When all three Channels are Operable, actuation of the safety function occurs on 2-out-of-3 voting logic. When any single Channel is inoperable, the inoperable Channel is required to be placed in trip, effectively changing the voting logic to 1-out-of-2, preserving the single failure protection.
>
> Any single Channel may be placed in bypass during performance of a required SR, effectively changing the voting logic to 2-out-of-2 (with two other Channels Operable) or 1-out-of-1 (with one other Channel Operable).

Additionally, the following note for SHINE TS LCO 3.2.4 is provided following Table 3.2.3, "TRPS Interlocks," of the SHINE FSAR:

> Any single required instrumentation Channel may be inoperable while the variable is in the condition of applicability for the purpose of performing a Channel Check or Channel Calibration.

However, the required actions in the TS do not include the requirement that "[w]hen any single Channel is inoperable, the inoperable Channel is required to be placed in trip, effectively changing the voting logic to 1-out-of-2, preserving the single failure protection." Furthermore, SHINE TS LCO 3.2.4 and the associated basis provide no restrictions on the length of time that

operation in this condition is allowed, and no explanation is provided as to why unrestricted operation in a condition where the single failure criteria is not met provides adequate safety.

Based on this information in the SHINE FSAR and TS, it appears that when a single channel is in bypass, the system cannot meet the single failure criterion. Further, because this LCO and associated basis provide no restrictions on the length of time that operation in this condition is allowed, the system can operate this way, in a condition where the single failure criteria is not met, for unlimited duration. Therefore, the NRC staff cannot determine how this unrestricted operation provides adequate safety to shut down the IF in the event of a single failure within the system.

Therefore, it seems the TS LCO is inconsistent with the description in the associated TS basis.

(1) Verify and update Chapter 7 of the SHINE FSAR and the proposed TS to clarify when a single channel is operable.

(2) Describe how placing a channel in bypass (i.e., reducing the number of operable channels) would affect the voting logic and preserve the single failure criteria.

SHINE Response

The SHINE Response to RAI 7-8 will be provided by August 31, 2020.

Chapter 12 – Conduct of Operations

SHINE FSAR Section 12.7, "Emergency Plan," and Enclosures 9 (non-public) and 10 (public), "Emergency Plan," of the SHINE Operating License Application

The following regulatory requirements are applicable to RAIs EP-1 through EP-7:

> Section 50.36(b)(5)(v) of 10 CFR requests that an applicant for an operating license include plans for coping with emergency, including the items specified in 10 CFR Appendix E, "Emergency Planning and Preparedness for Production and Utilization Facilities."

Following the guidance in Regulatory Guide 2.6, Revision 2, "Emergency Planning for Research and Test Reactors and Other Non-Power Production and Utilization Facilities," the NRC staff has reviewed the SHINE emergency plan and developed the following RAIs using the American National Standards Institute (ANSI)/American Nuclear Society (ANS) standard ANSI/ANS-15.16-2015, "Emergency Planning for Research Reactors." Regulatory Guide 2.6 endorses the use of this standard for non-power 10 CFR Part 50 facilities other than research and test reactors.

RAI EP-1

Section 3.3(2) of ANSI/ANS-15.16-2015 addresses authority and responsibilities for support agencies with a role in emergency preparedness and response.

Section 3.4, "Emergency Support Organizations," of the SHINE Emergency Plan states in part,

> In the event the decision is made by the Emergency Director to request support from offsite organizations, the following offsite support agencies and organizations would provide assistance as described below…***SHINE does not anticipate the need for State or Federal assistance.*** [emphasis added]

It is not clear to the NRC staff how SHINE determined that State or Federal assistance would not be needed.

Clarify whether the State of Wisconsin has been contacted to determine if it has the authority and responsibility for having radiological emergency responsibilities for emergency preparedness planning and emergency response assistance for the SHINE facility.

SHINE Response

Implementation of the SHINE Emergency Plan has been discussed with the State of Wisconsin. In the event of a declared emergency, the State of Wisconsin has the general authority and responsibility to assist local units of government and local law enforcement agencies in responding to a disaster or the imminent threat of a disaster.

In order for the State of Wisconsin to most effectively implement their responsibilities in the event of an emergency at the SHINE facility, SHINE will provide a notification to the State of Wisconsin following the declaration of an emergency, as described in the SHINE Response to EP-2, and will offer the State of Wisconsin the opportunity to participate in drills and exercises at the SHINE facility, as described in the SHINE Response to EP-3.

SHINE has revised Section 3.4 of the SHINE Emergency Plan to reflect the general authority and responsibility of the State of Wisconsin in the event of a declared emergency. Revision 5 of the SHINE Emergency Plan is provided as Attachment 2.

RAI EP-2

Section 3.7.1, “Activation of emergency organization,” of ANSI/ANS-15.16-2015 addresses notifications of off-site support organizations.

It is not clear to the NRC staff whether SHINE has coordinated off-site notifications of emergencies with the State of Wisconsin.

Clarify whether the State of Wisconsin been contacted to determine if it requests to be notified in the event of an emergency at the SHINE facility.

SHINE Response

Implementation of the SHINE Emergency Plan has been discussed with the State of Wisconsin and the State has requested to be notified in the event of an emergency at the SHINE facility.

SHINE has revised Section 7.3 of the SHINE Emergency Plan to add the requirement to provide a notification to the State of Wisconsin following the declaration of an emergency. Revision 5 of the SHINE Emergency Plan is provided as Attachment 2.

RAI EP-3

Section 3.10.1(2), of ANSI/ANS-15.16-2015 addresses provisions for coordinating periodic drills with off-site emergency personnel.

Clarify whether the State of Wisconsin and applicable local offsite response organizations has been contacted to determine if it requests to be offered the opportunity to participate in drills and exercises at the SHINE facility.

SHINE Response

Implementation of the SHINE Emergency Plan has been discussed with the State of Wisconsin and the State has requested to be offered the opportunity to participate in drills and exercises at the SHINE facility. Appendix 3 of the SHINE Emergency Plan provides agreement letters with local offsite response organizations, confirming their availability to assist in the implementation of the plan. These offsite response organizations will be invited to participate in drills and exercises in accordance with Section 11.4.2 of the SHINE Emergency Plan.

SHINE has added Section 3.4.5 to the SHINE Emergency Plan to explicitly include the State of Wisconsin as an off-site emergency support organization and has revised Section 11.4.2 of the SHINE Emergency Plan to clarify that off-site governments include State agencies. Revision 5 of the SHINE Emergency Plan is provided as Attachment 2.

RAI EP-4

Section 3.5, “Emergency Action Levels,” of ANSI/ANS-15.16 discusses the considerations for establishing emergency action levels to initiate protective actions for onsite personnel and the public.

Section 5, “Emergency Action Levels,” of the SHINE emergency plan states, in part, that Emergency Action Levels (EALs) for the three standardized classifications of emergencies 1) Notification of Unusual Event, 2) Alert, and 3) Site Area Emergency for the SHINE facility are found in Appendix 4, “Emergency Action Levels.” However, it is unclear to the NRC staff why the Emergency Classification of Notification of Unusual Event for Severe Natural Phenomena or External Event has duplicate EALs to that of the Emergency Classification of an Alert for the same event.

Explain why the Emergency Classification of Notification of Unusual Event for Severe Natural Phenomena or External Event has duplicate EALs to that of the Emergency Classification of an Alert for the same event. Specifically, address why items identified as (2) and (3) relating to seismic and flooding for the Notice of Unusual Event are the same criteria as (2) and (4) for an Alert.

SHINE Response

The Alert classification is intended to be an escalation of the Notification of Unusual Event classification for emergencies involving external events. Alert classifications involve external events that jeopardize the function of safety-related structures, systems, and components (SSCs) that provide a barrier to the release of radioactive materials or events having the potential to affect radioactive material.

SHINE has revised Appendix 4 of the SHINE Emergency Plan to clarify the differences between the EALs for a Notification of Unusual Event for Severe Natural Phenomena or External Event and an Alert for External Events Potentially Affecting Radioactive Material or Safety-Related SSCs. Revision 5 of the SHINE Emergency plan is provided as Attachment 2.

RAI EP-5

Section 3.7.4, “Protective Actions,” of ANSI/ANS-15.16 discusses considerations for monitoring radiation dose rates and contamination levels onsite and offsite during an emergency.

Section 8.7.3, “Onsite and Offsite Surveying,” of the SHINE emergency plan states that “[m]onitoring outside the facility and at the site boundary shall be implemented within four hours of declaring a Site Area Emergency involving a potential or actual release.” Section 3.3.4, “Radiation Safety Coordinator,” of the SHINE emergency plan states that the radiation safety coordinator has the responsibility of making onsite and offsite dose assessments and projections. However, this position is identified as “called-in upon activation of the ERO [Emergency Response Organization].” It further states that members of the radiation protection department and facility technical staff with radiation protection experience can fill this position. Additionally, Section 3.3.9, “Assessment Teams,” identifies this as one of the responsibilities of an Assessment Team. It is not clear to the NRC staff how SHINE determined that the proposed four-hour window for implementation of monitoring outside the facility and at the site boundary meets the criterion to take action promptly. It is also unclear what capabilities exist to monitor dose rates and contamination levels at the site boundary.

Clarify how the proposed four-hour window for implementation of monitoring outside the facility and at the site boundary meets the criteria to be able to take action promptly. Describe what capabilities exist on-shift to be able to monitor outside the facility and at the site boundary.

SHINE Response

At least one individual capable of monitoring radiation dose rates and contamination levels will be on-site at the SHINE facility whenever the facility is not secured. This individual will be responsible for monitoring for radiation or contamination outside the facility and at the site boundary.

To meet the criteria to be able to take prompt action to monitor for radiation or contamination outside the facility or at the site boundary, SHINE has revised the proposed four-hour window and instead proposes a two-hour window in which to implement monitoring in the event of a Site Area Emergency. The two-hour window is judged to be appropriate to allow the initial Radiation Safety Coordinator (i.e., an on-shift radiation protection department staff member) to assist the Emergency Director in recommending any immediately required protective actions and to obtain sampling and monitoring equipment prior to implementing monitoring outside the facility and at the site boundary. Portable instrumentation and equipment is discussed in Section 9.4.2 of the SHINE Emergency Plan.

SHINE has revised the following sections of the SHINE Emergency Plan to provide clarification of the radiation monitoring capabilities and responsibilities of facility personnel:

- Section 3.2.2 has been revised to clarify that an individual capable of monitoring radiation dose rates and contamination levels is included in on-shift personnel.

- Section 3.3.4 has been revised to specify that an on-site individual with radiation protection experience initially fills to role of the Radiation Safety Coordinator, and that the Radiation Safety Coordinator may collect on-site and off-site field monitoring data or monitor radiation dose rates and contamination levels if required.

- Section 3.3.9 has been revised to clarify that the role of the Assessment Teams is to assist the Radiation Safety Coordinator in making radiological assessments.

- Section 8.7.3 has been revised to change the requirement for implementing monitoring outside the facility and at the site boundary from four hours to two hours.

- Section 9.4.2 has been revised to change the normal storage location of portable instrumentation and equipment from the resource building to the storage building.

Revision 5 of the SHINE Emergency plan is provided as Attachment 2.

RAI EP-6

Section 3.8.3, “First Aid and Medical Facilities,” of ANSI/ANS-15.16 discusses the need for describing capabilities and measures for decontamination of persons exposed to radiation.

In Section 9.5, “Decontamination Facilities, Supplies, and Controls,” of the SHINE emergency plan SHINE states that “[p]ersonnel are considered contaminated if they are found by direct frisk or use of portal monitor to have contamination above background.” However, it is unclear if this statement is consistent with SHINE’s operating procedures.

Clarify whether the description of contaminated persons in the SHINE emergency plan is consistent with its facility operating procedures.

SHINE Response

SHINE facility procedures contain a definition of “background” contamination that acknowledges that background levels can vary significantly from location to location, within a given location, and across time, and that background contamination measurements tend to fluctuate.

SHINE has revised Section 9.5 of the SHINE Emergency Plan to clarify that personnel and equipment are considered contaminated if they are found to have contamination above background as defined in the Emergency Plan Implementing Procedure addressing Emergency Radiation Exposure Control. Revision 5 of the SHINE Emergency plan is provided as Attachment 2.

RAI EP-7

Section 3.10.1, “Training and Drills,” of ANSI/ANS-15.16 discusses provisions for conducting emergency drills.

Section 11.4.4, “Exercises,” of the SHINE emergency plan states that onsite and offsite emergency plans shall be exercised every two years. It further states that a criticality accident response exercise should be conducted at least every three years. It is unclear to the NRC staff whether these differences in timing of exercises could create schedule conflicts.

Clarify whether the conduct of the emergency plan and criticality accident response exercises on different intervals would cause a conflict in exercise scheduling.

SHINE Response

SHINE has reviewed the proposed scheduling of exercises and determined that a conflict would exist in exercise scheduling. Additionally, SHINE has determined the Emergency Plan contains inconsistent usage of the terms “exercise” and “drill”, based on differing usage of the terms in American National Standards Institute/American Nuclear Society (ANSI/ANS)-15.16-2015, “Emergency Planning For Research Reactors” (Reference 7) and ANSI/ANS-8.23-2007, “Nuclear Criticality Accident Emergency Planning And Response” (Reference 8).

To resolve issues of inconsistent terminology, SHINE has revised the SHINE Emergency Plan to remove the definitions of “exercise” and “drill” from Section 2, and update Section 11.4 to state:

> “Drills are primarily on-site tests of one or more portions of the integrated capability of emergency response plans, equipment, and organizations with off-site support functions being simulated. An exercise is a type of drill that is a full-scale test of the ERO, and off-site organizations are invited to participate.”

To resolve the exercise scheduling conflict, SHINE has removed the requirement for a criticality accident response exercise every three years from Section 11.4.4, and has added a requirement for an annual drill (or exercise) to include a realistic scenario involving a simulated criticality to Section 11.4.3, consistent with the guidance of ANSI/ANS 8.23-2007, Sections 8.2 and 8.2.1, and the usage of the term “drill” in the SHINE Emergency Plan.

Revision 5 of the SHINE Emergency Plan, which incorporates the above described changes, is provided as Attachment 2.

SHINE FSAR Section, 12.9 “Quality Assurance,” and Enclosure 7, “Quality Assurance Program Description,” of the SHINE Operating License Application, Supplement No. 2

The following regulatory requirements are applicable to RAIs QA-1 through QA-3:

> Paragraph 50.34(b)(6)(ii) of 10 CFR requires that managerial and administrative controls to be used to assure safe operation of the facility to be licensed.
>
> Section 50.9 of 10 CFR Part 50 requires information provided by an applicant be complete and accurate.

The NRC staff has reviewed SHINE’s quality assurance program description (QAPD) using ANSI/ANS-15.8, “Quality Assurance Program Requirements for Research Reactors,” as applied by SHINE to the design, fabrication, construction, and operation of the SHINE facility.

RAI QA-1

In Enclosure 7 of the SHINE operating license application, SHINE submitted Revision 15 of the QAPD. The NRC staff previously approved Revision 7 of the QAPD. It is not clear to the NRC how the QAPD is controlled as the current revision does not provide a complete record of the changes that includes the following:

- Revision date
- Revision number
- Description of revision, including whether revisions resulted in a reduction in effectiveness
- Record of revision management approval

Therefore, the SHINE QAPD may have potential reductions in commitments to the last NRC approved QAPD. The complete record of changes is necessary to ensure that SHINE is adequately implementing managerial and administrative controls at the facility and that information provided to the NRC staff is complete and accurate.

Provide a complete record of changes to the SHINE QAPD that includes the following:

- Revision date
- Revision number
- Description of revision, including whether revisions resulted in a reduction in effectiveness
- Record of revision management approval

SHINE Response

Changes made to the SHINE QAPD since the revisions previously approved by the NRC staff (i.e., Revision 7) are summarized in Table 1. In addition to a description of the change, Table 1 provides the revision date and an evaluation of whether the change represents a reduction in effectiveness against the QAPD previously approved by the NRC staff. In accordance with the SHINE Document Control procedure, each revision to the QAPD is approved by the Quality Assurance Manager.

SHINE has recently revised the QAPD to reflect organizational changes, as described in Table 1. Revision 16 of the SHINE QAPD is provided as Attachment 3.

Table 1: Summary and Evaluation of QAPD Changes since Previous NRC Approval

Revision Number	Revision Date	Description of Change	Evaluation of Change Against Previously Approved Commitments
8	05/20/2016	Revised Section 6, "References," to remove a canceled document (2000-10-01, "Glossary of Terms") and revised Section 1.3, "Definitions," to remove reference to the cancelled document. Revised Section 1.3 to add the definition of "safety-related activities." Updated cover page format to reflect the current approved template.	Change represents administrative improvements and clarifications. Therefore, the revision does not represent a reduction in effectiveness against the QAPD previously approved by the NRC staff.
9	06/01/2018	Revised to reflect organizational changes, reflect an update to the Policy Statement, add Enclosure 3, "Procedures that Implement the QAPD," to be made consistent with the FSAR.	Change represents administrative improvements and organizational revisions which maintain that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom. Therefore, the revision does not represent a reduction in effectiveness against the QAPD previously approved by the NRC staff.
10	01/08/2019	Revised Section 1.3, "Definitions," to replace the definition of "safety-related SSCs" with "safety-related items." Revised the organizational description in Section 2.1, "Organization," and Enclosure 1, "SHINE Functional Organizational Chart," to add the Chief Technology Officer (CTO) position and modify the position descriptions of the Chief Executive Officer (CEO), Chief Operating Officer (COO), and the Vice President of Regulatory Affairs and Quality (VPRA/Q). Revised Enclosure 2, "Graded Approach to Quality," to modify the definitions of QL-2 and QL-3.	Change represents administrative improvements and organizational revisions which maintain that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom. The SHINE Response to QA-2 provides additional information supporting the determination that the replacement of the definition of "safety-related SSCs" with "safety-related items" is considered an administrative improvement. Therefore, the revision does not represent a reduction in effectiveness against the QAPD previously approved by the NRC staff.

Revision Number	Revision Date	Description of Change	Evaluation of Change Against Previously Approved Commitments
11	05/23/2019	Revised the organizational description in Section 2.1, “Organization,” and Enclosure 1, “SHINE Functional Organizational Chart,” to modify the role and responsibilities of the President & Chief Financial Officer, Engineering Management, and Quality and Licensing Management. Revised Enclosure 3, “Procedures that Implement the QAPD,” to update the procedure number and title of the SHINE Implementing Procedure for QAPD Section 2.15.	Change represents administrative improvements and organizational revisions which maintain that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom. Therefore, the revision does not represent a reduction in effectiveness against the QAPD previously approved by the NRC staff.
12	07/02/2019	Revised the organizational description in Section 2.1, “Organization,” to modify the responsibility for the SHINE Document Control and Records Management program from the VPRA/Q to the COO and the Director of Engineering Support (DoS). Revised Enclosure 3, “Procedures that Implement the QAPD,” to update the procedure numbers and titles of the SHINE and Baker Implementing Procedures.	Change represents administrative improvements and organizational revisions which maintain that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom. Therefore, the revision does not represent a reduction in effectiveness against the QAPD previously approved by the NRC staff.
13	07/08/2019	Revised the Executive Summary to reflect the company name change from “SHINE Medical Technologies, Inc.” to “SHINE Medical Technologies, LLC.” Revised Enclosure 3, “Procedures that Implement the QAPD,” to update the procedure numbers and titles of the SHINE and Baker Implementing Procedures.	Change represents administrative improvements. Therefore, the revision does not represent a reduction in effectiveness against the QAPD previously approved by the NRC staff.

Revision Number	Revision Date	Description of Change	Evaluation of Change Against Previously Approved Commitments
14	11/05/2019	Revised Enclosure 2, “Graded Approach to Quality,” to remove the definition of QL-3. Revised the organizational description in Section 2.1, “Organization,” and Enclosure 1, “SHINE Functional Organization Chart,” to remove the role of CTO, add the role of Deputy to COO, and clarify the responsibilities of the Director of Engineering Construction. Revised Enclosure 3, “Procedures that Implement the QAPD,” to update the procedure numbers and titles of the SHINE and Baker Implementing Procedures. Typographical errors corrected throughout document.	Change represents administrative improvements and organizational revisions which maintain that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom. Therefore, the revision does not represent a reduction in effectiveness against the QAPD previously approved by the NRC staff.
15	02/14/2020	Revised the organizational description in Section 2.1, “Organization,” and Enclosure 1, “SHINE Functional Organization Chart,” to remove the role of Deputy to COO.	Change represents organizational revisions which maintain that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom. Therefore, the revision does not represent a reduction in effectiveness against the QAPD previously approved by the NRC staff.
16	05/06/2020	Revised to reflect organizational changes, including: replacing the role of Director of Process Engineering with the role of Vice President (VP) of Engineering, and the VP of Engineering role reporting to the CEO; replacing the role of DoS with the role of Director of Engineering Support and Auxiliary Systems, and the Director of Engineering Support and Auxiliary Systems reporting to the VP of Engineering; modifying the programmatic responsibility for Document Control and Records Management from the DoS to the COO. Editorial corrections throughout document.	Change represents administrative improvements and organizational revisions which maintain that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom. Therefore, the revision does not represent a reduction in effectiveness against the QAPD previously approved by the NRC staff.

RAI QA-2

SHINE uses a custom definition of safety-related SSCs that is applied to the Quality Level (QL) SSCs and uses a graded approach to quality for other SSCs. The graded approach to quality for this QAPD can be found in Enclosure 2, "Graded Approach to Quality," of the SHINE QAPD, which states that "QL-1 shall implement the full measures of the QAPD and shall apply to safety-related SSCs and safety-related activities."

In Section 1.3, "Definitions," of the SHINE QAPD, the definition of safety-related SSCs uses the definition of safety-related items as defined in ANSI/ANS 15.8-1995. This definition replaces SHINE's previous definition of safety-related SSCs that the NRC staff accepted in Revision 7 of the SHINE QAPD. It is not clear to the NRC staff whether the revised definition of safety-related SSCs represents a reduction in effectiveness of the implementation SHINE QAPD as applied to Quality Level 1 SSCs.

Provide information explaining whether the revised definition of safety-related SSCs in the SHINEN QAPD represents a reduction in effectiveness of the implementation SHINE QAPD as applied to Quality Level 1 SSCs.

SHINE Response

SHINE has replaced the previously NRC-approved definition of "safety-related SSCs" with a definition of "safety-related items" which is consistent with the definition provided in ANSI/ANS-15.8-1995, "Quality Assurance Program Requirements for Research Reactors" (Reference 9), which the NRC endorsed the use of via Regulatory Guide 2.5, Revision 1, "Quality Assurance Program Requirements for Research and Test Reactors" (Reference 10).

The revised definition of "safety-related items" is an administrative improvement, in that the definition now explicitly addresses controls whose intended function is to prevent accidents that could cause undue risk to health and safety of workers and the public. And, while the revised definition no longer contains explicit thresholds in determining the acceptability of the consequences of a postulated event, SHINE has retained similar safety criteria in the licensing basis, as described in Section 3.1 of the FSAR.

As the modified definition is consistent with a quality assurance standard approved by the NRC (i.e., the definition of "safety-related items" in ANSI/ANS-15.8-1995), and the licensing basis (i.e., Section 3.1 of the FSAR) contains the explicit safety criteria for the classification of physical SSCs as safety-related, SHINE determined the change does not represent a reduction in effectiveness against the QAPD previously approved by the NRC staff. Consistent with the graded approach to quality approved by the NRC staff in Revision 7 of the QAPD, the full measure of the QAPD (i.e., Quality Level-1) will continue to be applied those physical SSCs classified as safety-related.

RAI QA-3

Enclosure 3, "Procedures That Implement the QAPD," of the SHINE QAPD includes a column that is titled "Baker Implementing Procedures," listing procedures that correspond to sections of the QAPD and SHINE implementing procedures. However, the roles and responsibilities and relationship of Baker to SHINE is not described in the QAPD.

Clarify whether Baker is an Appendix B to 10 CFR Part 50 supplier of services or is a contractor working under SHINE's QAPD. Additionally, clarify what service Baker is providing during the operational phase of the SHINE Medical Isotope Production Facility.

SHINE Response

Baker Concrete Construction, Inc. (Baker) maintains a SHINE project-specific QAPD developed using the guidance of ANSI/ANS 15.8-1995, "Quality Assurance Program Requirements for Research Reactors," (Reference 9). SHINE has reviewed and approved the Baker QAPD as meeting the requirements of the SHINE QAPD. SHINE has qualified Baker as an approved supplier of Quality Level-1 procurement and construction services and added them to the SHINE Approved Supplier List (ASL). The Baker scope of services will be completed when construction of the SHINE facility is complete. Baker will not be involved in the operational phase of the SHINE facility.

SHINE FSAR Section 12.13, “Material Control and Accounting,” and Enclosure 8, “Material Control and Accounting Plan,” of the SHINE Operating License Application, Supplement No. 2

RAI MCA-1

Paragraphs 74.43(b)(1)(ii) and (iii) of 10 CFR require, in part, a management structure be established, documented, and maintained that is independent of production and manufacturing responsibilities and assures separation of key responsibilities. Section 74.43(b)(2) of 10 CFR requires the overall planning, coordination, and administration of the material control and accounting (MC&A) function be invested in a single individual at an organizational level sufficient to assure independence of action and objectiveness of decisions.

Section 3.2.5 of the SHINE MC&A plan states that the Chemistry Manager is responsible for the analytical laboratories and lists the MC&A-related functions for which the Chemistry Manager is also responsible. Section 3.2.5 further states that the Chemistry Manager acts as the MC&A Manager and lists the MC&A program responsibilities for the Chemistry Manager acting as the MC&A Manager. However, it is not clear to the NRC staff how the separation of key responsibilities, independence of action, and objectiveness of decision-making is maintained between these two positions.

Provide information that clarifies the positions of the Chemistry Manager and the MC&A Manager to assure separation of key responsibilities, independence of action, and objectiveness of decisions.

SHINE Response

See Enclosure 3 for the SHINE Response to MCA-1.

RAI MCA-2

Paragraph 74.43(b)(1)(iii) of 10 CFR requires, in part, a management structure be established, documented, and maintained that assures separation of key responsibilities.

Sections 3.3.1, 3.3.2, and 3.3.3 of the SHINE MC&A plan describe the responsibilities for MC&A activities related to accounting, measurement, and control, respectively. In each of the three areas, the responsibilities are assigned to a Chemistry Department staff member. Chapter 5, “Measurement Control System,” of the SHINE MC&A plan describes the various activities performed for measurement control, including activities by the laboratories, laboratory staff, laboratory analyst, or Chemistry staff. Two examples are in Section 5.2, “Calibrations,” which states that laboratory instruments are calibrated by a laboratory analyst, and that scales are calibrated by qualified Chemistry staff. There is not a clear separation of responsibilities between personnel with specific MC&A responsibilities and personnel performing measurements, performing calibrations, or handling special nuclear material (SNM).

Provide information that describes the position of a Chemistry Department staff member in areas other than MC&A that will ensure separation of key responsibilities.

SHINE Response

See Enclosure 3 for the SHINE Response to MCA-2.

RAI MCA-3

Paragraph 74.45(c)(1) of 10 CFR requires assigning responsibility for planning, coordinating, and administering a measurement control program to an individual who has no direct responsibility for performing measurements or for SNM processing or handling.

Section 3.3.2 of the SHINE MC&A plan states that a Chemistry Department staff member serves as the MC&A measurement control program coordinator. However, it is not clear to the NRC staff whether the program coordinator has responsibility for performing measurements or for SNM processing and handling.

Provide information that clarifies the positions of Chemistry Department staff members and the responsibilities of the measurement control program coordinator to ensure that the coordinator has no direct responsibility for performing measurements or for SNM processing or handling.

SHINE Response

See Enclosure 3 for the SHINE Response to MCA-3.

RAI MCA-4

Paragraph 74.43(b)(4) of 10 CFR requires, in part, that personnel who work in key MC&A positions where mistakes could degrade the effectiveness of the MC&A system are trained to maintain a high level of safeguards awareness.

Section 3.4, “Training and Qualification Requirements,” of the SHINE MC&A plan discusses the MC&A training program. The plan describes general training for all employees, and additional training for individuals that perform specific MC&A activities. The plan does not state whether these individuals that perform specific MC&A activities are the key MC&A positions and does not indicate that they will be trained to maintain a high level of safeguards awareness.

Provide information to identify the key MC&A positions and describe how personnel in those key MC&A positions are trained to maintain a high level of safeguards awareness.

SHINE Response

See Enclosure 3 for the SHINE Response to MCA-4.

RAI MCA-5

Paragraph 74.45(b)(1) of 10 CFR requires a program for the measurement of all SNM received, produced, transferred between internal control areas, on inventory, or shipped, discarded, or otherwise removed from inventory, except for the material types listed in 10 CFR 74.45(b)(1)(i)-(iv).

Sections 4.1, “Measurement Points,” and 4.2.1 of the SHINE MC&A plan state that a nominal uranium-235 (U-235) value may be used for calculating U and U-235 content of other SNM in the physical inventory. Table 4-1, “MC&A Measurement Points,” of the SHINE MC&A plan also indicates that nominal values for some material types may be used. However, it is unclear to the NRC staff how SHINE is justifying the alternative use of nominal values instead of measured values for U and U-235 on the material types listed in Table 4-1 of the SHINE MC&A plan.

Provide information to justify the alternative use of nominal values instead of measured values for U and U-235 on the material types listed in Table 4-1 of the SHINE MC&A plan. Also clarify whether the nominal values are used for determining U-235 only, or for determining both U and U-235.

SHINE Response

See Enclosure 3 for the SHINE Response to MCA-5.

RAI MCA-6

Paragraph 74.45(b)(1) of 10 CFR requires a program for the measurement of all SNM received, produced, transferred between internal control areas, on inventory, or shipped, discarded, or otherwise removed from inventory, except for the material types listed in 10 CFR 74.45(b)(1)(i)-(iv).

Section 4.1 of the SHINE MC&A plan states that plutonium (Pu) quantities in the neutron multipliers and in the target solution are calculated. Section 4.1 also states that because of the low concentration of Pu in solution, and because of the significant dilution required to lower dose rate of samples, the Pu concentration in a sample of solution is unmeasurable. However, it is unclear to the NRC staff how SHINE calculated Pu quantities in the target solution and neutron multipliers.

Provide a more detailed explanation of how the Pu quantities in the target solution and neutron multipliers are calculated.

SHINE Response

See Enclosure 3 for the SHINE Response to MCA-6.

RAI MCA-7

Paragraph 74.45(b)(1) of 10 CFR requires a program for the measurement of all SNM received, produced, transferred between internal control areas, on inventory, or shipped, discarded, or otherwise removed from inventory, except for the material types listed in 10 CFR 74.45(b)(1)(i)-(iv).

The introduction to Chapter 4, “Measurements,” of the SHINE MC&A plan states that SHINE has measurement systems in place for quantifying the mass of U and U-235 of all SNM received, shipped, discarded, or listed in the physical inventory. Section 4.1 states that U and U-235 content is measured for all items received or shipped. Section 4.2.1 of the SHINE MC&A plan states that element is measured for all SNM received, shipped, or inventoried, and that isotopic content is measured for all SNM received or shipped. In addition, Section 3.2.5 of the SHINE MC&A plan states that the Chemistry Manager is responsible for ensuring that all SNM items received, shipped, and inventoried are measured. None of the sections cited discuss measurement of SNM transferred between internal control areas. However, it is unclear to the NRC staff how SHINE is measuring SNM transferred between internal control areas.

Provide information on measurement of SNM transferred between internal control areas, or justify why SNM transferred between internal control areas is not measured as required by 10 CFR 74.45(b)(1).

SHINE Response

See Enclosure 3 for the SHINE Response to MCA-7.

RAI MCA-8

Paragraph 74.45(c)(3) of 10 CFR requires, in part, that potential sources of sampling error are identified and that samples are representative by performing process sampling tests using well characterized materials. It also requires that the tests are conducted, in part, whenever a new sampling procedure is used, a sampling procedure or technique is modified, or sample containers or storage are modified.

Section 4.2, “Measurement Systems,” of the SHINE MC&A plan states, in part, that detailed descriptions of sampling systems are provided in written procedures, and that sampling systems are evaluated using engineering studies to prove that samples are representative. Section 4.2.3, “Volume Measurement Systems,” also states that engineering studies are conducted to assure tank solutions are homogeneous and that samples are representative. The plan does not identify the potential sources of sampling error and does not indicate when sampling tests are to be conducted.

Provide a description of potential sources of sampling error and provide information on when sampling tests are conducted.

SHINE Response

See Enclosure 3 for the SHINE Response to MCA-8.

RAI MCA-9

Paragraph 74.45(c)(6) of 10 CFR requires, in part, the use of standards for the calibration and control of all measurement systems used for SNM accountability.

It further requires that calibrations shall be repeated whenever any significant change occurs in a measurement system or when program data indicate a need for recalibration.

Section 5.2, “Calibrations,” of the SHINE MC&A plan describes calibrations, and states that laboratory instruments are calibrated on a regular basis, and scales are calibrated annually. However, Section 5.2 does not indicate when calibrations are repeated.

Provide information on when measurement system calibrations are repeated.

SHINE Response

See Enclosure 3 for the SHINE Response to MCA-9.

RAI MCA-10

Paragraph 74.45(c)(7) of 10 CFR requires, in part, control measurements to provide current data for the determination of random error behavior. Paragraph 74.45(c)(7)(iii) of 10 CFR further states that the program shall include, as appropriate, replicate volume measurements of bulk process batches.

Section 5.4, “Replicate Measurements,” of the SHINE MC&A plan describes the use of replicate measurements in the measurement control program. Section 6.1.2 of the SHINE MC&A plan discusses the estimation of random uncertainty (random error). However, neither Section 5.4 nor Section 6.1.2 include information on replicate volume measurements of bulk process batches. It is noted that the table at the end of Section 6.1.2 does include some information on random variance determination for volume.

Provide information on the use of replicate measurements for volume determinations or, if not appropriate, justify why replicate measurements are not appropriate.

SHINE Response

See Enclosure 3 for the SHINE Response to MCA-10.

RAI MCA-11

Paragraph 74.45(c)(7) of 10 CFR requires, in part, control measurements to provide current data for the determination of random error behavior. Paragraph 74.45(c)(7)(v) of 10 CFR further states that the program shall include, as appropriate, replicate non-destructive assay (NDA) measurements of individual process containers (items), or alternatively, the use of data generated from the replicate measurements of NDA control standards as derived from the control standard program.

Section 5.4 of the SHINE MC&A plan describes the use of replicate measurements in the measurement control program. Section 5.4 states that for NDA systems, replicate measurements are not required because the quantity of SNM in waste measured by NDA is very small when compared with the total quantity of SNM in the inventory. Section 6.1.2 of the SHINE MC&A plan discusses the estimation of random uncertainty (random error). However, it does not include information on replicate NDA measurements.

Provide more detail on the use of replicate NDA measurements or, if not appropriate, justify why replicate measurements are not appropriate.

SHINE Response

See Enclosure 3 for the SHINE Response to MCA-11.

RAI MCA-12

Paragraph 74.45(c)(11) of 10 CFR requires, as part of the measurement control program, prompt investigation and appropriate corrective action whenever a control datum exceeds an 0.05 control limit.

Section 5.5, “Control Limits,” of the SHINE MC&A plan describes the use of control limits established to monitor measurement systems used for MC&A. Section 5.5.1 describes the measurement control data analysis including potential problem indicators, and Section 5.5.2 describes response actions for the indicators listed. However, Sections 5.5.1 and 5.5.2 do not discuss the investigation or corrective actions taken when a control datum exceeds the 0.05 limit.

Provide a description of the investigation and corrective actions taken when a control datum exceeds the 0.05 limit.

SHINE Response

See Enclosure 3 for the SHINE Response to MCA-12.

RAI MCA-13

Paragraph 74.43(c)(4) of 10 CFR requires that procedures are maintained and followed for confirming the validity of prior measurements associated with unencapsulated and unsealed items on ending inventory.

Chapter 7, “Physical Inventory Program,” of the SHINE MC&A plan provides a description of the physical inventory program. Chapter 8, “Item Control Program,” describes item identity controls, storage controls and item monitoring activities. Chapter 11, “Tamper-Safing,” describes the characteristics and use of tamper-indicating devices (TIDs) and the description of tamper-safing records. However, it is unclear whether there will be unencapsulated or unsealed items on ending inventory, nor whether there are procedures for confirming the prior measurement of those items.

Provide more detailed information on the use of TIDs, and on procedures for confirming the validity of prior measurements associated with unencapsulated and unsealed items on ending inventory, if applicable.

SHINE Response

See Enclosure 3 for the SHINE Response to MCA-13.

RAI MCA-14

Paragraph 74.43(c)(5)(v) of 10 CFR requires, in part, that inventory procedures are maintained and followed to assure that, upon completion of the physical inventory, all book and inventory records, for total plant and individual internal control areas, are reconciled with and adjusted to the results of the physical inventory.

Section 7.1, “General Description,” of the SHINE MC&A plan provides a general description of the physical inventory program. Section 7.1 states, in part, that differences between the accounting records and the ending physical inventory are investigated and reconciled. Section 7.2, “Organization, Procedures, and Schedules,” states, in part, that inventory activities include time to resolve differences between the book and physical inventories. Section 7.5, “Conducting Physical Inventories,” describes conducting the physical inventory, including activities undertaken after the inventory listing. These three sections discuss inventory reconciliation for

the entire facility, but it is not clear whether book and inventory records are reconciled to the results of the inventory for individual internal control areas.

Provide information on how book and inventory records are reconciled with and adjusted to the results of the physical inventory for individual internal control areas.

SHINE Response

See Enclosure 3 for the SHINE Response to MCA-14.

RAI MCA-15

Paragraph 74.43(c)(5)(iv) of 10 CFR requires that cutoff procedures for records and reports are established so that only transfers for the inventory and material balance interval are included in the records for the material balance period in question.

Chapter 7 of the SHINE MC&A plan provides a description of the physical inventory program. Specifically, Section 7.3, “Typical Inventory Composition,” describes cutoff procedures for transfers and processing, and Section 7.5 describes conducting the physical inventory, including information on cutoff times for movement and processing and cleanout activities. Neither section discusses cutoff procedures for records and reports.

Provide information on how cutoff procedures for records and reports are established so that only transfers for the inventory and material balance interval are included in the records for the material balance period in question.

SHINE Response

See Enclosure 3 for the SHINE Response to MCA-15.

RAI MCA-16

Paragraph 74.43(c)(8)(iii) of 10 CFR requires, in part, that any occurrence of standard error of the inventory difference (SEID) exceeding 0.125 percent of active inventory be investigated and reported to the NRC.

Section 7.5 of the SHINE MC&A plan describes conducting the physical inventory, and Section 7.6, “Inventory Difference Limits and Response Actions,” describes inventory difference limits and response actions. Section 6.2.2 of the SHINE MC&A plan describes calculation of the SEID. These sections do not describe the steps taken to investigate and report when the SEID exceeds 0.125 percent of the active inventory.

Provide a description of the actions taken to investigate and report when the SEID exceeds 0.125 percent of the active inventory.

SHINE Response

See Enclosure 3 for the SHINE Response to MCA-16.

RAI MCA-17

Paragraph 74.43(b)(6) of 10 CFR specifies items that are exempted from the item control program requirements of 10 CFR 74.43(b)(5).

Section 8.2, “General Description,” of the SHINE MC&A plan provides a general description of the SHINE item control program. Included in the description is a list of exceptions (exemptions) to the item control program. The list of items is based on exemptions not consistent with those in 10 CFR 74.43(b)(6), but rather reflects those proposed in a Part 74 rulemaking that was subsequently terminated.

Provide a list of items that will be excepted from the item control program that is consistent with the requirements of 10 CFR 74.43(b)(6).

SHINE Response

See Enclosure 3 for the SHINE Response to MCA-17.

RAI MCA-18

Paragraph 74.43(b)(7) of 10 CFR requires conducting and documenting shipper-receiver comparisons for all SNM receipts.

Chapter 9, “Receiving and Shipping Program,” of the SHINE MC&A plan describes how SHINE will conduct and document shipper-receiver comparisons. Section 9.1, “Receiving Procedures,” describes the SNM receiving procedures for the facility, and includes statements that the shipper’s gross weight may or may not include the TID, and that the information should be obtained from the shipper. It also states that the SHINE gross weight includes the SHINE TID, which makes verification of gross weight easier and more accurate if re-weighing is necessary. However, it is not clear to the NRC staff how the use of shipper or SHINE TIDs impacts conducting and documenting shipper-receiver comparisons.

Provide more detailed information on how the use of shipper or SHINE TIDs impacts conducting and documenting shipper-receiver comparisons.

SHINE Response

See Enclosure 3 for the SHINE Response to MCA-18.

RAI MCA-19

Paragraph 74.43(b)(8) requires, in part, performance of an independent assessment of the total MC&A system, assessing the performance of the system, reviewing its effectiveness, and documenting management’s action on prior assessment recommendations. In addition, an MC&A plan must demonstrate how the system capabilities contained in 10 CFR 74.41(c) are achieved and maintained, and how such capabilities are used to achieve the performance objectives listed in 10 CFR 74.41(a).

Chapter 10, “Assessment and Review of the MC&A Program,” of the SHINE MC&A plan describes the assessment and review of SHINE’s MC&A program. Throughout the chapter, the applicant describes actions that “should” be taken instead of the actions that are taken.

Provide information to show that an independent assessment of the total MC&A system will be performed as required by the system capability in 10 CFR 74.43(b)(8).

SHINE Response

See Enclosure 3 for the SHINE Response to MCA-19.

RAI MCA-20

Paragraph 74.43(b)(8) of 10 CFR requires, in part, that independent assessments include a review and evaluation of any contractor who performs SNM accountability measurements for the applicant.

Chapter 10 of the SHINE MC&A plan describes the assessment and review of SHINE's MC&A program. The description does not include a review of any contractor who performs SNM accountability measurements for SHINE.

Provide information to show that the independent assessment includes a review and evaluation of any contractor who performs SNM accountability measurements for SHINE.

SHINE Response

See Enclosure 3 for the SHINE Response to MCA-20.

RAI MCA-21

Paragraph 74.43(d)(1) of 10 CFR requires a recordkeeping program that maintains records of the receipt, shipment, disposal, and current inventory associated with all possessed SNM.

Chapter 15 of the SHINE MC&A plan describes the recordkeeping program. Chapter 15 contains a list of records, forms, reports, and procedures that are considered to be records, and a list of supplemental records which are necessary for MC&A. Neither list includes records of disposal of SNM.

Provide information on how records of disposal of SNM are included in the SHINE MC&A recordkeeping program.

SHINE Response

See Enclosure 3 for the SHINE Response to MCA-21.

References

1. NRC letter to SHINE Medical Technologies, LLC, “Issuance of Request for Additional Information Related to the SHINE Medical Technologies, LLC Operating License Application (EPID No. L-2019-NEW-0004),” dated May 26, 2020 (ML20148M278)

2. SHINE Medical Technologies, LLC letter to the NRC, “SHINE Medical Technologies, LLC Application for an Operating License,” dated July 17, 2019 (ML19211C143)

3. Lane, J.A., et al., “Fluid Fuel Reactors,” Reading, MA, 1958

4. Kimpland, R.H. and S.K. Klein, “A Generic System Model for a Fissile Solution Fueled Assembly,” LA-UR-13-22033, Los Alamos National Laboratory, 2013

5. Barbry F., “SILENE Reactor Results of Selected Typical Experiment,” SRSC-223, September 1994

6. Dunenfeld, M.S. and R.K. Stitt, “Summary Review of the Kinetics Experiments on Water Boilers,” NAA-SR-7087, February 1963

7. American National Standards Institute/American Nuclear Society, “Emergency Planning for Research Reactors,” ANSI/ANS-15.16-2015, La Grange Park, IL

8. American National Standards Institute/American Nuclear Society, “Nuclear Criticality Accident Emergency Planning and Response,” ANSI/ANS-8.23-2007, La Grange Park, IL

9. American National Standards Institute/American Nuclear Society, “Quality Assurance Program Requirements for Research Reactors,” ANSI/ANS-15.8-1995 (R2013), La Grange Park, IL

10. U.S. Nuclear Regulatory Commission, “Quality Assurance Program Requirements for Research and Test Reactors,” Regulatory Guide 2.5, Revision 1, June 2010 (ML093520099)

ENCLOSURE 2
ATTACHMENT 1

SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL TECHNOLOGIES, LLC OPERATING LICENSE APPLICATION
RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

FINAL SAFETY ANALYSIS REPORT CHANGES
(MARK-UP)

78 pages follow

LIST OF FIGURES

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 ~~SHINE~~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 ~~SHINE~~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 ~~SHINE facility~~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

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 ~~SHINE~~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

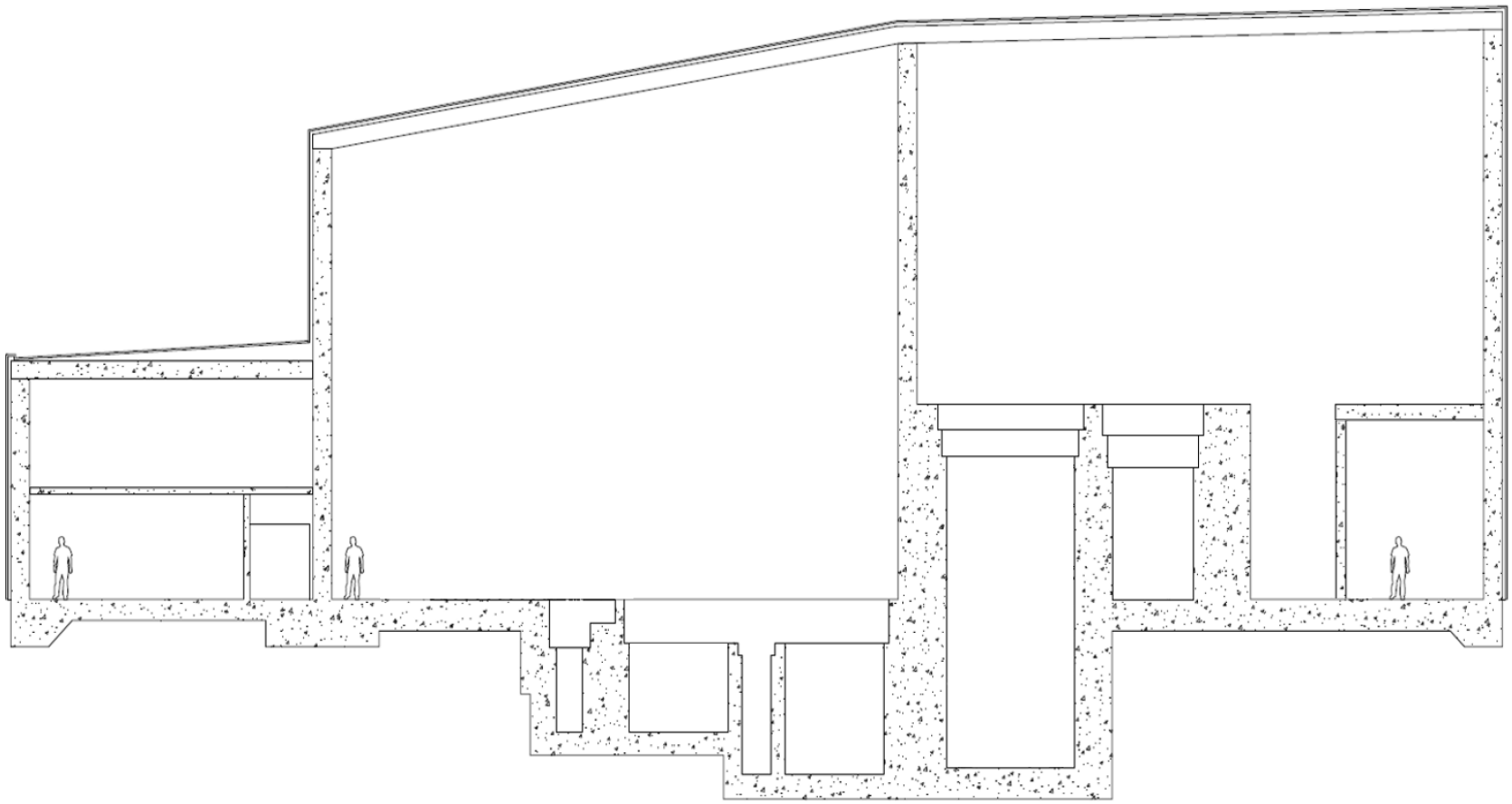
The irradiation units (IUs) are operated in a batch mode with an approximate week-long operating cycle. An operating cycle includes the following steps:

- 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.

Figure 1.3-1 – Main Production Facility Building General Arrangement

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



- $f_j(x,y)$ is the probability, given a crash, that the crash occurs in a 1-square mile area surrounding the facility
- A_j is the effective plant area

Tables B-14 and B-15 of DOE-STD-3014-96 (DOE, 2006) provide $N_jP_jf_j$ values for general aviation aircraft, air carriers, air taxis, and small military aircraft applicable for specific DOE sites. Tables B-14 and B-15 of DOE-STD-3014-96 (DOE, 2006) also provide crash probabilities for unspecified locations in the continental United States (CONUS), and Table B-43 of DOE-STD-3014-96 (DOE, 2006) provides a generic crash frequency for helicopters. Therefore, CONUS maximum values and generic helicopter values are used for the facility and are provided in Table 2.2-7 (DOE, 2006).

The effective plant area (A_j) for the safety-related structures of the facility depends on the length, width, and height of the facility, as well as the aircraft's wingspan, skid distance, and impact angle as explained below (DOE, 2006):

$$A_j = A_f + A_s \qquad \text{(Equation 2.2-2)}$$

Where

$$A_f = (W_{sj} + R) \times H \times cot(\varphi)_j + \frac{2 \times L \times w \times W_{sj}}{R} + L + w: \qquad \text{(Equation 2.2-3)}$$

And:

$$A_s = (W_{sj} + R)\ x\ S_j \qquad \text{(Equation 2.2-4)}$$

Where:

- A_f is the effective fly-in area
- A_s is the effective skid area
- W_{sj} is the aircraft wingspan (Table 2.2-7)
- R is the length of the diagonal of the facility = $\sqrt{(L^2 + W^2)}$
- H is the facility height
- $cot\varphi$ is the mean of the cotangent of the aircraft impact angle (Table 2.2-7)
- L is the length of facility, facility-specific
- W is the width of facility, facility-specific
- S_j is the aircraft skid distance (mean value) (Table 2.2-7)

The total effective area (Aj) for the safety-related structure facility was calculated. Dimensions of the main production facility used in the analysis include a length of 212 feet (ft.)-6 inches (in.), a width of 158 ft.-2 in., and a height of 56 ft.-0 in. Plan and elevation views of the main production facility structure (FSTR) are provided in Figure 1.3-1 and Figure 1.3-2.

The calculated effective area for the five aircraft types is provided in Table 2.2-8.

The crash impact probabilities for small non-military aircraft (i.e., general aviation and air taxi), large non-military aircraft (i.e., air carriers), and military aircraft (i.e., small aircraft and helicopter) from airways are provided in Table 2.2-9.

that contains 133,946 lb. (60,756 kg) is acceptable at 0.22 mi. (0.35 km). A tank of jet fuel containing 500,000 lb. (226,796 kg) is acceptable at 0.22 mi. (0.35 km). A tank of propane that contains 55,724 lb. (25,275 kg) is acceptable at 0.22 mi. (0.35 km). The closest safety-related SHINE area is located approximately 0.22 mi. (0.35 km) from US 51.

The propane truck was also analyzed for a boiling liquid expansion vapor explosion (BLEVE) overpressure. The standoff distance to a 1 psid (6.9 kPa) overpressure is 332 ft. (101 meters [m]). This is much less than the actual distance from US 51 to the facility (0.22 mi. [0.35 km]).

A tank containing 18,196 lb. (8253 kg) of hydrogen is acceptable at a distance of 0.22 mi. (0.35 km). The closest safety-related SHINE area is 2.1 mi. (3.4 km) from I-90/39.

The limiting stationary explosions are shown in Table 2.2-16.

Based on the above, an explosion involving potentially transported hazardous materials on US 51 or I-90/39, would not adversely affect operation of SHINE.

2.2.3.1.1.4 On-Site Chemicals

On-site stationary chemicals were analyzed using the TNT equivalency methodologies, as described in Subsection 2.2.3.1.1. One chemical was identified as being a potential explosive hazard on-site: deuterium/tritium.

The deuterium and tritium are used in the main production facility and are treated for this analysis as hydrogen gas. The maximum expected mass in one container is 0.39 lbs (0.18 kg) of deuterium and 0.25 lbs (0.10 kg) of tritium. These maximum expected masses are very low; however, because these chemicals are used in production, there is no separation between the hazard and the SHINE safety-related area. The deuterium and tritium gas systems and processes are designed to minimize the probability of an explosion. With safety features, and the very small mass of each chemical, the probability of an explosion causing enough damage to the facility to cause a radiological release to the public is low.

Therefore, an explosion of any of these chemicals would not adversely affect operation of SHINE.

2.2.3.1.1.5 Nearby Facilities and Railways

There are three additional off-site facilities and railways that have explosive chemicals that are identified as the bounding instances of explosion analysis. The hazardous materials stored at nearby facilities that were identified for further analysis with regard to explosive potential are ethylene oxide stored at Abitec and gasoline at Janesville Jet Center. The ethylene oxide is analyzed as a bounding instance between the stationary tank at the facility and the tank transported by rail. In addition, bounding instances of diesel fuel and jet fuel (kerosene) are analyzed. All other nearby chemicals or chemicals transported by railway were dispositioned as being bounded by one of these four bounding instances using the methodology discussed in Subsection 2.2.3.1.1.

A conservative analysis using TNT equivalency methods as described in Subsection 2.2.3.1 was used to determine standoff distances for the storage of the identified hazardous materials.

up or down to reflect a shift in the basin location. Based on available USGS flow data, March is a common month for floods in the Rock River (USGS, 2012a and FEMA, 2008).

The USGS web-based flow data were reviewed for the gauge site near Afton, located just across the river from the airport and just southwest of the site. This site has a period of record of nearly 100 years dating back to 1914 and is an applicable flow record of the Rock River near the site.

Measurements at the USGS gauge show a flow rate of about 10,000 to 13,000 cubic feet per second (cfs) (283 to 368 cubic meters per second [m^3/sec]) for the peak historical flood events, with the maximum flow rate being 16,700 cfs (473 m^3/sec) observed in June 2008. Based on this record, the flows of 10,000 to 13,000 cfs (283 to 368 m^3/sec) correspond approximately to the 10-year to 50-year events (FEMA, 2008). The peak flow of 16,700 cfs (473 m^3/sec) is generally consistent with the 100-year flood levels along the Rock River (Janesville, 2008 and FEMA, 2008). The flood level at the USGS gauge at Afton during the 2008 flood was approximately 755 ft. (230 m) in elevation (FEMA, 2008).

2.4.2.2 Flood Record Details and Elevations

The Federal Emergency Management Agency (FEMA) completed a flood hazard assessment for Rock County in August 2008 that looked at existence and severity of flood-related hazards, including the areas around the site. The study included the Rock River where it passes by the site (at approximately river mile 172 upstream from the confluence with the Mississippi River) and the unnamed tributary stream located just to the south of the site (Figure 2.4-1).

FEMA completed hydrologic and hydraulic analyses for the Rock River and the unnamed tributary stream to estimate flow magnitudes for various recurrence interval flood events and to estimate the water surface elevations for corresponding flood events. Table 2.4-5 provides a summary of flows for the Rock River for the reach from Janesville (river mile 178) to Afton near the USGS gauge (river mile 172), located just across the river from the site and the airport. Elevations are reported as an approximate range, based on the FEMA 2008 flood profiles, with the higher elevation corresponding to the upstream end of the reach at Janesville and the lower elevation at the downstream end near the USGS gauge at Afton. Table 2.4-6 provides a similar summary for the unnamed tributary to the Rock River for the reach between US 51 and Prairie Road just to the south of the site. The range of reported elevations is similarly derived from the FEMA 2008 flood profiles. Channel bottom elevations are based on surveys that supported the FEMA 2008 studies.

FEMA estimated the 100-year flood level as approximately 755 ft. (230 m) for the location of the USGS gauge at Afton (Table 2.4-5), which correlates well with the gauge flows and corresponding observed flood levels during the 2008 flood at the same location (FEMA, 2008). The estimated 500-year flood level is 756 ft. (230.4 m) (FEMA, 2008) (Table 2.4-5). The results show that the 100-year and 500-year floodwater surface elevations for the Rock River are well below the 825 ft. ground floor elevation of the main production facility and the ~~waste~~material staging ~~and shipping~~ building for the full reach of the Rock River extending from Janesville downstream and around the site through Afton (Table 2.4-5). Similarly, the 100-year and 500-year floodwater surface elevations for the unnamed tributary to the Rock River, for the reach just south of the site (Table 2.4-6), are well below the facility ground floor elevation.

approximately two miles south of the site. To determine the maximum water depth in the existing channel from PMP drainage, runoff from the entire 91 acre site was conservatively evaluated as conveyed by the existing channel. The runoff flow rate was calculated as 197 cfs. The maximum surface water elevation in the existing channel from a 100-year storm does not rise above the elevation of the banks. The water reaches an elevation of 826 ft. at the upstream end, below its bank elevation of 827 ft., and has an elevation of 818.5 ft. on its downstream end (south of the site), below its downstream bank elevation of 819.5 ft.

Stormwater inside the site boundary (e.g., paved areas) is directed to a stormwater management system (Figure 2.4-11). The facility design includes two infiltration cells that collect site runoff for the purpose of controlling total suspended solids (Figure 2.4-11). Infiltration cell #1 collects drainage, and at 810 ft. elevation, flows via a spillway to infiltration cell #2. The infiltration cells have a peak water surface elevation of 810 ft. during a 100-year storm event and will not pose a site flooding concern.

Site low points surrounding the main production facility were conservatively analyzed for maximum flood depth from the 100-year PMP event (Figure 2.4-12). The maximum depth in all low points from impounded water is below the ground floor elevations of the main production facility and ~~waste~~ material staging ~~and shipping~~ building, with margin.

PMP runoff flow rates for channel drainage were calculated using the Soil Conservation Service (SCS) methodology. Runoff, Q_{in}, for the 100-year storm event:

$$Q_{in} = \frac{(P - 0.2S)^2}{(P + 0.0S)^2} \qquad \text{Equation 2.4-1}$$

Where:

- Q is the Runoff (in.)
- P is the Rainfall (in., 24-hour period)
- S is the Potential maximum retention after runoff beings (in.)

$$S = \frac{1000}{CN} - 10 \qquad \text{Equation 2.4-2}$$

Where:

- CN is the Runoff Curve Number

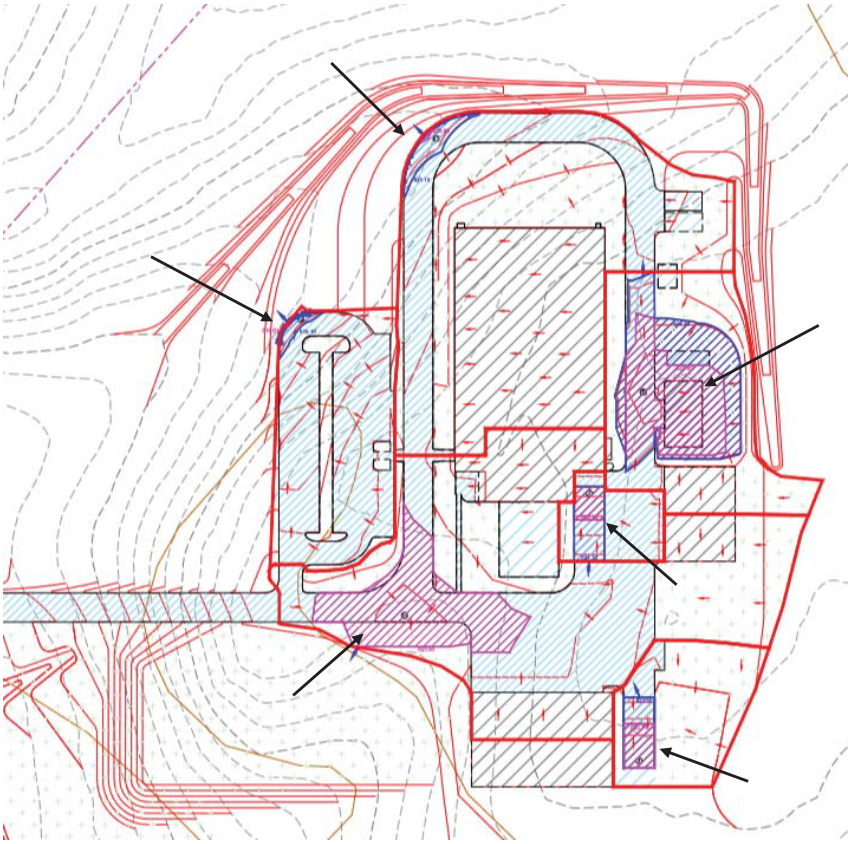
$$q_p = q_u \times A_m \times Q_{in} \times F_p \qquad \text{Equation 2.4-3}$$

Where:

- q_p is the Peak Discharge (cfs)
- q_u is the Unit Peak Discharge (csm/in.)
- A_m is the Drainage area (mi^2)
- Q_{in} is the Runoff (inches)
- F_p is the Pond and Swamp Adjustment Factor

PMP runoff flow rates for evaluating site impounded areas were calculated using the Rational Dekalb method:

Figure 2.4-12 – PMP 100-Year Event Facility Drainage[a]



a. Figure displays location of (six) localized low points subject to impoundment if drainage is assumed blocked. Surface elevation of impounded areas during a 100-year PMP event remain below the ground floor elevation of the main production facility and ~~waste~~material staging ~~and shipping~~ building.

3.2 METEOROLOGICAL DAMAGE

3.2.1 WIND LOADING

This subsection discusses the criteria used to design the ~~SHINE~~ main production facility for protection from wind loading conditions.

3.2.1.1 Applicable Design Parameters

The ~~SHINE~~main production facility structure is designed to withstand wind pressures based on a basic wind velocity of 90 miles per hour (mph) (145 kilometers per hour [kph]) adjusted for a mean recurrence interval of 100 years, per Figure 6-1 and Table C6-7 of American Society of Civil Engineers/Structural Engineering Institute (ASCE), Standard 7-05, Minimum Design Loads for Buildings and Other Structures (ASCE, 2006).

3.2.1.2 Determination of Applied Forces

The design wind velocity is converted to velocity pressure in accordance with Equation 6-15 of ASCE 7-05 (ASCE, 2006):

$$q_z = 0.00256 K_z K_{zt} K_d V^2 I \text{ (pounds per square foot [lb/ft}^2\text{])} \quad \text{(Equation 3.2-1)}$$

Where:

- K_z = velocity pressure exposure coefficient evaluated at height (z) in Table 6-3 of ASCE 7-05
- K_{zt} = topographic factor as defined in Section 6.5.7 of ASCE 7-05
- K_d = wind directionality factor in Table 6-4 of ASCE 7-05
- V = basic wind speed (3-second gust) obtained from Figure 6-1 of ASCE 7-05 for Wisconsin
- I = importance factor = 1.15

The design wind pressures and forces for the building at various heights above ground are obtained in accordance with Section 6.5.12.2.1 of ASCE 7-05 (ASCE, 2006) by multiplying the velocity pressure by the appropriate pressure coefficients, gust factors, accounting for sloped surfaces (i.e., the roof of the building). The building is categorized as an enclosed building according to Section 6.2 of ASCE 7-05 (ASCE, 2006) and, as a result, both external and internal pressures are applied to the structure. A positive and negative internal pressure is applied to the internal surfaces of the exterior walls as well as the roof.

3.2.2 TORNADO LOADING

This subsection discusses the criteria used to design the ~~SHINE~~main production facility to withstand the effects of a design-basis tornado phenomenon.

The Seismic Category I boundary provides missile walls to protect safety-related systems from damage due to tornado missiles. SSCs that are credited to prevent or mitigate potential accidents caused by a tornado event are protected by the design of the enclosed structure. The structural analysis does not credit venting of the Seismic Category I boundary during a tornado event. The differential pressure on all surfaces as an enclosed structure results in higher pressures, and the differential pressure would be reduced by the effects of venting. Therefore, there are no consequences to venting the building during a tornado event.

3.2.3 SNOW, ICE, AND RAIN LOADING

This subsection discusses the criteria used to design the ~~SHINE~~main production facility to withstand conditions due to snow, ice, and rain loading. Rain loading is not considered in the structural design of the building as the sloped roofs do not result in rain accumulation. As a result of the lack of rain accumulation, load due to ice is anticipated to be minimal and is enveloped by the design snow load.

3.2.3.1 Applicable Design Parameters

Snow load design parameters pertinent to the ~~SHINE~~main production facility are provided in Chapter 7 of ASCE 7-05 (ASCE, 2006).

3.2.3.2 Determination of Applied Forces

The sloped roof snow load is calculated in accordance with Sections 7.3 and 7.4 of ASCE 7-05 (ASCE, 2006). The combined equation utilized to calculate the sloped roof load is:

$$p_s = 0.7 C_s C_e C_t I p_g \qquad \text{(Equation 3.2-3)}$$

Where:

- C_s = roof slope factor as determined by Sections 7.4.1 through 7.4.4 of ASCE 7-05
- C_e = exposure factor as determined by Table 7-2 of ASCE 7-05
- C_t = thermal factor as determined by Table 7-3 of ASCE 7-05
- I = importance factor as determined by Table 7-4 of ASCE 7-05
- p_g = ground snow load as set forth in Figure 7-1 of ASCE 7-05

Unbalanced roof snow loads are computed in accordance with Section 7.6 of ASCE 7-05 (ASCE, 2006). The design snow drift surcharge loads are computed in accordance with Section 7.7.1 of ASCE 7-05 (ASCE, 2006).

3.3 WATER DAMAGE

The design basis precipitation, flood levels, and ground water levels for the ~~SHINE~~main production facility are as follows:

- Design basis flood level: 50 feet (ft.) (15.2 meters [m]) below grade.
- Design basis precipitation level: at grade.
- Maximum ground water level: 50 ft. (15.2 m) below grade.

Per Subsection 2.4.2.3, a local probable maximum precipitation (PMP) event creates a water level about level with grade. The first floor of the building is at least 4 inches (in.) (10.2 centimeters [cm]) above grade; therefore, water will not infiltrate the door openings in the case of a local PMP event.

Per Subsection 2.4.3, a local probable maximum flood (PMF) event creates a water level approximately 50 ft. (15.2 m) below grade. The water elevation for the PMF is derived from FEMA flood profiles. The lowest point of the facility is 26 ft. (7.9 m) below grade; therefore, flooding does not cause any structural loading in the case of a local PMF event.

The impact of internal flooding is determined by the maximum flow rate and the volume of water available to feed the flood. No active response is assumed to terminate the flow and the entire volume of available water is assumed to spill into the ~~SHINE~~main production facility. For water sources outside the building (fire water), automatic or operator actions are required to terminate the flow.

Berms and ramps are used within the facility to:

- Capture and contain water collected in the RCA resulting from postulated water system ruptures or fire system discharges above grade.
- Prevent water intrusion into the uranium receipt and storage system (URSS) and target solution preparation system (TSPS) rooms.
- Prevent a release of water from the RCA due to the postulated failure of the radioisotope process chilled water system (RPCS) room, the process chilled water system (PCHS), or the facility demineralized water system (FDWS).
- Prevent bulk release of water into the radioactive drain system (RDS) sump tanks thereby overfilling the sump collection piping.

Safety-related equipment vulnerable to water damage is protected by locating it in flood-protective compartments and/or installing it above flood elevation.

3.3.1 FLOOD PROTECTION

This subsection discusses the flood protection measures that are applicable to safety-related SSCs for both external flooding and postulated flooding from failures of facility components containing liquid.

Analyses of the worst flooding due to pipe and tank failures and their consequences are performed in this subsection.

3.3.1.1 Flood Protection Measures for Structures, Systems, and Components

Postulated flooding from component failures in the building compartments is prevented from adversely affecting plant safety or posing any hazard to the public. Exterior or access openings and penetrations into the ~~SHINE~~main production facility are above the maximum postulated flooding level and thus do not require protection against flooding.

3.3.1.1.1 Flood Protection from External Sources

Safety-related components located below the design (PMP) flood level are protected using the hardened protection approach described below. The safety-related systems and components are flood-protected because they are enclosed in a reinforced concrete safety-related structure, which has the following features:

a. Exterior walls below flood level are not less than 2 ft. (0.61 m) thick.
b. Water stops are provided in construction joints below flood level.
c. Waterproofing is applied to external surfaces exposed to flood level.
d. Roofs are designed to prevent pooling of large amounts of water.

Waterproofing of foundations and walls of Seismic Category I structures below grade is accomplished principally by the use of water stops at construction joints.

In addition to water stops, waterproofing of the ~~SHINE~~main production facility is provided up to 4 in. (10.2 cm) above the plant ground level to protect the external surfaces from exposure to water.

There is no fire protection piping in the RCA general area.

3.3.1.1.2 Flood Protection from Internal Sources

The total discharge from the fire protection discharge consists of the combined volume from any firefighting hoses. In accordance with National Fire Protection Association (NFPA) 801, Section 5.10 (NFPA, 2008), the credible volume of discharge is sized for a manual fire-fighting flow rate of 500 gallons per minute (1893 liters per minute) for a duration of 30 minutes (min.). Therefore, the total discharge volume is 15,000 gallons (56,782 liters). The resulting flooded water depth in the RCA from fire protection discharge is less than 2 in. This bounds the total water available in the PCHS and RPCS cooling systems that could cause internal flooding.

The floors of the URSS/TSPS rooms are elevated to prevent water intrusion in the event of an internal flood. Water sensitive safety-related equipment is raised from the floor 8 in. (20.3 cm) in the RCA to provide defense in depth. Therefore, the depth of water due to fire protection discharge is less than the elevation that water sensitive safety-related equipment is raised from the floor.

Outside of the RCA there is limited water discharge from fire protection systems. The safety-related function(s) of systems that are subject to the effects of a discharge of the fire suppression system are appropriately protected by redundancy and separation. The uninterruptible electrical power supply system (UPSS) has two trains to provide redundancy. These trains are isolated from each other to prevent one train from being damaged by discharge of the fire protection

3.4 SEISMIC DAMAGE

Seismic analysis criteria for the ~~SHINE~~main production facility conform to IAEA-TECDOC-1347, Consideration of External Events in the Design of Nuclear Facilities other than Nuclear Power Plants, with Emphasis on Earthquakes (IAEA, 2003), which provides generic requirements and guidance for the seismic design of nuclear facilities other than nuclear power plants. Additional criteria provided in the Regulatory Guides and NUREG-0800, Standard Review Plan for the Review of Safety Analysis for Nuclear Power Plants (SRP), provide more detailed guidance in the seismic analysis of the main production facility structure (FSTR).

The dimensions of the FSTR at grade level are approximately 212 feet (ft.) (64.6 meters [m]) in the north-south (N/S) direction and 158 ft. (48.2 m) in the east-west (E/W) direction. The main production facility is a single-story building with a mezzanine, with a roof height of approximately 58 ft. (17.7 m). The FSTR also includes an exhaust stack with a height of approximately 67 ft. (20.4 m). The ~~SHINE~~main production facility main floor has below grade reinforced concrete vaults for housing equipment. The roof of the facility is supported by a steel truss system.

The FSTR building is a box-type shear wall system of reinforced concrete. The major structural elements include the foundation mat, mezzanine floor, roof slab supported by roof trusses, and shear walls. The exterior building walls of the majority of the FSTR are thick cast-in-place concrete, and are designed to protect the people, materials, and equipment inside the facility from natural and manmade accidents.

The FSTR includes the irradiation facility (IF), the radioisotope production facility (RPF), the non-radiologically controlled seismic area, and a nonsafety-related area. The IF contains the irradiation units (IUs) and tritium purification system (TPS), and the RPF contains the supercell and below-grade tanks. The non-radiologically controlled seismic area contains the control room, battery rooms, uninterruptible electrical power supply rooms, and other miscellaneous support rooms. The RPF, IF, and non-radiologically controlled seismic area are within the seismic boundary and are classified as Seismic Category I. These areas contain the safety-related structures, systems, and components (SSCs). To the south of the seismic boundary are the shipping and receiving areas, as well as other areas that contain nonsafety-related support systems and equipment. This part of the structure is not Seismic Category I. The areas outside the seismic boundary do not contain safety-related SSCs.

The FSTR is modeled to the analyses described in this chapter. The concrete walls, slabs, and basemat are modeled using thick shell elements. The steel structural members are modeled using three-dimensional beam elements. Seismic mass is considered in the model in accordance with SRP Section 3.7.2 (USNRC, 2013a). Figure 3.4-1 and Figure 3.4-2 provide three-dimensional views of the structural model.

Certain material in this section provides information that is used in the technical specifications, including conditions for operation and design features. In addition, significant material is also applicable to, and may be referenced by, the bases that are described in the technical specifications.

3.4.2.2 Soil-Structure Interaction (SSI) Analysis

The SSI model provides structural responses for design basis level seismic loading of the ~~SHINE~~main production facility, including transfer functions, maximum seismic acceleration (zero period acceleration [ZPA]), and in-structure response spectra (ISRS) (horizontal and vertical directions) for various damping values. The SSI model is developed using the computer program Structural Analysis Software System Interface (SASSI2010), version 1.0.

Major structural elements of the ~~SHINE~~main production facility, including walls, slabs, beams and columns, are modeled with appropriate mass and stiffness properties. Major openings within walls and slabs are included in the SSI model. The model uses thick shell elements to represent concrete slabs and walls, and beam elements to represent steel members, mostly comprising the truss components in the facility. Elements are modeled at the geometric centerline of the structural member they represent with the following exceptions:

- The below grade and mezzanine slabs are modeled at their actual top-of-slab elevation.
- Minor adjustments are made to the dimensions and locations of wall openings to maximize mesh regularity in the model.
- Roof truss locations are adjusted to align with the roof shell element mesh.

In addition to self-weight of the structure, floor loads and equipment loads are converted to mass and included in the model. A portion of the loads are considered mass sources in the following manner according to SRP Section 3.7.2 (USNRC, 2013a):

- Dead Load ……100 percent
- Live Load……25 percent
- Snow Load……..75 percent

In addition to the loads that are converted to mass, the hydrodynamic mass of the water in the IU cells is included.

The SSI analyses are performed separately on an equivalent linear-elastic basis for mean (best estimate [BE]), upper bound (UB), and lower bound (LB) soil properties to represent potential variations in in-situ and backfill soil conditions around the building in accordance with SRP Section 3.7.2 (USNRC, 2013a). SSI analysis requires detailed input of the soil layers supporting the structure. Strain dependent soil properties were determined from geotechnical investigations and free field site response analysis. The free-field site response analysis is performed for the LB, BE, and UB soil properties. In accordance with SRP Section 3.7.2, the UB and LB values of the soil shear modulus, *G,* are obtained in terms of their BE through the equations shown below. Equations 3.4-2 and 3.4-3 are used to calculate the low strain properties for the LB and UB. The final soil properties are calculated from the SHAKE2000 program, version 3.5.

$$G_{LB} = \frac{G_{BE}}{(1 + COV)} \quad \text{(Equation 3.4-2)}$$

$$G_{UB} = G_{BE}(1 + COV) \quad \text{(Equation 3.4-3)}$$

Where, *COV* is the coefficient of variation. A COV of 0.5 is used because the site is well-investigated.

3.4.2.3 Combination of Earthquake Components

In order to account for the responses of the structures subjected to the three directional (two horizontal and the vertical) excitations, the maximum co-directional responses are combined using either the square root of the sum of the squares (SRSS) method or the 100-40-40 rule as described in Section 2.1 of Regulatory Guide 1.92, Revision 3, Combining Modal Responses and Spatial Components in Seismic Response Analysis (USNRC, 2012).

3.4.2.4 Seismic Analysis Results

The seismic loads are applied to the structural analysis model as described in Subsection 3.4.2.6 and utilized to develop in-structure response spectra of the facility for use in sizing equipment and components. Response spectra accelerations are output from SASSI at the 75 standard frequencies between 0.2 Hz and 34 Hz as suggested by Regulatory Guide 1.122, Revision 1, Development of Floor Design Response Spectra for Seismic Design of Floor-Supported Equipment or Components (USNRC, 1978). In addition, response spectra accelerations are specified to be output at frequencies of 37 Hz, 40 Hz, 43 Hz, 46 Hz and 50Hz.

3.4.2.5 Assessment of Structural Seismic Stability

The stability of the ~~SHINE~~main production facility is evaluated for sliding and overturning considering the following load combinations and factors of safety in accordance with Section 7.2 of American Society of Civil Engineers (ASCE)/Structural Engineering Institute (SEI) Standard 43-05, Seismic Design Criteria for Structures, Systems, and Components in Nuclear Facilities (ASCE/SEI, 2005) and SRP Section 3.8.5 (USNRC, 2013b):

Load Combination	Minimum Factor of Safety Sliding	Overturning	
$D + H + E'$	1.1	1.1	(Equation 3.4-4)
$D + H + W_t$	1.1	1.1	(Equation 3.4-5)
$D + H + W$	1.5	1.5	(Equation 3.4-6)

Where:

D = Dead Load
H = Lateral Earth Pressures
E' = Earthquake Load
W_t = Tornado Load
W = Wind Load

The base reactions due to seismic forces envelop the reactions due to wind and tornado loading; therefore, a stability analysis for wind and tornado is not required. Seismic excitation in each direction is considered using the 100-40-40 percent combination rule as specified in Subsection 3.4.2.3 above.

The lateral driving forces applicable to the seismic stability evaluation of the ~~SHINE~~main production facility include active lateral soil force, static surcharge lateral soil force, dynamic surcharge lateral soil, dynamic lateral soil force, and seismic lateral inertial force. The resistance for sliding is due to the static friction at the soil-basemat interface for sliding evaluation and passive lateral soil resistance. The self-weight of the structure is considered in the resistance to overturning effects.

3.4.2.6 Structural Analysis of Facility

3.4.2.6.1 Description of the Structures

The ~~SHINE~~main production facility is a box-type shear wall system of reinforced concrete with reinforced concrete floor slabs. The major structural elements in the ~~SHINE~~main production facility include the shear walls, the floor and roof slabs, and the foundation mat.

3.4.2.6.2 Applicable Codes and Standards

- ACI 349-13, Code Requirements for Nuclear Safety-Related Concrete Structures and Commentary (ACI, 2014)
- ANSI/AISC N690-12, Specification for Safety-Related Steel Structures for Nuclear Facilities (ANSI/AISC, 2012)

3.4.2.6.3 Site Design Parameters

The following subsections provide the site-specific parameters for the design of the facility.

3.4.2.6.3.1 Soil Parameters

The soil parameters for the facility are provided below.

- Net allowable static bearing pressure at 3 ft. below grade: 2380 pounds per square foot (psf) (114 kilopascal [kPa]).
- Net allowable static bearing pressure at 17 ft. below grade: 1230 psf (58.9 kPa).
- Minimum average shear wave velocity: 459 ft./sec (140 m/s).
- Minimum unit weight: 117 pounds per cubic foot (lb/ft^3) (1874 kilograms per cubic meters [kg/m^3]).

3.4.2.6.3.2 Maximum Ground Water Level

- 50 ft. (15.2 m) below grade level.

3.4.2.6.3.3 Maximum Flood Level

- Section 2.4 describes the probable maximum precipitation (PMP).
- Section 2.4 describes the probable maximum flood (PMF).

3.4.2.6.3.4 Snow Load

- Snow load: 30 psf (1.44 kPa) (50-year recurrence interval).
- A factor of 1.22 is used to account for the 100-year recurrence interval required.

3.4.2.6.3.5 Design Temperatures

- The winter dry-bulb temperature (-7°F [-22°C]).
- The summer dry bulb temperature (88°F [31°C]).

3.4.2.6.3.6 Seismology

- SSE peak ground acceleration (PGA): 0.20 g (for both horizontal and vertical directions).
- SSE response spectra: per Regulatory Guide 1.60 (USNRC, 2014a).
- SSE time history: envelope SSE response spectra in accordance with SRP Section 3.7.1 (USNRC, 2014b).

3.4.2.6.3.7 Extreme Wind

- Basic wind speed for Wisconsin: 90 miles per hour (mph) (145 kilometers per hour [kph]) (50-year recurrence interval).
- A factor of 1.07 is used to account for the 100-year recurrence interval required.
- Exposure Category C.

3.4.2.6.3.8 Tornado

- Maximum tornado wind speed (Region 1): 230 mph (370 kph).
- Radius of maximum rotational speed: 150 ft. (45.7 m).
- Tornado differential pressure: 1.2 pounds per square inch (psi) (8.3 kPa).
- Missile Spectrum: see Table 2 of Regulatory Guide 1.76 (USNRC, 2007a).

3.4.2.6.3.9 Rainfall

- The ~~SHINE~~main production facility's sloped roof and building configuration preclude accumulation of rainwater; therefore, rain loads are not considered in this evaluation.

3.4.2.6.4 Design Loads and Loading Combinations

3.4.2.6.4.1 Dead Load

Dead loads consist of the weight of all materials of construction incorporated into the building, as well as the following:

- Concrete cover blocks for below grade tanks and trenches.
- Fixed equipment (includes tanks and hot cells).
- Partition walls.
- Precast tank vaults in the RPF.
- Weight of commodities attached to structural elements.
- Crane dead loads as described in Subsection 3.4.2.6.4.6.

3.4.2.6.4.2 Live Load

The building is evaluated for live loads consistent with the use of and occupancy of the facility. This includes minimum live loads driven by occupancy and non-permanent loads caused by equipment or required during plant operations.

The following categories encompass the live loads for the ~~SHINE~~main production facility:

- A distributed live load of 125 psf (5.99 kPa) is used for areas designated as light manufacturing.
- A distributed live load of 250 psf (12.0 kPa) is used for areas designated as heavy manufacturing.

Additionally, the following categories are considered as live loads in the areas where they occur:

- Concrete cover block laydown load.
- Supercell drum export system and shield gate live load.
- Forklift live load associated with the movement of a shipping container throughout the radiologically controlled area (RCA).
- Roof live load.
- Equipment live loading.

3.4.2.6.4.3 Snow Load

The snow load is based on a ground snow load of 30 psf (1.44 kPa) with an importance factor of 1.2 and a mean recurrence interval of 100 years.

3.4.2.6.4.4 Wind Load

The wind load is based on a basic wind speed of 90 mph (145 kph) with an importance factor of 1.15 and a mean recurrence interval of 100 years.

3.4.2.6.4.5 Earthquake Load

Dynamic analysis is conducted with a portion of the loads considered as mass sources in the following manner according to SRP Section 3.7.2 (USNRC, 2013a):

- Dead Load ……100 percent
- Live Load……25 percent
- Snow Load……75 percent
- Parked Crane Load…….100 percent
- Hydrodynamic Load……100 percent

Earthquake load is applied in a SAP2000 model (version 17.2) on an equivalent static basis. The equivalent static model represents the soil as dynamic springs, developed in accordance with ASCE 4-98 (ASCE, 2000). Maximum seismic acceleration at each node of the structure is determined by SSI analysis using SASSI2010, as discussed in Subsection 3.4.2.2. Figures 3.4-3 through 3.4-6 show selected response spectra locations throughout the FSTR.

The SAP2000 and SASSI2010 models are both three-dimensional models that represent the structural elements with equivalent mass and stiffness properties. The lumped masses at each node of the SAP2000 analysis are multiplied by the peak accelerations determined from the SSI analysis to determine an equivalent static earthquake load at each node. The direction of load application is iterated to obtain nine seismic force terms.

3.4.2.6.4.6 Crane Load

The building is evaluated for loads associated with two overhead bridge cranes, one servicing the IU cell area and one servicing the RPF area. Crane loading is evaluated in accordance with American Society for Mechanical Engineers (ASME) NOG-1, Rules for Construction of Overhead and Gantry Cranes (ASME, 2004).

3.4.2.6.4.7 Soil Pressure

Sub-grade walls of the ~~SHINE~~main production facility are designed to resist static lateral earth pressure loads, compaction loads, static earth pressure, dynamic surcharge loads, and elastic dynamic soil pressure loads. Static earth pressure consists of at-rest, active, and passive soil pressure loads, which are applied as required to ensure the stability of the building.

3.4.2.6.4.8 Fluid Load

The hydrostatic loading is calculated based on the actual dimensions of the IU cells and applied in the model as lateral hydrostatic pressure on the walls and vertical hydrostatic pressure on the bottom slabs.

3.4.2.6.4.9 Tornado Load

The tornado load is based on a tornado wind speed of 230 mph (370 kph) and a tornado missile spectrum as described in Table 2 of Regulatory Guide 1.76 (USNRC, 2007a). The tornado load, W_t, is further defined by the following combinations:

$$W_t = W_p \quad \text{(Equation 3.4-7)}$$

$$W_t = W_w + 0.5W_p \quad \text{(Equation 3.4-8)}$$

$$W_t = W_w + 0.5W_p + W_m \quad \text{(Equation 3.4-9)}$$

Where:

W_p = load from tornado atmospheric pressure change

W_w = load from tornado wind

W_m = load from tornado missile impact

3.4.2.6.4.10 Accidental Eccentricity

As required by Section 3.1.1(e) of ASCE 4-98, Seismic Analysis of Safety-Related Nuclear Structures and Commentary (ASCE, 2000), the structure is evaluated for a torsional moment due

to accidental eccentricity. The torsional moment is taken equal to the story shear at the elevation and in the direction of interest times a moment arm equal to 5 percent of the building dimension. The torsional moment is distributed to the building shear walls based on the relative rigidity of the walls in plane. The loads are applied statically and account for variability in the load direction.

3.4.2.6.5 Structural Analysis Model

A three-dimensional finite element model of the ~~SHINE~~main production facility structure was created using the computer program SAP2000 (version 17.2) to represent the mass and stiffness of the major structural elements, equipment, and components of the FSTR. The model utilizes shell elements to represent slabs and walls, and frame elements to represent columns and beams. Elements are modeled at the geometric centerline of the structural member they represent with the following exceptions:

- The below grade and mezzanine slabs are modeled at their actual top-of-slab elevation.
- Minor adjustments are made to the dimensions and locations of wall openings to maximize mesh regularity in the model.
- Roof truss locations are adjusted to align with the roof shell element mesh.

The adjustments described above are intended to maintain mesh regularity to the extent possible.

3.4.2.6.6 Structural Analysis Results

Concrete walls and slabs in the ~~SHINE~~main production facility are designed for axial, flexural, and shear loads per provisions of ACI 349-13 (ACI, 2014) considering all applicable design basis load combinations. Walls and slabs are modeled in SAP2000 using shell elements. To determine the longitudinal and transverse reinforcement required within a wall or slab, the design is performed on an element basis. Using resultant forces obtained from SAP2000 model data, the element is designed as a reinforced concrete section per ACI 349-13 (ACI, 2014). The required area of steel is determined for combined axial and flexural loads, in-plane shear loads, and out-of-plane shear loads. Using these results, reinforcement size and spacing is specified.

3.4.3 SEISMIC CLASSIFICATION AND QUALIFICATION

This subsection discusses the methods by which the SHINE facility SSCs are classified and qualified to ensure functional integrity.

3.4.3.1 Seismic Classification

Facility SSCs, including their foundations and supports, that must perform safety function(s) after an SSE are designated as Seismic Category I. Safety-related SSCs are classified as Seismic Category I.

SSCs that are co-located with a Seismic Category I SSC and must maintain structural integrity in the event of an SSE to prevent unacceptable interactions with a Seismic Category I SSC, but are not required to remain functional, are designated as Seismic Category II.

The seismic classifications of SSCs are shown in Table 3.4-1.

performance of the active components during the tests. For acceptability, the components shall demonstrate their ability to perform their intended safety functions when subjected to all applicable loads.

3.4.3.2.3 Comparison with Existing Databases

ISRS are used to develop RRS for comparison with existing response from a database. The candidate equipment must be similar to equipment in the existing seismic experience databases.

3.4.3.2.4 Combined Methods of Qualification

Based on the available information, component complexity, and functional requirements, the above mentioned analytical and test methods may be combined in various sequence and content to achieve seismic qualification of the subject components.

3.4.4 SEISMIC INSTRUMENTATION

Seismic instrumentation is not required under Section IV(a)(4) of Appendix S to 10 CFR 50 or Section VI(a)(3) of Appendix A to 10 CFR 100 because the ~~SHINE~~main production facility is not a nuclear power plant. However, the facility has nonsafety-related seismic instrumentation to record accelerations experienced at the site during a seismic event.

The seismic instrumentation establishes the acceptability of continued operation of the plant following a seismic event. This system provides acceleration time histories or response spectra experienced at the facility to assist in verifying that safety-related SSCs at the ~~SHINE~~main production facility can continue to perform their safety functions.

Seismic monitoring is performed by the process integrated control system (PICS), which is described in Section 7.3. Indication of a seismic event results in an alarm in the facility control room.

3.4.5 SEISMIC ENVELOPE DESIGN FOR EXTERNAL HAZARDS

3.4.5.1 AIRCRAFT IMPACT ANALYSIS

The safety-related structures at the SHINE facility are evaluated for aircraft impact loading resulting from small aircraft which frequent the Southern Wisconsin Regional Airport (SWRA). The analysis consists of a global impact response analysis and a local impact response analysis.

The global impact response analysis is performed using the energy balance method, consistent with U.S. Department of Energy (DOE) Standard DOE-STD-3014-2006 (DOE, 2006). The permissible ductility limit for reinforced concrete elements is in accordance with Appendix F of ACI 349-13 (ACI, 2014). The permissible ductility limit for truss members is determined from Chapter NB of ANSI/AISC N690-12 (ANSI/AISC, 2012). The calculated values are then used to create the appropriate elastic or elastic-plastic load deflection curves. From these curves, the available energy absorption capacity of the structure at the critical impact locations is determined. The Challenger 605 was selected as the critical aircraft for the global impact analysis based on a study of the airport operations data. The Challenger 605 is evaluated as a design basis aircraft impact. The probabilistic distributions of horizontal and vertical velocity of impact are determined from Attachment E of Lawrence Livermore National

4a2.6 NUCLEAR DESIGN

The irradiation unit (IU) for the ~~SHINE~~main production facility employs an aqueous homogeneous target solution of uranyl sulfate which is irradiated by an external neutron source for production of medical isotopes. The irradiation facility (IF) consists of eight independent IUs, each consisting of the neutron driver assembly system (NDAS), subcritical assembly system (SCAS), primary closed loop cooling system (PCLS), target solution vessel (TSV) off-gas system (TOGS), light water pool, and supporting systems. The tritium purification system (TPS) is shared between the eight IUs. These systems operate in conjunction to achieve conditions and neutron fluxes sufficient to reach desired fission (molybdenum-99 [Mo-99] production) rates. The subsections that follow outline the nuclear parameters and characteristics of the subcritical assembly throughout its life cycle. These analyses show that the system is inherently stable during both steady-state and transient operations.

4a2.6.1 NORMAL OPERATING CONDITIONS

The normal operating conditions for the subcritical assembly are most significantly affected by four factors:

- uranium concentration in the target solution;
- fill height of the TSV;
- target solution temperature; and
- neutron driver neutron generation rate.

The SCAS is designed to remain in the subcritical operating region in all operating modes. The five modes that are used to describe the subcritical assembly status:

- Mode 0 – Solution Removed: No target solution in the SCAS
- Mode 1 – Startup: Filling the TSV
- Mode 2 – Irradiation: Operating mode (neutron driver active)
- Mode 3 – Post-Irradiation: TSV dump valves open
- Mode 4 – Transfer to radioisotope production facility (RPF): Dump tank drain valve opens to permit solution transfer

Modes 1, 2, and 3 are relevant to the nuclear design and are discussed in this section. Figure 4a2.1-2 provides the configuration of the SHINE subcritical assembly and is a useful reference in understanding this subsection and the relationship between components in the different operating modes. These modes are also described in Section 7.3.

Mode 1: Startup Mode

Prior to entering startup mode (filling the TSV), the TSV dump tank is empty and the target solution hold tank is filled with target solution (see Figure 4a2.2-1). Chemical and physical properties of the target solution are described in Subsection 4a2.2.1. The target solution uranium concentration, catalyst concentration, and pH are measured and adjusted as necessary to ensure parameters are within the prescribed technical specification limits. At a minimum, sampling is performed after preparation of a new batch and after making adjustments to an existing batch, prior to transferring the batch to the TSV.

4a2.8 GAS MANAGEMENT SYSTEM

4a2.8.1 SYSTEM DESCRIPTION

The gas management system is the target solution vessel (TSV) off-gas system (TOGS). The TOGS removes radiolysis gases and a portion of the iodine in the gas space from the TSV during irradiation operation and from the TSV dump tank during target solution cooldown to maintain concentrations within safe limits.

The TOGS equipment is located in the TOGS cell and irradiation unit (IU) cell. A total of eight independent instances of TOGS are installed in the ~~SHINE~~irradiation facility (IF), one for each IU. Each instance of TOGS consists of two separate recombiner loops, both of which must be operating during irradiation. One recombiner loop is equipped with hydrogen sensors, oxygen sensors, and a zeolite bed for iodine capture. During a loss of off-site power (LOOP), at least one recombiner loop must continue to operate for a short period of time to assure safe shutdown.

4a2.8.2 SYSTEM PROCESS AND SAFETY FUNCTIONS

The process functions of the TOGS are listed below:

- TOGS sweeps the TSV headspace to dilute radiolytic hydrogen generated by the target solution in the TSV during irradiation, maintaining bulk hydrogen concentration within the primary system boundary (PSB) below the lower flammability limit (LFL) to prevent deflagration during normal operation.
- TOGS sweeps the TSV dump tank headspace to dilute radiolytic hydrogen generated by the target solution in the TSV dump tank during shutdown conditions, maintaining bulk hydrogen concentration within the PSB below the LFL to prevent deflagration during normal operation.
- TOGS absorbs iodine in the sweep gas to maintain iodine concentrations within the PSB gas space below the limits defined by the safety analysis.
- TOGS condenses water vapor generated by the target solution in the TSV and returns the condensate to the TSV to limit water holdup in TOGS to less than 3 liters.
- TOGS captures target solution droplets entrained in the sweep gas and returns them to the TSV to minimize buildup of fissile material in TOGS.
- The sections of the TOGS pressure boundary that form a portion of the PSB provide containment of fission product and decay product gases generated during target solution irradiation and cooldown.
- TOGS maintains the pressure within the PSB slightly sub-atmospheric with respect to the IU cell during normal conditions.

The safety functions of the TOGS are listed below:

- Provide confinement of target solution and fission products as part of the PSB to prevent release of radioactive material that could cause undue risk to health and safety of workers and the public.
- Maintain hydrogen concentrations below values which could result in a hydrogen explosion overpressure capable of rupturing the PSB, preventing release of radioactive material that could cause undue risk to health and safety of workers and the public.
- Remove a portion of the iodine from the sweep gas to mitigate the dose consequences of accidents involving loss of PSB integrity.

5a2.2 PRIMARY CLOSED LOOP COOLING SYSTEM

5a2.2.1 DESIGN BASES AND FUNCTIONAL REQUIREMENTS

The primary closed loop cooling system (PCLS) provides forced convection water cooling to the target solution vessel (TSV) and neutron multiplier during irradiation of the target solution and immediately prior to transferring target solution from the TSV to the TSV dump tank. The PCLS also provides indirect cooling of the light water pool via natural convection heat transfer to the PCLS components submerged in the pool, as described in Subsection 4a2.7.3. The PCLS rejects heat to the radioisotope process facility cooling system (RPCS). A total of eight independent instances of PCLS are installed in the ~~SHINE~~irradiation facility (IF), one for each irradiation unit (IU). There are no common pressure retaining components between the instances of PCLS. The major PCLS equipment is located in the primary cooling room and the IU cell.

Each instance of PCLS includes two pumps, a heat exchanger, and a cooling water clean-up side stream located in the primary cooling rooms adjacent to the east side of each IU cell. In the IU cell, the PCLS is connected to the subcritical assembly system (SCAS) and includes an air separator, an expansion tank, and a nitrogen-16 (N-16) delay tank. Figure 5a2.2-1 provides a PCLS flow diagram.

The process functions of the PCLS cooling system are to:

- remove heat from each TSV and neutron multiplier during full-power IU operation;
- cool the light water pool by natural convection heat transfer to PCLS components inside the light water pool;
- maintain water quality to reduce corrosion and scaling;
- limit concentrations of particulate and dissolved contaminants that could be made radioactive by neutron irradiation;
- reduce N-16 radiation exposure within the primary cooling room in support of as low as reasonably achievable (ALARA) goals; and
- remove entrained gases from the cooling water.

PCLS removes heat from the TSV and neutron multiplier during startup and irradiation by circulating water in an upward direction [ ]PROP/ECI along the exterior surfaces of the TSV and neutron multiplier walls. The subcritical assembly support structure (SASS) provides the shell side pressure boundary to direct the cooling water flow past the TSV and neutron multiplier. The PCLS is attached to the SASS upper and lower plenums.

PCLS is designed to remove a minimum of 580,000 British thermal units per hour (Btu/hr) (170 kilowatts [kW]) of heat from each IU during full-power operation and during shutdown conditions when target solution is in the TSV.

PCLS is designed to maintain the pressure of the cooling water in the SASS higher than the internal pressure of the TSV. The TSV is designed and fabricated to prevent target solution from leaking into the PCLS. See Section 4a2.4 for additional information related to the TSV.

The PCLS cleanup side stream maintains system cooling water quality. The PCLS is designed to operate without corrosion inhibiting chemicals in the process fluid. The cleanup side stream can

5a2.7 NITROGEN-16 CONTROL

Nitrogen-16 (N-16) is generated in the PCLS and light water pool by the neutron activation of oxygen. The N-16 control is provided by the primary closed loop cooling system (PCLS) delay tank. As shown in Figure 5a2.2-1, a liquid delay tank is located downstream of the air separator, in the PCLS cooling loop flow path.

The N-16 delay tank provides additional holdup time to allow for sufficient decay of N-16 prior to exiting the shielding to meet with as low as reasonably achievable (ALARA) goals and the radiation protection program. In addition, to allowing a portion of the N-16 to decay, a reduction in shielding wall thickness is realized as well as a reduction in the PCLS equipment radiation tolerance requirements.

The PCLS uses an air separator to remove entrained gases from the cooling water flow path. The PCLS air separators are vented to the headspace of the corresponding IU cell expansion tank inside the primary confinement boundary. The headspace of the PCLS expansion tank accepts separated gases, including N-16, and directs those gases via vent lines through the primary confinement boundary and into the radiological ventilation zone 1 exhaust (RVZ1e). The gas volumes of the expansion tank headspace and vent lines are sufficient to allow adequate decay of N-16 prior to the gases leaving the IU cell shielding.

Subsection 11.1.1 provides a discussion of airborne and liquid radiation sources at the ~~SHINE~~main production facility, including N-16.

6a2 IRRADIATION FACILITY ENGINEERED SAFETY FEATURES

6a2.1 SUMMARY DESCRIPTION

This section provides a summary of the engineered safety features (ESFs) installed in the irradiation facility (IF). Table 6a2.1-1 contains a summary of the ESFs and the IF design basis accidents (DBAs) they are designed to mitigate. Table 6a2.1-2 provides unmitigated and mitigated doses for the public and the worker, with one DBA selected per confinement system, to demonstrate the mitigative effects of the confinements. The same methods described in Section 13a2.2 were used to calculate the unmitigated doses, but with a leak path factor of 1 for both the worker and public. A block diagram for the IF ESFs is provided as Figure 6a2.1-1. This block diagram shows the location and basic function of the structures, systems, and components (SSCs) providing the ESFs in the IF portion of the ~~SHINE~~main production facility.

Confinement Systems

Confinement systems are provided for protection against the potential release of radioactive material to the IF and the environment during normal conditions of operation and during and after DBAs. Passive confinement is performed by physical barriers such as concrete or steel boundaries, sealed access plugs, and sealed doors. The confinement systems provide active isolation of penetrations during and after certain DBAs that include process piping and heating, ventilation, and air conditioning (HVAC) systems penetrating confinement boundaries. The IF uses two confinement systems: (1) the primary confinement barrier for the irradiation unit (IU) cells, target solution vessel (TSV) off-gas system (TOGS) shielded cells, and the IU cell and TOGS cell HVAC enclosures; and (2) the tritium confinement barrier for the tritium purification system (TPS). A detailed description of these confinement systems is provided in Subsection 6a2.2.1.

The accidents for which IF confinement systems are credited are described in detail in Section 13a2.1 and listed in Table 6a2.1-1. The accident sequences in the IF which require confinement are related to the release of irradiated target solution, radioactive off-gas from TOGS, or the release of tritium from the TPS.

The IF confinement systems remain operational during and following any of the DBAs, including seismic events and loss of off-site power. Active components which comprise portions of the confinement boundary are designed to fail safe on a loss of control or actuating power and maintain the integrity of the confinement boundary.

A listing of the automatic isolation valves included in the confinement boundaries is provided in Section 7.4 and Section 7.5.

Combustible Gas Management

The combustible gas management systems perform mitigation functions for the primary system boundary (PSB). The combustible gas management system uses the nitrogen purge system (N2PS), PSB piping, and the process vessel vent system (PVVS) to establish an inert gas flow through the IUs.

One of the functions of the TOGS is to maintain PSB hydrogen concentrations below values which could result in a hydrogen explosion overpressure capable of rupturing the PSB during

6b RADIOISOTOPE PRODUCTION FACILITY ENGINEERED SAFETY FEATURES

6b.1 SUMMARY DESCRIPTION

This section provides a summary of the engineered safety features (ESFs) installed in the radioisotope production facility (RPF). Table 6b.1-1 contains a summary of the ESFs and the RPF design basis accidents (DBAs) they are designed to mitigate. Table 6b.1-2 provides unmitigated and mitigated doses for the public and the worker, with one DBA selected per confinement system, to demonstrate the mitigative effects of the confinements. The same methods described in Section 13a2.2 were used to calculate the unmitigated doses, but with a leak path factor of 1 for both the worker and public. A block diagram for the RPF ESFs is provided as Figure 6b.1-1. This block diagram shows the location and basic function of the structure, system and components (SSCs) providing the ESFs in the RPF portion of the ~~SHINE~~main production facility.

Confinement Systems

Confinement systems provide active and passive protection against the potential release of radioactive material to the environment during normal conditions of operations and during and after a DBA. Passive confinement is performed by physical barriers such as concrete or steel boundaries, sealed access plugs, and sealed doors. The confinement systems provide active isolation of penetrations that include process piping and heating, ventilation, and air conditioning (HVAC) systems penetrating confinement boundaries during and after certain DBAs. The process confinement boundary includes two areas: (1) the supercell confinement, which includes the extraction, purification, and packaging hot cells and the process vessel ventilation system (PVVS) hot cell; and (2) the below grade confinement, which confines the PVVS delay beds, the target solution hold, storage, and waste tanks, the pipe trench and valve pits, and the waste processing tanks. A detailed description of the confinement systems is provided in Subsection 6b.2.1.

The accidents for which confinement is credited are described in detail in Section 13b.1 and listed in Table 6b.1-1. The accident sequences in the RPF which require confinement are related to the release of radioactive liquids and gases from irradiated target solution, waste streams, or processing streams.

The RPF confinement systems remain operational during and following any of the DBAs, including seismic events and loss of off-site power. Active components which comprise portions of the confinement boundaries are designed to fail safe on a loss of actuating power and maintain the integrity of the confinement boundaries.

A listing of the automatic isolation valves included in the confinement boundaries is provided in Section 7.4 and Section 7.5.

Process Vessel Ventilation System Isolation

The PVVS is equipped with isolation valves that actuate to confine and extinguish fires, which may occur in the PVVS carbon guard beds or carbon delay beds. These isolation functions are described in detail in Subsection 6b.2.2. The PVVS is described in detail in Section 9b.6.

CHAPTER 7 – INSTRUMENTATION AND CONTROL SYSTEMS

7.1 SUMMARY DESCRIPTION

The instrumentation and control (I&C) systems provide the capability to monitor and control the SHINE facility systems manually and automatically during normal conditions and maintain the facility in a safe condition under accident conditions.

This chapter describes the design of the I&C systems, including classification, functional requirements and architecture, and demonstrates the systems' capabilities to perform safety and nonsafety-related functions. The scope of the information provided in this chapter includes systems that are safety-related as defined by SHINE's Quality Assurance Program Description and nonsafety-related I&C systems that perform specific regulatory required functions.

Section 7.1 provides an introduction and overview of I&C systems, which include safety-related and nonsafety-related systems. Systems and topics addressed in this chapter include:

- the process integrated control system (PICS)
- the target solution vessel (TSV) reactivity protection system (TRPS)
- the engineered safety feature actuation system (ESFAS)
- the highly integrated protection system (HIPS) underlying TRPS and ESFAS
- facility control room control consoles and displays
- radiation monitoring, including
  - safety-related process radiation monitors considered part of the ESFAS, TRPS, and tritium purification system (TPS)
  - nonsafety-related process radiation monitors included as part of other facility processes
  - the radiation area monitoring system (RAMS)
  - the continuous air monitoring system (CAMS)
  - the stack release monitoring system (SRMS)
  - the criticality accident alarm system (CAAS)
- the neutron flux detection system (NFDS)

The architectural design of I&C systems is based on providing clear interconnection interfaces of facility I&C structures, systems, and components. Each irradiation unit (IU) has an independent safety-related TRPS and NFDS. A single nonsafety-related PICS provides the nonsafety functions of the IUs and facility level nonsafety-related functions. An ESFAS is provided for safety-related functions that are common to the entire facility. The CAAS, RAMS, CAMS, and SRMS provide their functions at a facility level separate from the irradiation units.

A simplified block diagram of the overall I&C system architecture is provided in Figure 7.1-1.

7.1.1 PROCESS INTEGRATED CONTROL SYSTEM

The PICS is a nonsafety-related distributed digital control system that provides monitoring and control of the various processes throughout the ~~SHINE~~main production facility. The PICS includes system controls, both automated and manual, and human system interfaces (HSIs) necessary to provide the operator interaction with the necessary process control mechanism. The HSIs are provided in the facility control room (FCR) and are described in Section 7.6.

The principal functions of the PICS are to control and monitor facility systems and components. This includes systems and components within the irradiation facility (IF). PICS also interfaces with the systems and components in the radioisotope production facility (RPF).

The functions of the PICS enable the operator to perform irradiation cycles, transfer target solution to and from the IU as well as throughout the RPF, and interface with the TPS, processes in the supercell, waste handling operations, and the auxiliary systems.

The PICS is further described in Section 7.3.

7.1.2 TARGET SOLUTION VESSEL REACTIVITY PROTECTION SYSTEM

The purpose of the TRPS is to monitor process variables and provide automatic initiating signals in response to off-normal conditions, providing protection against unsafe IU operation during the IU filling, irradiation, and post-irradiation modes of operation. Each IU has its own TRPS, configured as shown in Figure 7.1-2. The major safety function of the TRPS is to monitor variables associated with the IU and trip the neutron driver and actuate the engineered safety features when specified setpoints, based on analytical limits, are reached or exceeded.

The TRPS maintains the modes of operation of the IU and creates the necessary interlocks and permissives on each safety function needed for the different modes. Modes are transitioned sequentially using an operator input.

The TRPS also transmits status and information signals to the nonsafety-related maintenance workstation (MWS) and to the PICS for display in the FCR, trending, and historian purposes.

The TRPS is built utilizing the HIPS as described in Subsection 7.1.4. HIPS is a field programmable gate array (FPGA)-based system. The TRPS incorporates the fundamental I&C principles of independence, redundancy, predictability and repeatability, and diversity and defense-in-depth as used by the HIPS platform.

The TRPS includes the following safety-related (except where noted otherwise) components:

- three divisions of input modules, signal conditioning, and trip determination
- two divisions of power distribution panels
- power supplies for sensors and TRPS components
- two nonsafety-related MWSs
- two divisions of voting and actuation equipment
- manual input switches

The boundary of the TRPS extends from the terminations of the cabling at the output of the sensors to the terminations of the cabling to each actuation component of the TRPS.

The TRPS is further described in Section 7.4.

7.1.3 ENGINEERED SAFETY FEATURES ACTUATION SYSTEM

The purpose of the ESFAS is to monitor process variables and provide automatic initiating signals in response to off-normal conditions, providing protection against unsafe conditions in the ~~SHINE~~main production facility. The ESFAS is a plant level control system not specific to any

- Enable nonsafety disabled
- Manual controls from the PICS

Discrete logic is used for the APL for actuation of components based on the prioritization design. PICS is only allowed control by the APL logic if the enable nonsafety enable permissive signal is active and no manual or automated protective functions are present.

The circuitry of the APL is designed so that, when an actuation signal is received, either through the safety data path or manually through the HWM, the APL ensures the action carries through until completion. Upon a reset of the sense and command features, the APL continues to hold the actuated components on the requested position until deliberate operator action is taken to change the component's state.

7.1.5 CONTROL CONSOLE AND DISPLAYS

The operator workstations and main control board are provided as the HSI subset of components for the FCR. These components are included as part of the PICS and are classified as nonsafety-related.

The two operator workstations provide operators with interactive displays to perform daily activities for the ~~SHINE~~main production facility. The displays at the operator workstation are capable of being changed to the appropriate screen applicable to the activities that the operator is performing during day-to-day operations of the ~~SHINE~~main production facility.

The main control board, located in front of the two operator workstations, includes both digital displays and limited manual interfaces.

The main control board provides the operator with multiple digital displays, configured to continuously display variables important to safety-related system status for individual IUs and the balance of the main production facility. The displays on the main control board are used to support manual actuation of safety-related systems and to verify correct operation of the safety-related systems in the event of an actuation.

The main control board provides operator interfaces for:

- manual actuation of the TRPS and ESFAS protective functions,
- the enable nonsafety function, which allows PICS control of the APL output state (i.e., deenergized or energized), and
- the facility operating permissive key, which is used to place the ~~SHINE~~main production facility into a secure state.

The supervisor workstation is located at the rear of the facility control room and acts as an extension of the operator workstations. The supervisor workstation is equipped with equipment display screens that allow the supervisor to monitor system status, but not control facility components.

Facility controls are designed and located using consideration of human factors engineering principles. The SHINE Human Factors Engineering Program is used to facilitate the safe, efficient, and reliable performance of operations, maintenance, tests, inspections, and

surveillance tasks, and to ensure the implementation of operator interfaces, indicators, and controls are standardized across vendors.

These systems are further described in Section 7.6.

7.1.6 RADIATION MONITORING

Radiation monitoring is used to monitor radiation levels within the SHINE facility, to provide alarms for personnel within the facility and the control room, to provide actuation signals to safety-related control systems, and to monitor airborne effluent streams from the facility.

Safety-related process radiation monitoring is performed by ESFAS, TRPS and TPS radiation monitors. These monitors provide input into the safety-related controls to provide input for safety actuations and interlocks, and provide indication and alarm signals to the FCR.

Nonsafety-related process radiation monitors are used in select facility processes to provide status information and diagnose off-normal process conditions.

Area radiation monitoring and local alarms within the general areas of the facility radiologically controlled area (RCA) are provided by the RAMS. This nonsafety-related system also provides signals to the FCR to inform operators of abnormal conditions within the facility.

Airborne contamination monitoring within general areas of the facility RCA is performed by the CAMS. The CAMS units are nonsafety-related devices that provide local alarms and provide signals to the FCR to inform operators of the occurrence and approximate location of abnormal conditions.

Normal airborne facility effluents are directed into a single facility stack and are monitored by the stack release monitor. An alternate safety-related vent path for the nitrogen purge system is monitored by the carbon delay bed effluent monitor. These nonsafety-related effluent monitors provide control room indication and alarm. The ~~SHINE~~main production facility does not have a normal liquid effluent path from the RCA, and as such no liquid effluent monitoring system is provided.

Criticality accident monitoring and alarm is provided by the facility CAAS. The CAAS provides alarms both locally and within the FCR.

These systems are further described in Section 7.7.

7.1.7 NEUTRON FLUX DETECTION SYSTEM

The NFDS is used for monitoring the reactivity and power of the subcritical assembly system in the IU. The NFDS is a safety-related system with redundant channels of neutron flux detectors. The NFDS detects and provides remote indication of the neutron flux levels during TSV filling and irradiation to determine the multiplication factor and power levels, respectively. The NFDS provides safety-related outputs to the TRPS used for trip determination. The NFDS also provides nonsafety-related outputs to the PICS, which are used for monitoring of conditions within the IU.

Three watertight fission chamber NFDS detectors are provided for each IU, located in the light water pool surrounding the subcritical assembly support structure (SASS).

The physical layer of a CM used for intradivisional communication is a multidrop topology; however, the flexibility afforded by FPGAs allows implementation of a simple virtual point-to-point communication protocol. Autonomous modules allow for simpler component testing, implementation, and integration.

Use of fundamentally different FPGA architectures provides a simple and verifiable approach to equipment and design diversity. By simply implementing safety functions on an SFM based on its inputs, safety functions have been segmented to provide functional diversity. The discrete and programmable logic circuits on an EIM provide a clear distinction between those portions that are and are not vulnerable to a software common cause failure (CCF). These diversity attributes simplify the TRPS and ESFAS systems design by not having to install a separate diverse actuation system to address software CCF concerns.

Implementation of triple redundant communication within a division of a HIPS platform increases the number of components (e.g., additional communication modules) but provides simpler maintenance and self-testing. A single communication path would be vulnerable to undetectable failures. Failure of a data path or CM with triple redundant communication is simpler in comparison. A single failure does not cause all safety functions of that division to be inoperable.

Functions within the FPGA of each module are implemented with finite state machines in order to achieve deterministic behavior. Deterministic behavior allows implementation of a simple communication protocol using a predefined message structure with fixed time intervals. This simple periodic communication scheme is used throughout the architecture. Communication between SFMs and CMs is implemented through a simple and well-established RS-485 physical layer. The configurable transmit-only or receive-only ports on a communication module use a point-to-point physical layer. Communication between modules is done asynchronously which simplifies implementation by avoiding complex syncing techniques.

The NFDS is an analog system with no digital communications.

7.2.3 SYSTEM DESCRIPTION

In the ~~SHINE~~main production facility, instrumentation and controls are composed of the following systems:

- PICS
- TRPS
- ESFAS
- facility control room control consoles and displays
- radiation monitoring, including
  - the radiation area monitoring system (RAMS)
  - the continuous air monitoring system (CAMS)
  - safety-related process radiation monitoring considered part of the ESFAS and tritium purification system (TPS)
  - nonsafety-related process radiation monitoring included within individual process systems

7.3 PROCESS INTEGRATED CONTROL SYSTEM

The process integrated control system (PICS) is a nonsafety-related digital control system that performs various functions throughout the ~~SHINE~~main production facility. PICS functions include signal conditioning, system controls, interlocks, and monitoring of the process variables and system status.

7.3.1 DESIGN CRITERIA

Table 3.1-1 shows the SHINE design criteria applicable to the PICS. The SHINE design criteria are described in Section 3.1.

Additional criteria applicable to the PICS are as follows:

7.3.1.1 Access Control

PICS Criterion 1 - The PICS design shall incorporate design or administrative controls to prevent/limit unauthorized physical and electronic access to critical digital assets (CDAs) during the operational phase, including the transition from development to operations. CDAs are defined as digital systems and devices that are used to perform or support, among other things, physical security and access control, safety-related functions, and reactivity control.

7.3.1.2 Software Requirements Development

PICS Criterion 2 - A structured process, which is commensurate with the risk associated with its failure or malfunction and the potential for the failures challenging safety systems, shall be used in developing software for the PICS.

PICS Criterion 3 - The PICS software development life cycle process requirements shall be described and documented in appropriate plans which shall address verification and validation (V&V) and configuration control activities.

PICS Criterion 4 - The configuration control process shall assure that the required PICS hardware and software are installed in the appropriate system configuration and ensure that the correct version of the software/firmware is installed in the correct hardware components.

7.3.1.3 Fail Safe

PICS Criterion 5 - The PICS shall assume a defined safe state with loss of electrical power to the PICS.

7.3.1.4 Effects of Control System Operation/Failures

PICS Criterion 6 - The PICS shall be designed so that it cannot fail or operate in a mode that could prevent the target solution vessel (TSV) reactivity protection system (TRPS) or engineered safety features actuation system (ESFAS) from performing their designated functions.

7.3.1.5 Operational Bypass

PICS Criterion 7 - Bypasses of PICS interlocks, including provisions for testing, shall be under the direct control of a control room operator and shall be indicated on control room displays.

7.3.1.6 Surveillance

PICS Criterion 8 - Subsystems of and equipment in the PICS shall be designed to allow testing, calibration, and inspection to ensure functionality.

PICS Criterion 9 - Testing, calibration, and inspections of the PICS shall be sufficient to confirm that surveillance test and self-test features address failure detection, self-test capabilities, and actions taken upon failure detection.

7.3.2 DESIGN BASIS

The PICS is designed to allow the operator to perform irradiation cycles, transfer target solution to and from the irradiation unit (IU) as well as through the radioisotope production facility, and interface with the tritium purification system (TPS), supercell, waste handling, and auxiliary systems.

The modes of operation for the functions of the PICS that interface with individual IUs correspond to the mode of that IU (see Subsection 7.3.3). Portions of the PICS that monitor or control common or facility-wide systems are not mode-dependent.

The PICS control cabinets are located in the non-radiologically controlled areas of the main production facility and PICS components are in various plant areas with varying environmental conditions. The PICS is designed for the normal environmental and radiological conditions provided in Tables 7.2-1 through 7.2-6.

7.3.3 DESCRIPTION

The PICS is a collection of instrumentation and control equipment located throughout the facility to support monitoring, indication, and control of various systems. Decentralized implementation of the PICS functions allows subsets of the system to perform functions independent of each other. A portion of the PICS supports the main control board and operator workstations in the facility control room by receiving operator commands and collecting and transmitting facility information to the operators, as described in Section 7.6. A summary of the PICS facility system interfaces is provided in Figure 7.3-1.

7.3.3.1 Irradiation Unit Systems

The PICS is used to monitor parameters and perform manual and automatic actions during each of the operational modes of a subcritical assembly system (SCAS):

Mode 0 - Solution Removed: No target solution in the SCAS
Mode 1 - Startup: Filling the TSV
Mode 2 - Irradiation: Operating mode (neutron driver active)
Mode 3 - Post-Irradiation: TSV dump valves open
Mode 4 - Transfer to RPF: Dump tank drain valve opens to permit solution transfer

7.4 TARGET SOLUTION VESSEL REACTIVITY PROTECTION SYSTEM

7.4.1 SYSTEM DESCRIPTION

The target solution vessel (TSV) reactivity protection system (TRPS) performs various design basis safety functions for accelerator-based irradiation processes taking place within each irradiation unit (IU) cell of the ~~SHINE~~main production facility. While operating, the TRPS performs various detection, logic processing, control, and actuation functions associated with the SHINE irradiation process. The TRPS includes input/output capabilities necessary to interface with various indications and control components located within the facility control room. The TRPS also provides nonsafety-related system status and measured process variable values to the facility process integrated control system (PICS) for viewing, recording, and trending.

The TRPS monitors variables important to the safety functions of the irradiation process during each operating mode of the IU to perform one or more of the following safety functions:

- IU Cell Safety Actuation
- IU Cell Nitrogen Purge
- IU Cell TPS Actuation
- Driver Dropout

The TRPS also performs the nonsafety defense-in-depth Fill Stop function.

The TRPS monitors the IU cell from filling of the TSV through irradiation of the target solution, dumping of the target solution, and transfer of the target solution to the radioisotope production facility (RPF). All advances to the modes of operation throughout the irradiation process are manually initiated by the operator and the TRPS implements the required mode-specific system interlocks and bypasses; however, the TRPS does not automatically determine the mode of operation. If at any point during the irradiation process a monitored variable indicating unsafe conditions exceeds its setpoint, the TRPS automatically places the IU into a safe state. The TRPS logic diagrams are shown in Figure 7.4-1.

The TRPS uses redundant and independent sensors through three divisions to complete the logical decisions necessary to initiate the required protective trips and actuations. When a TRPS input channel exceeds a predetermined limit, the trip determinations from each division of the TRPS are sent to voting logic where a two-out-of-three coincident logic vote is performed to initiate a trip or actuation. The general architecture of the TRPS is shown in Figure 7.1-2.

When a TRPS output is in its normal, energized state, it does not control the position of the actuation component. Instead, the TRPS and the PICS are arranged in a series configuration for the PICS to control the component normally, and deenergizing the output of the TRPS forces the component to its safe state via the physical design of the valve or breaker. The only exception to this control configuration is for the nitrogen purge system inerting gas valves, TSV off-gas system (TOGS) radioisotope process facility cooling system (RPCS) supply and return isolation valves, TOGS nitrogen vent isolation valves, and the radiological ventilation IU cell dampers. For these components, the TRPS assumes normal control, and PICS only has control of the component when appropriate permissives are active.

7.5 ENGINEERED SAFETY FEATURES ACTUATION SYSTEM

7.5.1 SYSTEM DESCRIPTION

The engineered safety features actuation system (ESFAS) is a three-division safety-related instrumentation and control (I&C) system that performs various control and actuation functions credited by the SHINE safety analysis as required to prevent the occurrence or mitigate the consequences of design basis events within the ~~SHINE~~main production facility. The ESFAS provides sense, command, and execute functions necessary to maintain the facility confinement strategy and provides process actuation functions required to shutdown processes and maintain processes in a safe condition. The ESFAS also provides nonsafety-related system status and measured process variable values to the facility process integrated control system (PICS) for viewing, recording, and trending.

The ESFAS monitors variables important to the safety functions for confinement of radiation and tritium within the irradiation facility (IF) and the radioisotope production facility (RPF) and for criticality safety to perform the following functions:

- Radiologically Controlled Area (RCA) Isolation
- Supercell Isolation
- Carbon Delay Bed Isolation
- Vacuum Transfer System (VTS) Safety Actuation
- Tritium Purification System (TPS) Train Isolation
- TPS Process Vent Actuation
- Irradiation Unit (IU) Cell Nitrogen Purge
- RPF Nitrogen Purge
- Molybdenum Extraction and Purification System (MEPS) [ ]$^{PROP/ECI}$ Isolation
- Extraction Column Alignment Actuation
- Iodine and Xenon Purification and Packaging (IXP) Alignment Actuation
- Dissolution Tank Isolation

The ESFAS monitors the IF and the RPF continually throughout the operation of processes within the main production facility, via the use of radiation monitoring and other instrumentation. Interlocks and bypass logic necessary for operation are implemented within the ESFAS. If at any point a monitored variable exceeds its predetermined limits, the ESFAS automatically initiates the associated safety function. ESFAS logic diagrams are provided in Figure 7.5-1 and the general architecture of the ESFAS is provided in Figure 7.1-3.

7.5.2 DESIGN CRITERIA

The SHINE design criteria are described in Section 3.1. Table 3.1-1 shows the SHINE design criteria applicable to the ESFAS.

7.5.2.1 Access Control

ESFAS Criterion 1 – The ESFAS shall require a key or combination authentication input at the control console to prevent unauthorized use of the ESFAS.

7.6 CONTROL CONSOLE AND DISPLAY INSTRUMENTS

The ~~SHINE~~ facility control room contains the necessary workstations, displays, and control cabinets needed for the operation of the ~~SHINE~~main production facility. Within the facility control room there is a main control board, two operator workstations, and a supervisor workstation. The operator workstations consist of equipment control display screens and human interface equipment, and the main control board consists of status indication panels, static display screens, and manual actuation interfaces. The supervisor workstation is similar to the other operator workstations, with the exception that the display screens, called equipment display screens, are for monitoring purposes only. The main control board, operator and supervisor workstations, and associated control cabinets are considered part of the process integrated control system (PICS). As part of the PICS, the main control board, operator workstations, and supervisor workstation are not credited with performing safety functions and only assist operators in performance of normal operations or diverse actuations to the safety systems.

7.6.1 DESCRIPTION

7.6.1.1 Main Control Board

The main control board is located on the east wall of the facility control room between the two entrances to the room, as shown in Figure 7.6-1. The main control board sits 25 feet wide along the east wall and contains eight status indication panels, each dedicated to a single irradiation unit (IU), and a ninth status indication panel section dedicated to other processes within the facility. The ninth panel for the facility is located between the fourth and fifth IU panel sections.

The static display screens, which show the variables important to the safety functions of the IU and other facility processes, are located on the upper half of the main control board. The configuration of the status indication panels, including the location of the static display screens, is shown in Figure 7.6-2. The static display screens are used by the operator to verify the status of the ~~SHINE~~main production facility. The current mode of operation for each IU is displayed on a static display screen on the associated status indication panel.

Manual actuation interfaces (i.e., physical push buttons and switches), which provide diverse means to actuate automated safety functions, are located in the space directly below the static display screens at each status indication panel, as shown in Figure 7.6-2. In the same area as the manual actuation interfaces, there is an enable nonsafety switch (labeled “E/D” for “Enable/Disable”), which allows operators to enable the PICS ability to manipulate equipment after control had been overwritten by the target solution vessel (TSV) reactivity protection system (TRPS) or the engineered safety features actuation system (ESFAS). Manual actuations are not required to ensure adequate safety of the facility, as described in Chapter 13.

The facility status indication panel also includes the facility master operating permissive (labeled “O/S” for “Operating/Secure”) in the same area as the manual actuation interfaces.

Facility and IU alarms are visually alerted on the main control board above the associated static display screens.

supervisor workstation and status indication panel. The displays and controls are grouped by system to aid the operator in the recognition and operation of the controls. Displays that an operator may use to perform a task are placed such that they are visible from the operator workstation, with the displays most frequently used being placed closest to the operator.

The supervisor workstation is placed and arranged so that the supervisor has a visual of both operator workstations, the displays that the operators are working from, and the main control board. Operator workstations are oriented such that the status indication panels associated with the IUs the operator is responsible for are directly ahead of the operator from the operator workstation. The point where the main control board transitions from displays that are associated from one operator to the next is occupied by the facility status indication panel, as both operators are typically responsible for information on the static display screens located there.

The manual actuation push buttons are located directly below the static display screens so that the operator can be directly monitoring the variables important to the safe operation of the facility when the manual actuation is performed. The use of selector switch and push buttons in the same product line ensure consistency in look and function. These push buttons also include a positive position indication and a protective guard to prevent inadvertent actuation.

7.6.4 OPERATIONAL PERFORMANCE OVERVIEW

7.6.4.1 Displays

Displays of information related to the operation of the ~~SHINE~~main production facility are available to the operator on the workstations and the main control board. The displays at each of the operator workstations, supervisor workstation, and main control board are digital displays. Displays are programed such that the range of the displayed information includes the expected range of variation of the monitored variable.

Each of the variables listed in Table 7.4-1 and Table 7.5-1 is continuously displayed on the static displays of the main control board. The position indication of actuation components identified in Sections 7.4 and 7.5 are also available on the static display screens.

Variables available to the PICS, including the variables from Table 7.4-1 and Table 7.5-1, are available for display on the various PICS displays on the equipment control displays at the operator workstations and supervisor workstation.

Display of interlock and bypass status is available on each of the PICS displays of the equipment control display screens for the equipment or instrument channel that has been bypassed. Bypassed channels for the safety systems are also visible on the maintenance workstation.

Included in displayed variables at the equipment control displays, the following variables associated with a breach of the primary system boundary are uniquely identified:

- TSV level
- TSV dump tank level

Also included in displayed variables at the equipment control displays, the following variables used in determining and assessing the magnitude of radioactive material release are provided for display on equipment control display screens:

7.7 RADIATION MONITORING SYSTEMS

This section describes systems and components that perform radiation monitoring functions within the SHINE facility. Radiation monitoring systems and components include:

- safety-related process radiation monitors included as part of the engineered safety features actuation system (ESFAS), target solution vessel (TSV) reactivity protection system (TRPS), and tritium purification system (TPS);
- nonsafety-related process radiation monitors included as part of other facility processes;
- area radiation monitoring consisting of the radiation area monitoring system (RAMS);
- continuous air monitoring consisting of the continuous air monitoring system (CAMS);
- effluent monitoring consisting of the stack release monitoring system (SRMS); and
- criticality accident monitoring consisting of the criticality accident alarm system (CAAS).

The objective of the radiation monitoring systems is to:

- provide ~~SHINE~~ facility control room personnel with a continuous record and indication of radiation levels at selected locations within processes and within the facility;
- provide local radiation and criticality safety information and alarms for personnel within the facility;
- provide input to safety-related control systems to actuate safety systems; and
- provide the ability to monitor radioactive releases to the environment.

A diagram showing how the facility radiation monitoring systems relate to the overall facility instrumentation and control (I&C) architecture is provided as Figure 7.1-1.

7.7.1 SAFETY-RELATED PROCESS RADIATION MONITORING

7.7.1.1 System Description

Safety-related process radiation monitors provide input to the safety-related ESFAS or TRPS control systems. These components monitor for either fission products (via beta detection) or tritium. Beta detection radiation monitors are part of the ESFAS or TRPS. The type of safety-related process radiation monitor (fission product or tritium) is selected based on the location and identity of the radioactive material present. The ESFAS and TRPS process radiation monitors (beta detection) are intended to detect abnormal situations within the facility ventilation systems and provide actuation signals to the ESFAS controls. Safety-related tritium monitors are part of the TPS. The TPS monitors are installed within various portions of the TPS to detect potential tritium releases, provide actuation signals to the ESFAS controls, and provide interlock inputs to the TRPS controls. Information from safety-related process radiation monitors is displayed in the facility control room on the operator workstations (via the process integrated control system [PICS]).

A list of safety-related process radiation monitors is provided in Table 7.7-1.

Logic diagrams depicting how the safety-related process radiation monitors provide inputs to ESFAS and TRPS are provided in Figures 7.4-1 and 7.5-1.

tritium CAMS unit has a minimum sensitivity of 1 $\mu Ci/m^3$, with a span of at least four decades of monitoring capability.

Alarm setpoints are set conservatively as required to notify workers to potential hazards or significant changes to radiological conditions in the area. Monitors are periodically calibrated using calibration sources that are traceable to factory tests that verified initial calibration and accuracy. The calibration of instrumentation is at least annually and as recommended by the instrument manufacturer. Operation and response tests of instruments are performed consistent with the manufacturer's recommendations and are conducted at a frequency consistent with industry practices.

7.7.4.5 Technical Specifications

There are no technical specifications applicable to the CAMS.

7.7.5 EFFLUENT MONITORING

7.7.5.1 System Description

Effluent monitoring for the facility is provided by the SRMS. The SRMS is composed of two monitoring units: the main facility stack release monitor (SRM), and the carbon delay bed effluent monitor (CDBEM).

The SRM is used to demonstrate that gaseous effluents from the ~~SHINE~~main production facility are within regulatory limits and does not have an accident mitigation or personnel protection function. The SRM performs its function by drawing a representative air sample from the stack and providing a means to measure the air sample for noble gases (continuous measurement) and capturing particulates, iodine, and tritium for collective measurement.

The CDBEM monitors for noble gases at the exhaust of the process vessel vent system (PVVS) carbon delay beds to provide information about the health of the PVVS carbon delay beds and to provide the ability to monitor the safety-related exhaust point effluent release pathway when it is in use. The CDBEM is used on an as needed basis to demonstrate that gaseous effluents from the ~~SHINE~~main production facility are within regulatory limits (e.g., during a loss of off-site power when the normal heating, ventilation, and air conditioning (HVAC) systems and the PVVS are not operating) and does not have an accident mitigation or personnel protection function. Two particulate and iodine filters (redundant configuration) are provided for in-line capturing and collective measurement when the safety-related exhaust point is in use.

The locations of the SRM and CDBEM within the facility ventilation systems are shown in Figure 7.7-1.

7.7.5.2 Design Criteria

The SHINE design criteria are described in Section 3.1. The SHINE design criteria applicable to the SRMS are provided in Table 3.1-2.

LIST OF FIGURES

9a2 IRRADIATION FACILITY AUXILIARY SYSTEMS

9a2.1 HEATING, VENTILATION, AND AIR CONDITIONING SYSTEMS

9a2.1.1 RADIOLOGICALLY CONTROLLED AREA VENTILATION SYSTEM

The radiological ventilation (RV) systems include supply air, recirculating, and exhaust subsystems required to condition the air and provide the confinement and isolation needed to mitigate design basis accidents. The ~~SHINE~~main production facility utilizes three ventilation systems in the radiologically controlled area (RCA) to maintain the temperature and humidity of the RCA and to progress air from areas of least potential for contamination to areas with the most potential for contamination:

- Radiological ventilation zone 1 (RVZ1)
  - RVZ1 recirculating subsystem (RVZ1r)
  - RVZ1 exhaust subsystem (RVZ1e)
- Radiological ventilation zone 2 (RVZ2)
  - RVZ2 exhaust subsystem (RVZ2e)
  - RVZ2 supply subsystem (RVZ2s)
  - RVZ2 recirculating subsystem (RVZ2r)
- Radiological ventilation zone 3 (RVZ3)

Figure 9a2.1-1 provides the ventilation zone designations within the ~~SHINE~~main production facility.

Chapter 6 provides a detailed description of the SHINE confinement strategy for limiting the potential for release of radioactive materials to occupied spaces and the environment.

9a2.1.1.1 Design Bases

The design bases of the RV systems include:

- Provide confinement at ventilation zone 1 confinement boundaries. See Chapter 6 for a description of the specific portions of the RVZ1 system credited as being a confinement boundary.
- Provide isolation at the RCA boundary. See Section 7.5 for a description of the specific portions of the RVZ1, RVZ2, and RVZ3 systems that provide the isolation functions.
- Confine airborne radiological materials in an accident scenario.
- Provide ventilation air and condition the RCA environment for workers.
- Provide makeup air and condition the RCA environment for process equipment.
- Filter exhaust streams prior to them being exhausted out of the RCA.
- Maintain occupational exposure to radiation as low as reasonably achievable (ALARA) and to ensure compliance with the requirements of 10 CFR 20.
- Exhaust hazardous chemical fumes.

Nonsafety-related portions of the RV systems are constructed to the requirements of Chapters SPS 362, SPS 363 and SPS 364 of the Wisconsin Administrative Code. Nonsafety-related piping is designed, installed, tested and inspected in accordance with American Society of Mechanical Engineers (ASME) B31.9, Building Services Piping (ASME, 2017).

Details of the inspection and testing requirements of safety-related RV systems are provided in Subsection 9a2.1.1.5.

9a2.1.1.2 System Description

Radiological Ventilation Zone 1

RVZ1 is divided into two subsystems: RVZ1r and RVZ1e. A flow diagram of RVZ1r is provided in Figure 9a2.1-2. A flow diagram of RVZ1e is provided in Figure 9a2.1-3.

RVZ1r provides cooling for systems within the irradiation unit (IU) cell and the target solution vessel (TSV) off-gas system (TOGS) cell. RVZ1r recirculates, filters, and cools air within the IU cell and the TOGS cell. The system includes two fan coil units and associated ductwork and dampers per each set of IU/TOGS cells. Each set of RVZ1r units is located within the cooling room and forms a portion of the confinement boundary for the IU/TOGS cells that it serves. RVZ1r provides sampling, ventilation, and cleanup connections for the primary confinement.

RVZ1e exhausts air from the areas with a high potential for contamination in the facility. The air is filtered and directed out of the ~~SHINE~~main production facility through the exhaust stack. The subsystem includes fans, filters, ductwork, dampers, and high efficiency filter banks. It also includes the necessary transfer ductwork to allow makeup from the RCA general area into the exhausted areas.

RVZ1e is designed to maintain ventilation zone 1 areas at a lower pressure than ventilation zone 2 areas. The design inhibits backflow with the use of backflow dampers at the discharge of the RVZ1e and RVZ2e exhaust fans in order to minimize the spread of contamination. RVZ1e ductwork provides sampling locations for radiation detectors, fire detection equipment, stack release monitoring, and an exhaust stack connection point for RVZ2e and the process vessel vent system (PVVS).

The RVZ1 serves the following areas:

- IU cells
- TOGS cells
- Tritium purification system (TPS) process equipment
- Primary closed loop cooling system (PCLS) expansion tank
- Uranium receipt and storage system (URSS) glovebox
- Radioactive liquid waste immobilization (RLWI) shielded enclosure
- Supercell
- Target solution preparation system (TSPS) glovebox
- Target solution dissolution tanks
- Target solution preparation tank

Radiological Ventilation Zone 2

RVZ2 includes three subsystems: RVZ2e, RVZ2s, and RVZ2r. A flow diagram of RVZ2e is provided in Figure 9a2.1-4. A flow diagram of RVZ2s air handling units (AHUs) is provided in Figure 9a2.1-5. A flow diagram of RVZ2s distribution and RVZ2r is provided in Figure 9a2.1-6.

9a2.1.1.4 Instrumentation and Control

The RV systems are designed such that the process integrated control system (PICS) monitors the system equipment, flow rates, pressures, and temperatures. Instrumentation monitors the ventilation systems for off-normal conditions and signal alarms as required. The PICS starts, shuts down, and operates the RV system in normal operating modes. Coordinated controls maintain negative pressurization to create flow patterns that direct air toward areas of increasing contamination potential.

PICS monitors the differential pressures across all the filters in the RVZ1e and RVZ2e filter banks and produces an alarm if the differential pressure of any filter is above its established limit.

9a2.1.1.5 Inspection and Testing

The ventilation systems are balanced upon installation. Control systems are tested to assure that control elements are calibrated and properly adjusted. Safety-related isolation dampers are inspected and tested as required by, and in accordance with, Section DA of ASME AG-1, Code on Nuclear Air and Gas Treatment (ASME, 1999). Safety-related ductwork will be inspected and tested as required by, and in accordance with, Section SA of ASME AG-1 (ASME, 1999).

9a2.1.1.6 Nuclear Criticality Safety

Subsection 6b.3.2.7 provides a discussion related to the nuclear criticality safety requirements for the URSS glovebox ventilation. Subsection 6b.3.2.4 provides discussion related to the nuclear criticality safety requirements for the TSPS glovebox ventilation.

9a2.1.1.7 Technical Specifications

Certain material in this subsection provides information that is used in the technical specifications. This includes limiting conditions for operation, setpoints, design features, and means for accomplishing surveillances. In addition, significant material is also applicable to, and may be used for, the bases that are described in the technical specifications.

9a2.1.2 NON-RADIOLOGICAL AREA VENTILATION SYSTEM

The non-radiological area ventilation system is the facility ventilation zone 4 (FVZ4) system.

Ventilation zone 4 consists of areas which are located within the ~~SHINE~~main production facility, but outside of the RCA. The FVZ4 system is completely independent of the RV systems described in Subsection 9a2.1.1. The FVZ4 system supply AHUs draw at least 10 percent outside air to make up for air exhausted and exfiltrated. The outside air is mixed with recirculated air and conditioned through the AHUs before being supplied to FVZ4 areas. FVZ4 exhaust streams exhaust directly to the outside of the ~~SHINE~~main production facility. No radiation detectors are provided in the FVZ4 exhaust, as contamination is not expected to be present in the FVZ4 system.

The FHWS is constructed to the requirements of Chapters SPS 341 and SPS 365 of the Wisconsin Administrative Code. Natural gas piping and natural gas piping installations comply with National Fire Protection Association (NFPA) 54, National Fuel Gas Code (NFPA, 2018), as required by Chapter SPS 365 of the Wisconsin Administrative Code.

9a2.1.4.2 System Description

The FHWS is nonsafety-related.

The FHWS consists of equipment required to deliver heating hot water to RVZ2 and FVZ4 AHUs in non-RCA portions of the ~~SHINE~~main production facility. The boilers, pumps, air separator and expansion tank are in the resource ~~out~~building. Three boilers and three pumps are provided to maintain the system flow rate and supply temperature. When one pump or boiler is down for maintenance, two 50 percent capacity pumps and boilers are capable of meeting system demands. Two pumps each are provided on the FVZ4s subsystem and the RVZ2s subsystem to maintain freeze protection. When one pump is down for maintenance the other can ensure freeze protection.

The primary components of the FHWS include:

- three 50 percent natural gas-fired boilers;
- three 50 percent centrifugal hot water pumps;
- eight 100 percent centrifugal hot water circulating pumps for heating coil freeze protection;
- an air separator; and
- an expansion tank.

9a2.1.4.3 System Operation

A single set of pumps provides flow through both the boilers and the heating coils. The flow through the system is varied by modulating the pump speed based upon maintaining the temperature differential across the boilers. A bypass valve (supply to return) is installed at the end of the coil loop piping to maintain the minimum flow required to operate the pumps.

Each boiler is a natural gas-fired, fully modulating condensing type with high mass and high volume to allow large variations in flow through the boiler with no minimum return water temperature requirement and low water pressure drop.

9a2.1.4.4 Radiation Protection and Criticality Safety

There are no radiation contamination hazards or nuclear criticality safety hazards associated with the FHWS.

9a2.1.4.5 Instrumentation and Control

The FHWS provides the necessary output signal to the PICS for the monitoring of heating water temperatures, pressures, and flow rates. Low water cutoff controls and flow sensing controls are provided which automatically stop the combustion operation of the boiler when the water level drops below the lowest acceptable water level or when water circulation stops. Boilers are equipped with controls and limit devices, as required by the manufacturer.

Figure 9a2.1-1 – Ventilation System Zone Designations Within the ~~SHINE~~Main Production Facility

9a2.5 POSSESSION AND USE OF BYPRODUCT, SOURCE, AND SPECIAL NUCLEAR MATERIAL

This section applies to the possession and use of byproduct, source, and special nuclear material (SNM) within the irradiation facility (IF). Refer to Section 9b.5 for the discussion of possession and use of byproduct, source, and special nuclear material in the radioisotope production facility (RPF).

The IF is designated as a radiologically controlled area as shown in Figure 1.3-1. Radiation protection program controls and procedures, including the as low as reasonably achievable (ALARA) program, applicable to the IF are described in Section 11.1. Radioactive waste management is discussed in Section 11.2. A discussion of the Security Plan is provided in Section 12.8. Discussion of the Emergency Plan is included in Section 12.7. Fire protection details applicable to the IF are described in Section 9a2.3. Technical Specifications include limits that apply to the possession, management, and use of byproduct, source, and SNM.

9a2.5.1 BYPRODUCT MATERIAL

The SHINE facility is designed to generate byproduct materials (e.g., molybdenum-99) for use as medical isotopes. Byproduct materials within the IF include fission and activation products generated during irradiation unit (IU) operations, as well as tritium which is used within the neutron driver assembly system (NDAS) to create deuterium-tritium fusion reactions as described in Section 4a2.1.

The tritium purification system (TPS) controls the distribution and processing of tritium for the NDAS as described in Section 9a2.7. The quantity of tritium within the facility is described in Table 11.1-5. The types and quantities of fission and activation byproduct materials, as well as the systems where these byproduct materials are located, are discussed in Section 11.1.

Additionally, up to eight (alpha, neutron) neutron sources (e.g., Am-241/Be) with combined strength up to [ ]^{SRI} are used, one in each IU, for IU start-up operations, as described in Section 4a2.2.

9a2.5.2 SOURCE MATERIAL

Source materials in the IF include the depleted uranium (DU) within TPS and the natural uranium neutron multiplier within the subcritical assembly. The DU within TPS is used as storage beds for tritium gas as described in Section 9a2.7. The use of source material within the neutron multiplier is described in Section 4a2.2. SHINE uses up to 330 lbs (150 kg) of DU and 51,000 lbs. (23,000 kg) of natural uranium for these purposes.

9a2.5.3 SPECIAL NUCLEAR MATERIAL

Special nuclear material (SNM) in the IF includes low enriched uranium (LEU) within the target solution vessel (TSV). LEU is irradiated to produce molybdenum-99 by fission within the IF. During this process, plutonium is generated in the target solution and the neutron multiplier. Up to [ ]$^{PROP/ECI}$ of LEU are used in the IF to support facility operations. The total LEU inventory for the ~~SHINE~~radioisotope production facility is discussed in Section 9b.5.

Commissioning, maintenance, and disposal activities associated with the NDAS and performed in the NSC are summarized below.

- Commissioning
  An NDAS may be tested in the NSC prior to installation in an IU cell. The NDAS sub-assemblies will be staged, mounted to the supporting pads in the NSC, and assembled with the support of the facility crane. The assembled NDAS is connected to service utilities such as electrical, control, cooling water, and supply gases inside and outside the NSC. The commissioning activities to be carried out in the NSC may include establishing vacuum, helium leak rate testing, filling the pressure vessel with sulfur hexafluoride (SF_6) gas, and beam performance testing.
- Maintenance
  If portions of an NDAS require maintenance or replacement, it may be moved from an IU cell to the NSC. The NDAS is lifted by the IF bridge crane and transferred to the NSC where work can be performed.
- Disposal
  The NSC may also be used to disassemble an NDAS into smaller parts that can fit more easily into containers before sending to an appropriate waste repository.

9a2.7.2.3 Radiological Protection

Gamma radiation monitoring of the NSC is provided to allow for safe operation and interlocking of activities in the NSC. The NSC has a directed airflow system to manage residual tritium contamination of NDAS components. This airflow system maintains the capability to interface with the facility heating, ventilation, and air conditioning (HVAC) through radiological ventilation zone 2 exhaust (RVZ2e). A passive tritium sample collector at the interface to RVZ2e provides a record of tritium content entering RVZ2e from the NSC. The NSC provides a real-time tritium monitor at the interface to the RVZ2e to measure real-time tritium content in exhaust gas from NDAS testing sent to RVZ2e.

The NSC shield walls are made from approximately 24-inch (61 centimeter) thick concrete walls with reinforcing carbon steel bars. Additional local shielding, such as water or polycarbonate blocks, may also be installed during testing in the NSC. Implementation of local shielding in the pit, and around an installed NDAS as necessary, provides radiation shielding during NDAS testing. This local shielding functions in conjunction with the shielding provided by the NSC shield walls and door to maintain occupational exposures to neutron and gamma radiation to within ALARA program goals. Table 11.1-4 provides radiation areas at the ~~SHINE~~main production facility, and includes dose rates to the IF general area during accelerator testing in the NSC. Calculated dose rates during accelerator operation in the NSC are approximately 8 mrem/hr outside the NSC walls. The annual average neutron flux to the NSC surrounding soil is expected to be less than 100 n/cm^2-s.

9a2.7.2.4 Instrumentation and Controls

The NSC provides instrumentation and controls to perform testing of an NDAS to verify proper operation before returning to service. Interlocks for safe testing of the NDAS, such as preventing operation of the NDAS while the service cell door is open are provided. A radiation interlock button located inside the NSC prevents or shuts down operation of the NDAS when actuated by personnel in the NSC.

9b RADIOISOTOPE PRODUCTION FACILITY AUXILIARY SYSTEMS

9b.1 HEATING, VENTILATION, AND AIR CONDITIONING SYSTEMS

The heating, ventilation, and air conditioning (HVAC) systems for the ~~SHINE~~main production facility are common to the irradiation facility (IF) and the radioisotope production facility (RPF). The ~~SHINE~~main production facility HVAC systems are described in Section 9a2.1.

- The quality control and analytical testing laboratories (LABS), as described in Subsection 9b.5.4. The LABS analyze samples containing byproduct materials taken from various locations throughout the SHINE process.
- The target solution staging system (TSSS), as described in Subsection 4b.1.3.5. The TSSS is a set of tanks and piping used to provide staging and storage of irradiated target solution containing byproduct materials.
- The vacuum transfer system (VTS) as described in Subsection 9b.2.5. The VTS provides transfer of radioactive liquids containing byproduct materials throughout the RPF and also provides vacuum service to the MIPS and the TOGS.
- The molybdenum extraction and purification system (MEPS) as described in Subsection 4b.3.1. The MEPS extracts molybdenum from irradiated target solution and prepares a concentrated form of molybdenum.
- The iodine and xenon purification and packaging (IXP) system as described in Subsection 4b.3.1. The IXP extracts iodine from an acidic solution following target solution irradiation.

The types and quantities of byproduct materials within the ~~SHINE~~main production facility are discussed in Section 11.1.

9b.5.1.1 Byproduct Materials Extraction and Purification

Extraction and purification of byproduct materials occur in the MEPS and IXP. The MEPS and the IXP are described in Subsection 4b.3.1. The primary byproduct material separated in the MEPS is molybdenum-99. The primary byproduct materials separated in the IXP are iodine-131 and xenon-133. A batch of molybdenum-99 is up to [ ]$^{PROP/ECI}$ and up to 8 batches of molybdenum-99 may be produced a week. A batch of iodine-131 is up to [ ]$^{PROP/ECI}$ and up to 8 batches of iodine-131 may be produced a week. A batch of xenon-133 is up to [ ]$^{PROP/ECI}$ and up to 8 batches of xenon-133 may be produced a week.

9b.5.2 SOURCE MATERIAL

Source material is not normally possessed or used within the RPF. There is a potential for radioactive waste containing source material to be processed within the RPF. This may include IF components such as tritium storage beds (i.e., depleted uranium) or neutron multipliers. The types and quantities of source material within these components are described in Section 9a2.5. Radioactive waste management is discussed in Section 11.2.

9b.5.3 SPECIAL NUCLEAR MATERIAL

SNM in the RPF includes low enriched uranium (LEU) as well as plutonium generated in irradiated target solution located in systems throughout the RPF. The systems in which SNM may be present in the RPF are:

- The target solution preparation system (TSPS), as described in Subsection 4b.4.2. The TSPS is used to prepare LEU uranyl sulfate solution.
- The RDS, as described in Subsection 9b.7.6. The RDS contains liquids containing SNM collected in the event of a leak, spill, or overflow, and routes these liquids to a controlled location.

- The RLWS system, as described in Subsection 9b.7.4. The RLWS system provides receipt, mixing and storage for liquid radioactive wastes containing SNM generated by processing operations in the RCA.
- The RLWI system, as described in Subsection 9b.7.3. The RLWI system immobilizes liquid radioactive wastes containing SNM.
- The SRWP system, as described in Subsection 9b.7.5. The SRWP system packages solid waste containing SNM.
- The TSSS, as described in Subsection 4b.4.1.1. The TSSS is a set of tanks and piping used to provide staging and storage of LEU uranyl sulfate target solution.
- Uranium receipt and storage system (URSS), as described in Subsection 4b.4.2. The URSS provides for receipt and storage of LEU metal and LEU oxide and converts LEU metal to LEU oxide.
- The LABS, as described in Subsection 9b.5.4. The LABS analyze samples containing SNM taken from various locations throughout the SHINE process.
- The VTS, as described in Subsection 9b.2.5. The VTS provides transfer of radioactive liquids containing SNM throughout the RPF.
- The MEPS, as described in Subsection 4b.1.3.2. The MEPS extracts molybdenum from irradiated target solution. SNM is only present in significant quantities in MEPS while extraction of molybdenum is taking place.
- The IXP system, as described in Subsection 4b.1.3. The IXP system extracts iodine from an acidic solution following target solution irradiation. SNM is only present in significant quantities in IXP while extraction of iodine is taking place.

Up to 6600 lbs. (3000 kg) of LEU, representing the total inventory of LEU for the ~~SHINE~~main production facility, is used in the RPF to support facility operations.

9b.5.4 QUALITY CONTROL AND ANALYTICAL TESTING LABORATORIES

The quality control and analytical testing laboratories (LABS) consist of the wet laboratory and the instrument laboratory. The LABS are located in the RPF.

9b.5.4.1 Design Basis

The LABS design basis is to provide analytical laboratory support relative to the production of molybdenum-99, iodine-131, xenon-133, qualification and production of target solution, and analysis of other process samples, as necessary. Analysis is used to determine: (1) enrichment, purity, and conversion of uranium; (2) identification, activity, concentration, and purity of molybdenum-99, iodine-131, and xenon-133 products; (3) process stream chemical and radionuclide analyses; and (4) chemical and radionuclide analysis for waste characterization and disposition.

9b.5.4.2 System Description

The LABS analyze samples taken from various locations throughout the SHINE process. The system processes samples using two adjacent laboratories designated the wet lab and the instrument lab which are further described below. The wet lab is used for sample preparation, and the instrument lab is used for sample analysis. The purpose of separating these two labs is to decrease the likelihood for cross-contamination and to protect the analytical instrumentation from exposure to environments that may impact calibration and accuracy.

9b.6 COVER GAS CONTROL IN THE RADIOISOTOPE PRODUCTION FACILITY

This section discusses radiolytic gas management systems located in the radioisotope production facility (RPF) that manage radioactive gases associated with SHINE facility processes.

9b.6.1 PROCESS VESSEL VENT SYSTEM

The process vessel vent system (PVVS) collects and treats the off-gases from processes in the ~~SHINE~~main production facility. The PVVS collects off-gases from each RPF tank containing irradiated solutions, from the vacuum transfer system (VTS) vacuum pump discharge, and periodically from the target solution vessel (TSV) off-gas system (TOGS). The PVVS consists of acid adsorbers, carbon filters, high-efficiency particulate air (HEPA) filters, condensers, reheaters, carbon beds, and blowers which are employed to vent treated gases out of the radiologically controlled area (RCA). A description of system interfaces is provided in Table 9b.6-1.

9b.6.1.1 Design Bases

The design bases of the PVVS include:

- Mitigate radiolytic hydrogen generation in the headspace of RPF tanks and vessels;
- Capture radioiodine from the off-gas stream;
- Delay the release of radioactive noble gases in gaseous effluents to the environment;
- Filter radioactive particulates from the gaseous effluents;
- Maintain RPF tanks and vessels at a negative pressure;
- Accept VTS vacuum pump discharge;
- Accept TOGS pressure relief discharge;
- Accept purges of TOGS, resulting from either a loss of TOGS capability to mitigate radiolytic hydrogen generation or maintenance requirements;
- Accept any sweep gases from TOGS used to purge gas analyzer instrumentation;
- Condition collected off-gas to improve reliability and performance of filtration equipment; and
- Discharge off-gases to the facility stack.

9b.6.1.2 System Description

The PVVS provides radiolytic hydrogen mitigation capability for the RPF by ventilating the process tanks and vessels. The PVVS also accepts gases discharged from VTS and TOGS. Flows from VTS and TOGS include vacuum pump discharge, sweep gas from gas analyzer instruments, nitrogen purges, and pressure relief. PVVS blowers upstream of the stack induce flow through the ventilation system. Flow rate requirements for PVVS are constant for nominal ventilation in the RPF but increase when tanks are sparged for mixing, when VTS is operating, or during TOGS transients such as a purge during fill or maintenance, or pressure relief. PVVS equipment is designed for the maximum off-gas flow rate that could require processing at any one time.

The off-gases are processed to remove or delay iodine, noble gases, and radioactive particulates prior to gas being discharged to the facility stack. PVVS blower placement results in the system being maintained at a negative pressure relative to ventilation zone 2. Intakes

nitrogen supply that is piped into the main production facility. A liquid nitrogen supply line upstream of the vaporizers supplies liquid nitrogen from the bulk storage tank into the main production facility via vacuum jacketed cryogenic piping.

The FNHS supplies liquid nitrogen to an adjustable pressure phase separator inside the main production facility that has the capability to store and deliver high quality liquid nitrogen to the TPS. Liquid nitrogen is supplied to a fill station inside the main production facility. The fill station is installed to fill portable dewars for the disbursement of liquid nitrogen in small quantities as needed by facility processes. Liquid nitrogen dewars supplying the IXP are equipped with an excess flow check valve for the protection of supercell and downstream equipment. Off-gassing from the FNHS phase separator and fill station are ventilated through a connection to the radiological ventilation zone 2 exhaust subsystem (RVZ2e) inside the IF.

Inside the RCA a portion of the nitrogen supply gas is piped to a main receiver storage tank which feeds the FNHS ring header. The remainder of the nitrogen supply gas is piped to the TPS room serving the TPS.

A FNHS remote receiver tank is maintained on the FNHS ring header to supply abrupt demands and provide consistent nitrogen gas flow and pressure to all serviced areas in the RCA. The FNHS ring header supplies nitrogen gas to sampling equipment, tank sparging and mixing equipment, and level indication equipment. The FNHS ring header supplies nitrogen gas to each FNHS cooling room receiver tank where it is used by TOGS.

Table 9b.7-5 identifies the systems which interface with the FNHS. Figure 9b.7-6 provides a process flow diagram for the FNHS.

9b.7.8.3 Operational Analysis and Safety Function

The FNHS bulk liquid nitrogen storage tanks are continuously pressurized by the naturally occurring liquid to gas phase change inside the tank with the presence of liquid nitrogen. The FNHS bulk liquid nitrogen storage tank head space pressure is regulated to provide flow to the vaporizer. A pressure relief system with a vent path to the atmosphere is maintained on each bulk liquid storage tank to prevent overpressurization of the vessel.

Liquid nitrogen is directed from the pressurized bulk storage tank to vaporizers where it is heated and vaporized to nitrogen gas. The gaseous nitrogen supply is regulated through a control manifold designed to control the pressure and prevent possible liquid carryover to the FNHS end users. The FNHS bulk liquid nitrogen storage tank and vaporizers supply nitrogen gas to the main FNHS receiver tank, the facility nitrogen gas ring header, and the FNHS remote receiver tank located inside the RCA. The control manifold ensures that adequate pressure is maintained within the main production facility. Overpressure protection is provided on the FNHS gaseous facility supply line.

The FNHS cooling room receiver tanks are filled from the facility nitrogen gas ring header by opening a normally closed manual valve allowing flow to the tank corresponding to the actuated valve. Once pressure has equalized the valve is closed and the tank is placed in service.

Redundant isolation upstream of the cooling room remote receiver tanks ensures that a direct path from the atmosphere inside confinement boundaries to outside those areas are not created. The manual isolation provided is maintained normally closed and administrative controls ensure

LIST OF TABLES

CHAPTER 11 – RADIATION PROTECTION PROGRAM AND WASTE MANAGEMENT

11.1 RADIATION PROTECTION

11.1.1 RADIATION SOURCES

The SHINE facility is designed to generate molybdenum-99 (Mo-99) for use as a medical isotope. The process of producing Mo-99 involves irradiating a uranyl sulfate target solution with a neutron source in a subcritical assembly to cause fission. Irradiation of the target solution creates Mo-99 along with other radioactive fission and activation products. When the irradiation cycle is complete, the radioactive materials are transferred to various locations in the facility to complete the separation and purification processes. This section identifies sources of radiation and radioactive materials received, used, or generated in the facility; sources and the nature of airborne, liquid or solid radioactive materials; and the type of radiation emitted (alpha, beta, gamma, and neutron).

Analysis has been performed that quantifies the radionuclide inventory for normal operations in the ~~SHINE~~main production facility. The highest radionuclide inventory for one target solution batch exists in the target solution vessel (TSV) at the end of the irradiation cycle. As the target solution is processed in the facility for Mo-99 and other medical isotope extraction, solution adjustments, and waste handling, radiation sources are transferred within the facility by means of pipes in shielded trenches.

There are two scenarios with assumptions listed in Table 11.1-1: nominal and safety basis. The nominal parameter values or ranges are the best estimate operating conditions for full power operation of the facility. The safety basis parameter values define the bounding radionuclide inventory relative to the TSV, TSV dump tank, and supercell.

The safety basis inventories throughout the facility are generated by using the limiting values for each parameter to maximize the individual inventories. This includes using bounding values for element partitioning during the extraction process. This approach of maximizing inventories at each location results in an overall facility fission product inventory that is greater than originally generated in the irradiation process. This ensures that the individual safety basis inventories are bounding when being used to calculate releases for the safety analysis but makes them unsuitable for use in analyzing normal operations.

Operation of the TSV results in the production of radioactive fission products and actinides predominantly through neutron capture in uranium. Table 11.1-2 provides a summary of the results for total activity in curies (Ci) from actinides and fission products contained within each TSV batch of target solution after [ ]$^{PROP/ECI}$ of irradiation, [ ]$^{PROP/ECI}$ nominal cycles or [ ]$^{PROP/ECI}$ safety basis cycles. The “at shutdown” values represent the activity contained within the target solution immediately after shutdown of the neutron driver. The “pre-extraction” values are the target solution activity when it is ready to be transferred from the TSV dump tank in the irradiation unit (IU) cell to one of the supercells in the radioisotope production facility (RPF) to begin the molybdenum extraction process. This represents the maximum expected activity for a target solution batch as it is processed through the RPF. For the nominal inventory, the “post extraction” values are the activity remaining in the target solution following extraction of Mo and other elements according to best estimate partitioning fractions. For the safety basis inventory, only noble gases were removed during extraction, at bounding (low) element partitioning fractions.

Table 11.1-3 lists the activity associated with the radionuclides listed in NUREG/CR-4467, Relative Importance of Individual Elements to Reactor Accident Consequences Assuming Equal Release Fractions (USNRC, 1986) for the nominal and safety basis radionuclide inventories after [ ]PROP/ECI of irradiation and the subsequent decay time in the TSV dump tank. At this time, it is ready to be pumped into the supercell to begin the molybdenum extraction and fission product removal processes. The cycle and decay times used for the radionuclide inventory generation are listed in Table 11.1-1.

SHINE uses the following radiation area designations, as defined in 10 CFR 20, including consideration for neutron and gamma dose rates:

- Unrestricted Area means an area to which access is neither limited nor controlled by SHINE. This would be the area beyond the site boundary.
- Radiation Areas (RAs) are those accessible areas in which radiation levels could result in an individual receiving a dose equivalent in excess of 5 millirem (mrem) in 1 hour (hr) at 30 centimeters from the radiation source or from any surface that the radiation penetrates.
- High Radiation Areas (HRAs) are those accessible areas in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 100 mrem in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.
- Very High Radiation Areas (VHRAs) are those accessible areas in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rads in 1 hour at 1 meter from the radiation source or 1 meter from any surface that the radiation penetrates.

The SHINE facility is designed and constructed so that the measurable dose rate in the unrestricted area due to activities at the plant are less than the limits of 10 CFR 20.1301(a)(2).

The radiation shielding is designed to ensure that during normal operation internal facility radiation dose rates are consistent with as low as reasonably achievable (ALARA) radiological practices required by 10 CFR 20. The goal for the normal operations dose rate for normally occupied locations in the facility is 0.25 mrem/hr at 30 centimeters from the surface of the shielding. Radiation levels may rise above the 0.25 mrem/hr level during some operations such as tank transfers. At full-power operation of the eight units, portions of the normally occupied area in IF and RPF exceed the 0.25 mrem/hr goal but remain below 5 mrem/hr, except in small sections above the pipe trench during solution transfers. These dose rates were calculated using the maximum specified shield plug gap sizes, minimum density shielding materials, and the nominal inventories for full power operation.

A tabulation of normally and transient-occupied areas, dose rates, and designations is provided in Table 11.1-4. Figure 11.1-1 provides the probable radiation area designations, above grade, within the radiologically controlled area (RCA) at the ~~SHINE~~main production facility.

Procedures for transient access to shielded vaults, cells, and rooms ensure doses are maintained ALARA by addressing the following:

- job planning,
- radiation protection coverage,
- survey techniques and frequencies,

- training of workers,
- pre-work briefing,
- frequency for updating radiation work permits or their equivalent, and
- placement of measuring and alarming dosimeters.

Shielded vaults, cells, and rooms designated as high radiation areas or very high radiation areas as denoted in Figure 11.1-1 are not normally occupied when those conditions exist. Administrative procedures address the management oversight and specific control measures needed for entry into high radiation areas and very high radiation areas, if it is ever necessary to do so. The procedures include the process for gaining entry to these areas, such as the control and distribution of keys.

Typical transient access for maintenance or other necessary work to the shielded vaults, cells, and rooms that are usually high radiation areas or very high radiation areas is normally performed after dose rates have been reduced to at least the level of a radiation area. This is done by removing the radioactive materials or changing the conditions (such as shutting down the accelerator in an IU cell), using temporary shielding, and waiting for sufficient decay.

Major radiation sources in the facility originate in the target solution. At the end of the TSV irradiation cycle, irradiated target solution is transferred to one of the three extraction cells for processing. Off-gas that is purged from the primary system boundary (PSB) is sent to the process vessel vent system (PVVS), where it travels through carbon guard beds and a series of carbon delay beds to allow for capture of iodine and decay of short-lived noble gas nuclides before being released through the facility exhaust stack. Facility special nuclear material (SNM) inventories are tabulated in Table 4b.4-1.

The three sections below describe the major radiation sources in the facility. Other radiological sources in the facility are bounded by the fission product source coming from the TSV described in Subsection 11.1.1.2.

11.1.1.1 Airborne Radioactive Sources

Radioactive sources that could become airborne at the ~~SHINE~~main production facility are primarily tritium and radioactive gases produced as a byproduct of the Mo-99 production process. The systems handling gaseous radioactive materials include the tritium purification system (TPS) and the TSV off-gas system (TOGS), both located in the irradiation facility (IF) area; and the PVVS and vacuum transfer system (VTS) located in the RPF. These airborne radioactive materials are contained within closed systems consisting of piping components and tanks. Table 11.1-5 provides information on the various locations, types, and expected dose rates from gaseous radioactive sources.

Argon-41 is produced in the IU cells during irradiation. Due to the low flow rate out of the primary confinement boundary to radiological ventilation zone 1 (RVZ1), most argon-41 decays prior to being released. Approximately 0.02 curies per year (Ci/yr) of argon-41 are released to the environment through the facility stack.

Nitrogen-16 is produced within the primary cooling loop and the light water pool. Dose rates from these sources are mitigated by delay tanks and biological shielding that limits radiation dose to occupied areas adjacent to the shielding.

The design of the ~~SHINE~~main production facility maintains airborne radioactive material at very low concentrations in normally occupied areas. Confinement and ventilation systems are designed to protect workers from sources of airborne radioactivity during normal operation and minimize worker exposure during maintenance activities, keeping with the ALARA principles outlined in 10 CFR 20.

Although most process gas systems within the facility are maintained below atmospheric pressure, some leakage of process gases is expected due to the difference in partial pressure between the system and the surrounding environment. A conservative best estimate of airborne releases due to normal operation and maintenance was performed to estimate derived air concentrations (DACs) for the facility.

Leakage from process systems was estimated based on the number of components and fittings, achievable leak tightness per fitting, permeation through equipment, and partial pressures of airborne radionuclides. For processes in hot cells that require routine disconnection of components (e.g., extraction columns) special fittings are used to minimize process leakage.

The effects of the confinement systems are incorporated into the analysis. The results of the evaluation, broken down into particulates, halogens, noble gases, and tritium, are provided in Table 11.1-6. These values provide a conservative best estimate of the facility DACs. Figure 11.1-2 provides the DAC zoning map for the facility, using the following definitions:

- Zone 1 (< 1.0 DAC);
- Zone 2 (1.0 – 10 DAC); and
- Zone 3 (> 10 DAC).

Gaseous activity from the TSV and process operations is routed through the PVVS which includes carbon delay beds to allow for airborne radionuclides to decay to low enough levels such that normal releases are below the 10 CFR 20 limits. Additional airborne release pathways are RVZ1 ventilation of the facility hot cells, flow out of the primary confinement boundary to RVZ1, and radiological ventilation zone 2 (RVZ2) ventilation of any leakage to the general area (material evaluated for the DAC). These additional pathways do not pass through the carbon delay beds but do contain filters as described in Subsection 9a2.1.1. Table 11.1-7 lists key parameters used in the normal release calculation. Tritium releases that are treated by TPS are negligible in comparison to tritium releases to the general area due to maintenance and leakage and are not included in Table 11.1-7 or Table 11.1-8.

Annual off-site doses due to the normal operation of the SHINE facility have been calculated using the computer code GENII2 (PNNL, 2012). The GENII2 computer code was developed for the Environmental Protection Agency (EPA) by Pacific Northwest National Laboratory (PNNL) and is distributed by the Radiation Safety Information Computational Center (RSICC). Annual average relative atmospheric concentration (χ/Q) values were determined using the methodology in Regulatory Guide 1.111, Methods for Estimating Atmospheric Transport and Dispersion of Gaseous Effluents in Routine Releases from Light-Water-Cooled Reactors (USNRC, 1977) with the meteorological data in Section 2.3. The χ/Q values for the maximally exposed individual (MEI), which is the nearest point on the site boundary, and the nearest full-time resident are 7.1E-5 sec/m^3 and 5.3E-6 sec/m^3, respectively.

Table 11.1-8 contains the estimated annual release from maintenance and normal operation of eight irradiation units. The release is comprised of release inventories from the four airborne release pathways described above: PVVS, hot cells, primary confinement boundary, and material leaked to the general area. The dominant source term is the process gases released through PVVS. Only nuclides with greater than 1 Ci/yr released are included in the table.

The dose analysis considered the release of airborne radionuclides and exposure to off-site individuals through direct exposure and potential environmental pathways, such as leafy vegetable ingestion, meat ingestion, and milk ingestion. The analysis considered variations in consumption and other parameters by age group. The estimated annual doses at the MEI and the nearest resident are 3.9 mrem and 0.3 mrem, respectively, which are less than the limit in 10 CFR 20.

Calculational methodologies related to accidental releases of airborne radioactive sources are discussed in Chapter 13.

11.1.1.2 Liquid Radioactive Sources

There are numerous locations within the ~~SHINE~~main production facility where the presence of radioactive liquids results in a source of radiation. These sources (except for as noted below) are derived from the irradiated uranyl sulfate target solution as it is being processed through the facility. The first exception is the primary cooling water, which carries nitrogen-16 and other activation products as it is pumped through the primary closed loop cooling system (PCLS). The second exception is the production of low-activity fresh uranyl sulfate target solution. These radioactive materials are contained within closed systems consisting of piping components and tanks.

In addition, there are two locations where tritium is expected to collect due to operation of the neutron driver assembly system (NDAS). These are the light water pool and the oil used in the NDAS pumps. The small quantities of tritium released into the IU cell by permeation through and leakage from the NDAS components is expected to be converted to tritiated water and slowly increase the tritium concentration in the pool water. The oil used in the NDAS pumps is in direct contact with the tritium in the accelerator, causing it to become contaminated with tritium over time. Table 11.1-9 provides information on the various locations, types, and expected doses from liquid radioactive sources.

Liquid radioactive wastes generated at the facility are generally solidified and shipped to a disposal facility. Table 11.2-1 contains a list of liquid radioactive waste generated at the facility including the annual quantities and disposal destinations. Radioactive liquid discharges from the ~~SHINE~~main production facility to the sanitary sewer are made in accordance with 10 CFR 20.2003 and 10 CFR 20.2007. See Section 11.2 for additional information on liquid discharges from the RCA.

11.1.1.3 Solid Radioactive Sources

Solid radioactive sources exist in several locations in the SHINE facility. Fresh, low enriched uranium is received at the facility in the form of uranium metal or uranium oxide that has been enriched to a nominal 19.75 percent by weight in uranium-235 (U-235). If uranium metal is received, it is converted to uranium oxide and then to a liquid uranyl sulfate solution. Other solid

Environmental monitoring is conducted at potential receptor locations. Details of the REMP are presented in the following sections.

11.1.7.2 Effluent Release Pathways

Airborne effluents from the facility include noble gases, iodine and other halogens, particulates, and tritium. The following pathways represent plausible public exposure scenarios from airborne effluents:

- Direct radiation exposure pathway monitored using dosimeters.
- Inhalation pathway monitored using continuous air samples.
- Ingestion exposure pathway.

There are no routine radioactive liquid effluent discharges from the RCA. Radioactive liquid discharges from the SHINE facility to the sanitary sewer are infrequent and made in accordance with 10 CFR 20.2003 and 10 CFR 20.2007. There are no piped liquid effluent pathways from the RCA to the sanitary sewer. Sampling is used to determine suitability for release. See Section 11.2 for additional information on liquid discharges from the RCA.

11.1.7.2.1 Direct Radiation Monitoring

Direct exposure to gamma and beta emitting radionuclides released through the stack of the ~~SHINE~~main production facility is monitored and measured at receptor locations using environmental dosimeters. The dosimeters measure direct radiation from radiation sources contained within the SHINE main production facility, from sources within the material staging building, from radioactivity in the airborne effluent, and from deposition of airborne radioactivity onto the ground.

A description of dosimeter locations and the rationale for locations are provided in Table 11.1-14. Dosimeter locations are shown on Figure 11.1-4. Table 3.12-1 of NUREG-1301 (USNRC, 1991) recommends 40 dosimeter locations (i.e., an inner ring and an outer ring of dosimeters with one dosimeter in each ring at each of the 16 meteorological sectors and the balance of dosimeters to be located at special interest areas). At least one dosimeter is to serve as a control, i.e., located a significant distance from the facility such that it represents a background dose. Considering the size of the SHINE facility and the low power level of the SHINE subcritical IUs, 24 dosimeter locations are specified. These dosimeters are located in order to provide annual direct dose information at on-site locations which are expected to have occupancy and at property line locations which ensure all directions are monitored. The property line locations include the direction of the theoretical MEI and the direction of the nearest occupied structure. At least one location includes a paired dosimeter so that data quality can be determined. Three of the dosimeters are stationed off site at special interest areas and one dosimeter is located a significant distance from the facility to represent background dose.

Dosimeter values are calculated using the reports from the laboratory providing results.

Background radiation is subtracted from the dosimeter results. The background radiation values are those established during the baseline environmental survey which obtained baseline dosimeter readings at each dosimeter location.

11.1.7.2.2 Iodine and Particulate Monitoring for Releases via Airborne Pathway

Airborne effluent releases from the SHINE facility contribute to off-site doses. Air monitoring detects iodine or particulate releases from the SHINE facility. Noble gas and tritium measurements are not included in the REMP. Noble gas and tritium measurements are performed by the radiation protection program.

Environmental airborne sampling is performed to identify and quantify particulates and radioiodine in airborne effluents. Regulatory Position C.3.b of Regulatory Guide 4.1 (USNRC, 2009) indicates that airborne sampling should always be included in the environmental monitoring programs for nuclear power plants since the airborne effluent pathway exists at all sites. Since the SHINE facility includes airborne effluent releases and radioactivity in the airborne effluent can result in measurable off-site doses and since there is a potential for a portion of the dose to be attributable to radioactive iodine and airborne particulate radioactivity releases, the REMP includes airborne sampling.

11.1.7.2.2.1 Air Sampling Locations

The DQO process and the guidance provided in Table 3.12-1 of NUREG-1301 (USNRC, 1991) were used to establish locations for airborne sample acquisition, sampling frequency, and type of sample analysis. Continuous air sample locations are specified in accordance with guidance provided in Table 3.12-1 of NUREG-1301 (USNRC, 1991). The continuous air sampling is performed using continuous air samplers (CAS) which include a radioiodine canister for iodine-131 (I-131) analysis and a particulate sampler which is analyzed for gross beta radioactivity.

Four CAS locations (CAS 2 – CAS 5) are near the facility property line in the north, south, east and west direction sectors co-located with ED1, ED9, ED5, and ED13 (refer to Figure 11.1-4), respectively, to ensure all directions are monitored. The north and east direction sectors (with respect to the SHINE facility vent stack) have the highest calculated annual ground level deposition factor (D/Q) values (CAS 2 and CAS 4). There is also a control CAS (CAS 1) located a sufficient distance from the SHINE ~~medical isotope production~~ facility to provide background information for airborne activity. Table 3.12-1 of NUREG-1301 (USNRC, 1991) suggests an additional air sample location in the vicinity of a community having the highest calculated annual average ground level deposition factor, D/Q. This CAS requirement is combined with the air sample location at the site boundary location in the north direction (refer to Table 11.1-14). A description of air sample locations and the rationale for air sample locations are provided in Table 11.1-14.

The air sampling data is used to validate the effluent monitoring and dose compliance data sets. Results are compared to the radionuclide-specific values provided in 10 CFR 20, Appendix B. A sum-of-the fractions approach is used wherein the isotopic values measured are compared with their associated limits in 10 CFR 20, Appendix B. This allows the calculation of dose due to iodine and particulate activities and includes both inhalation dose and cloud immersion dose. Background subtraction is based on results of the baseline environmental survey, thus providing a location-specific and statistically valid means to subtract background.

Table 11.1-4 – Radiation Areas at the ~~SHINE~~Main Production Facility

Area	Dose Rate	Designation
Normally occupied areas within the RCA TPS room NDAS service cell without accelerator operation	≤ 5 mrem/hr	Normally occupied area
IU cells, hot cells, and other shielded vaults; cells; and rooms – material not present or accelerator not in operation, after sufficient decay period Above RPF trench during solution transfers Primary cooling rooms during operation IF general area during accelerator operation in NDAS service cell	> 5 mrem/hr but ≤ 100 mrem/hr	Radiation Area (transient occupation)
IU cells, hot cells, and other shielded vaults; cells; and rooms – material present or accelerator in operation or shutdown without sufficient decay period NDAS service cell with accelerator operation	> 100 mrem/hr (High Radiation Area) or > 500 rad/hr (Very High Radiation Area)	High Radiation Area or Very High Radiation Area (rarely occupied, per ALARA controls)

Upon completion of a review, a written report of any findings and recommendations of the review and audit committee shall be provided to SHINE executive management.

12.2.4 AUDIT FUNCTION

The audit function will include selective (but comprehensive) examination of operating records, logs, and other documents. Discussions with personnel and observation of operations will be used as appropriate. In no case will the individual immediately responsible for the area perform an audit in that area. SHINE will work to establish relationships with other entities to participate in audits of the facility. The following items will be audited:

- Facility operations for conformance to the technical specifications and applicable license conditions (including organization and responsibilities, training, operations, procedures, logs and records, health physics, technical specification compliance, and surveillances): at least once per calendar year (interval between audits not to exceed 15 months).
- The retraining and requalification program for the operating staff: at least once every other calendar year (interval between audits not to exceed 30 months).
- The results of action taken to correct those deficiencies that may occur in the ~~production~~SHINE facility equipment, systems, structures, or methods of operations that affect nuclear safety: at least once per calendar year (interval between audits not to exceed 15 months).
- The SHINE facility emergency plan and implementing procedures: at least once every other calendar year (interval between audits not to exceed 30 months).
- The radiation protection plan: at least once per calendar year (interval between audits not to exceed 15 months).
- The quality assurance program description: at least once every other calendar year (interval between audits not to exceed 30 months).
- The physical security plan: at least once every other calendar year (interval between audits not to exceed 30 months).

Deficiencies identified during the audit will be entered into the corrective action program. Deficiencies uncovered that affect nuclear safety shall immediately be reported to Level 1 management. A written report of the findings of the audit shall be submitted to Level 1 management and the review and audit committee members within three months after the audit has been completed.

12.3 PROCEDURES

Procedures for the operation and use of the SHINE facility provide appropriate direction to ensure that the facility is operated normally within its design basis and in compliance with technical specifications. These procedures are written, reviewed, and approved by appropriate management, as well as controlled and monitored to ensure that the content is technically correct and the wording and format are clear and concise.

The process required to make changes to procedures, including substantive and minor permanent changes, and temporary deviations to accommodate special or unusual circumstances during operation is in compliance with American National Standards institute/ American Nuclear Society (ANSI/ANS) 15.1-2007 (ANSI/ANS, 2007a).

SHINE will prepare, review, and approve written procedures for the following basic topics:

1. startup, operation, and shutdown of the irradiation unit (IU);
2. target solution fill, draining, and movement within the ~~SHINE~~main production facility;
3. maintenance of major components of systems that may have an effect on nuclear safety;
4. surveillance checks, calibrations and inspections required by the technical specifications;
5. personnel radiation protection, consistent with applicable regulatory guidance. The procedures shall include management commitment and programs to maintain exposures and releases as low as reasonably achievable in accordance with applicable guidance;
6. administrative controls for operations and maintenance and for the conduct of irradiations that could affect nuclear safety;
7. implementation of required plans (e.g., emergency, security); and
8. use, receipt, and transfer of byproduct material.

The specific procedures within these topic areas are developed in accordance with Section 2.5 of the SHINE Quality Assurance Program Description (QAPD).

SHINE shall review and approve written procedures prior to initiating any of the activities listed above. The procedures shall be reviewed by the SHINE review and audit committee and approved by Level 2 management or designated alternates, and such reviews and approvals shall be documented in a timely manner.

Substantive changes to procedures related to the activities listed above shall be made effective only after documented review by the SHINE review and audit committee and approval by Level 2 management or designated alternates. Minor modifications to the original procedure that do not change their original intent may be made by Level 3 management or higher, but the modifications must be approved by Level 2 or designated alternates. Temporary deviations from the procedures may be made by a senior licensed operator or higher individual present, in order to accommodate special or unusual circumstances or conditions. Such deviations shall be documented and reported within 24 hours or the next working day to Level 2 management or designated alternates. Review and approval of procedural changes shall be documented in a timely manner, in accordance with the SHINE document control procedure.

Revisions to the procedures for the operation and use of the SHINE facility are initiated and tracked through the document control processes. Following preparation, procedure revisions receive a technical review, which will include a screening for 10 CFR 50.59 applicability and are then reviewed and approved as described above.

13a2 IRRADIATION FACILITY ACCIDENT ANALYSIS

The purpose of this section is to identify the postulated initiating events and credible accidents that form the design basis for the irradiation facility (IF), which includes the irradiation units (IUs) and supporting systems. Section 13b identifies the postulated initiating events and credible accidents within the radioisotope production facility.

Design basis accidents were identified using the following sources of information:

- NUREG-1537 (USNRC, 1996) and the Interim Staff Guidance Augmenting NUREG-1537 (USNRC, 2012a);
- Process hazard analysis method within the safety analysis; and
- Experience of the hazard analysis team.

Each identified accident scenario was qualitatively evaluated for its potential chemical or radiological consequences. For accident scenarios with potential consequences that could exceed the appropriate evaluation guidelines for worker or public exposure, controls were applied to ensure that the scenario is prevented or that consequences are mitigated to within acceptable limits. For accident scenarios which are not prevented, the radiological or chemical consequences were quantitatively evaluated to demonstrate the effectiveness of the selected mitigative controls or shown to be bounded by other quantitative analysis.

The quantitative analysis includes:

1) Identification of the limiting initiating event, initial conditions, and boundary conditions.
2) Review of the sequence of events for functions and actions that change the course of the accident or mitigate the consequences.
3) Identification of damage to equipment or the facility that affects the consequences of the accident.
4) Review of the potential radiation source term and radiological consequences.
5) Identification of safety controls to prevent or mitigate the consequences of the accident.

The results of these analyses are provided in Section 13a3. The analyses identify those safety-related structures, systems, and components (SSCs) and engineered safety features for each accident, and demonstrate that the mitigated consequences do not exceed the radiological accident dose criteria, described in Section 13a2.2.

13a2.1 ACCIDENT-INITIATING EVENTS AND SCENARIOS

The design basis accidents (DBAs) identified in this section are credible accident scenarios that range from anticipated events, such as a loss of electrical power, to events that are still credible, but considered unlikely to occur during the lifetime of the plant. The ~~irradiation facility (~~IF~~)~~ maximum hypothetical accident (MHA) is also defined to result in the bounding radiological consequences for the IF.

Based on the guidance provided in the Interim Staff Guidance (ISG) Augmenting NUREG-1537 (USNRC, 2012a), the following accident categories were used to identify potential accident sequences:

- Maximum hypothetical accident (Subsection 13a2.1.1)
- Excess reactivity insertion (Subsection 13a2.1.2)
- Reduction in cooling (Subsection 13a2.1.3)
- Mishandling or malfunction of target solution (Subsection 13a2.1.4)
- Loss of off-site power (LOOP) (Subsection 13a2.1.5)
- External events (Subsection 13a2.1.6)
- Mishandling or malfunction of equipment (Subsection 13a2.1.7)
- Large undamped power oscillations (Subsection 13a2.1.8)
- Detonation and deflagration in the primary system boundary (Subsection 13a2.1.9)
- Unintended exothermic chemical reactions other than detonation (Subsection 13a2.1.10)
- System interaction events (Subsection 13a2.1.11)
- Facility-specific events (Subsection 13a2.1.12)

The effects of losses of electrical power and operator errors were considered as initiating events within the scope of the process hazard analysis (PHA) process and are therefore considered within each event category.

13a2.1.1 IF MAXIMUM HYPOTHETICAL ACCIDENT

In accordance with the guidance in the ISG Augmenting NUREG-1537 (USNRC, 2012a), a postulated fission-product release with radiological consequences that exceed those of any accident considered to be credible is analyzed.

The IF MHA is an accident scenario defined to result in the most limiting consequences for the target solution and associated fission products in the IF. Although the MHA is an accident scenario, it does not need to have a credible or defined initiating event or accident progression, except as necessary to evaluate the consequences. The MHA itself is therefore not a DBA; however, it is used as a metric for understanding radiological risk from the facility.

The ~~SHINE~~main production facility is divided into two major process areas: the IF and the radioisotope production facility (RPF). The IF includes eight irradiation units (IUs) each containing, among other components, a subcritical assembly system (SCAS) (including the target solution vessel [TSV] and TSV dump tank), light water pool system (LWPS), and the TSV off-gas system (TOGS). The TSV, TOGS, TSV dump tank, and associated components make up the primary system boundary (PSB). The RPF consists of several process areas that prepare target solution, extract and purify the radioisotope products, and process waste streams. The major process systems include the uranium receipt and storage system (URSS), target solution preparation system (TSPS), target solution staging system (TSSS), vacuum transfer system (VTS), process vessel vent system (PVVS), radioactive liquid waste storage (RLWS) system, and the radioactive liquid waste immobilization (RLWI) system. The RPF also includes the supercell which is comprised of several internal cells, including the molybdenum extraction areas, purification areas, an iodine and xenon purification and packaging (IXP) cell, PVVS equipment, and packaging areas, that form one hot cell structure.

The ISG Augmenting NUREG-1537, Part 1 (USNRC, 2012a) identifies several possible MHAs that could be considered. The ISG Augmenting NUREG-1537, Part 2 (USNRC, 2012b), Section 13a2.1, indicates that the MHA should release fission products from the uranium target solution (fuel). As such, SHINE has selected the IF MHA based on accidents involving the PSB. Accidents that only involve tritium are not considered for the MHA. SHINE has established the

loss of the safety-related PVVS effluent release path, which can then lead to a deflagration in the facility. Severe weather may also disrupt the nitrogen gas resupply following a N2PS activation.

The facility structure is designed to withstand heavy snow and ice loading to prevent damage. The exhaust point for the safety-related PVVS effluent path is designed to be above the design snow accumulation level, and the ventilation system air intakes are above the potential snow drift height. The N2PS system is supplied with enough nitrogen for three days of operation which is adequate to allow a resupply of the nitrogen tanks. No chemical or radiological consequences result from severe weather accident scenarios.

Transportation Accidents

The main production facility is designed to withstand credible aircraft impacts and transportation accidents, as discussed in Subsection 3.4.5.

External Flooding Affecting the IF and RPF

The main production facility was evaluated for external flood events. The results of the evaluation show that external flood events do not have an impact on the IF or RPF, as described in Subsection 2.4.2.

External Fires from Natural Sources

The main production facility was evaluated for the potential for external fires from natural causes. The results of the evaluation show that external fires from natural sources do not have an impact on the main production facility as described in Subsection 2.2.3.

13a2.1.6.3 Accident Consequences

The failure of eight NDAS pressure boundaries as a result of a seismic event (Scenario 3) results in potential radiological exposure to workers and the public. The primary confinement boundaries are credited to mitigate the consequences of this failure. The accident consequences associated with this external event are discussed further in Subsection 13a2.2.6.

13a2.1.7 MISHANDLING OR MALFUNCTION OF EQUIPMENT

The waste gases from irradiation of the target solution are of two major types: the hydrogen and oxygen produced by radiolysis of water in the target solution, and radioactive fission product gases. Mishandling or malfunction of equipment within the IU or TOGS cells has the potential to cause leakage of these gases. Specifically, a failure of the TOGS portion of the PSB could allow escape of fission product gases or hydrogen into the primary confinement boundary and the radiologically controlled area (RCA). Analysis of this event and other potential mishandling or malfunction of equipment events, excluding detonation or deflagration of hydrogen within TOGS and other exothermic chemical reactions within the PSB, are included in this section.

- Events involving the mishandling or malfunction of target solution are discussed in Subsection 13a2.1.4.
- The detonation or deflagration of hydrogen within the TOGS or otherwise affecting the PSB is analyzed in Subsection 13a2.1.9.

Human-Intervention Interactions

Human-intervention interactions are adverse system interactions caused by human errors in the RPF which can cause adverse system performance in the subcritical assembly during irradiation operations. Human errors are identified as potential causes for other accident sequences and are not explicitly identified in this section. For example, human interactions or errors considered as potential causes for accident sequences include:

- Failure to operate equipment when required
- Inappropriate operation of equipment
- Maintenance error affecting operating equipment
- Testing error affecting operating equipment

Human errors downstream in the RPF processes that are related to mixing or transfer of target solution are considered in Subsection 13b.2.5.

13a2.1.11.1 Identification of Causes, Initial Conditions, and Assumptions

The identification of causes of system interaction events are provided in the subsections in Chapter 13 as referenced below. There are no unique initial conditions or assumptions associated with system interaction events.

13a2.1.11.2 General Scenario Descriptions

The following section discusses the system interactions that can occur at the ~~SHINE~~main production facility. System interactions that are already analyzed in other parts of Chapter 13 are referenced to those subsections and not evaluated in this subsection. System interactions that are not described in other subsections are discussed below.

Functional Interactions

Loss of Off-Site Power

LOOP events are described in Subsection 13a2.1.5.

Reduction of Cooling

Events that could cause a reduction of cooling include PCHS or RPCS failure, LOOP, or external events.

- Reduction in cooling due to PCHS or RPCS failure is described in Subsection 13a2.1.3.
- Reduction in cooling following a LOOP is described in Subsection 13a2.1.5.
- Reduction in cooling due to external events is described in Subsection 13a2.1.6.

Loss of Ventilation

A loss of ventilation could be caused by equipment failure, a LOOP, or external events.

intact during normal operation as well as during design basis earthquake and design basis accident events. Penetrations through the light water pool liner are above the minimum water level. The light water pool is also equipped with a leak chase system to detect leaks.

Flooding caused by external events is discussed in Subsection 13a2.1.6.

Dynamic Effects

Process systems in the ~~SHINE~~main production facility operate at low temperatures (i.e., generally less than 200°F [93°C], except for the TOGS hydrogen recombination components) and low pressures (i.e., less than 100 psig [689 kPa gauge]), which are not subject to dynamic effects as are found in high energy systems. As needed, safety-related systems are protected from the dynamic effects related to equipment failure and external events. No consequences result from dynamic effects interactions in the ~~SHINE~~main production facility.

Human Intervention Interactions

Human interventions can cause adverse system interactions because of the single common control room at the ~~SHINE~~main production facility. Operators are able to control multiple systems within the IF and the RPF from the control room. Operator errors may occur including performing control operations on the wrong system, failing to perform required actions, or performing actions out of sequence.

Maintenance is performed as a normal scheduled activity and as a response to emergent equipment problems. Maintenance may occur during all modes of operation, including while irradiation or processing activities are in progress. Errors that occur during maintenance activities can cause failures in operating systems such as support systems. Maintenance errors may be detected upon return to service through post-maintenance testing. However, undetected errors may result in system failures at some later point in time.

Human intervention interactions as accident scenario initiating events are described in other sections in this chapter as applicable and are not evaluated further in this section.

13a2.1.11.3 Accident Consequences

The system interactions described in the preceding sections do not result in radiological consequences. Accident consequences resulting from system interactions that are referenced to other subsections in Chapter 13 are evaluated in those subsections.

Further discussion regarding system interaction events described in this section is provided in Subsection 13a2.2.11.

13a2.1.12 FACILITY-SPECIFIC EVENTS

Several accident scenarios that are unique to the ~~SHINE facility~~IF and have the potential for inadvertent radiation exposure to workers or members of the public were evaluated. Facility-specific accident scenarios are associated with the NDAS, the TPS, and potential IF damage resulting from heavy load drops.

13a2.1.12.1 Identification of Causes, Initial Conditions, and Assumptions

General scenario descriptions for events involving the NDAS, TPS, and heavy load drop include causes of each scenario.

For accident scenarios involving the NDAS, the following initial conditions and assumptions apply:

- The NDAS contains the bounding inventory of tritium gas for full power.
- The NDAS pressure vessel contains the maximum inventory of sulfur hexafluoride (SF_6) gas.
- The primary confinement boundary for an affected IU cell is operable, including the RVZ1e radiation detection and isolation valves.

For accident scenarios involving the TPS, the following initial conditions and assumptions apply:

- The TPS glovebox confinement is operable, including the confinement isolation valves.
- The glovebox atmosphere is inerted with helium.
- Automatic isolation valves are installed in the system to isolate sections of the system to minimize system release.
- Leakage of tritium from the glovebox enclosure or the external piping is detected by the continuous airborne monitoring system (CAMS) or other leakage detection systems to provide alarms for facility personnel evacuation.
- The TPS-NDAS interface lines contain the maximum inventory of tritium gas.

For accident scenarios involving heavy load drops, the following initial conditions and assumptions apply:

- An IU cell is in maintenance with the IU cell shielding plug removed and the TSV and NDAS empty, or
- An IU cell is in service with IU cell shielding plug in place.

13a2.1.12.2 General Scenario Descriptions

Neutron Driver Assembly System Event Descriptions

There are four scenarios that are specific to the operation of the NDAS in the ~~SHINE facility~~IF. These scenarios are: (1) inadvertent exposure to neutrons within the IU, (2) inadvertent exposure to neutrons in the NDAS service cell (NSC), (3) catastrophic failure of the NDAS, and (4) an NDAS vacuum boundary failure.

NDAS Scenario 1 – Inadvertent Exposure to Neutrons within the IU

Inadvertent exposure to neutrons may be caused by operation of a neutron driver while personnel are in the IU cell, such as during maintenance or assembly/disassembly activities, inadvertent access to an IU cell during irradiation operations, or failure to properly install IU cell shielding following access. An operator error which results in the neutron driver becoming energized with nearby personnel or without adequate shielding results in a significant neutron dose to workers. Operator error is the most likely cause of inadvertent exposure to neutrons within the IU.

Tritium Purification System Event Descriptions

There are five scenarios that are specific to the operation of the TPS in the ~~SHINE facility~~IF. These scenarios are: (1) TPS piping failure due to deflagration, (2) release of tritium into the IF due to glovebox deflagration, (3) release of tritium to the facility stack, (4) excessive release of tritium from the tritium storage bed, and (5) release of tritium into the IF due to TPS-NDAS interface line mechanical damage.

TPS Scenario 1 – TPS Piping Failure due to Deflagration

Improper system restoration following maintenance allowing air intrusion into TPS piping or by air in-leakage from the NDAS may result in a deflagration within the TPS piping that causes a piping failure and a release of tritium gas into the TPS glovebox. The release of tritium gas into the TPS glovebox results in higher dose to workers and to members of the public.

The release of tritium is confined within the tritium confinement boundary, including the TPS glovebox and secondary enclosure cleanup subsystem. The tritium confinement boundary is described in detail in Section 6a2.2. Isolation of the TPS room ventilation is also credited for mitigation.

TPS Scenario 2 – Release of Tritium into the IF due to Glovebox Deflagration

Leakage of TPS piping may lead to TPS glovebox failure caused by deflagration that causes the tritium confinement boundary to fail. TPS piping leakage may be the result of improper restoration to operating conditions from maintenance or of liquid nitrogen ingress into the gaseous nitrogen lines which causes embrittlement and failure of the TPS piping. Failure of the tritium confinement boundary releases tritium into the TPS room and results in higher dose to workers and to members of the public.

The TPS gloveboxes are designed such that the minimum size prevents the possibility of reaching the lower flammability limit for the quantity of available hydrogen. The TPS gloveboxes are also inerted with helium which prevents the presence of oxygen. Based on the glovebox design and inert atmosphere, a deflagration in a glovebox is not considered credible and is not analyzed further.

TPS Scenario 3 – Release of Tritium to the Facility Stack

A release of tritium directly to the facility stack may be caused by improper restoration to operating conditions from maintenance which results in a leak of tritium into a glovebox and a concurrent misalignment of the VAC/ITS valves following maintenance. A release of tritium to the facility stack results in higher worker and public dose.

The protection in place to mitigate a release of tritium to the facility stack is the tritium monitor on the TPS glovebox pressure control and VAC/ITS process vent exhaust to RVZ1e, which causes an isolation of the glovebox as part of the tritium confinement boundary.

TPS Scenario 4 – Excessive Release of Tritium from the Tritium Storage Bed

Excessive release of tritium from the tritium storage bed may be caused by failure of the storage bed heater control resulting in excessive heat input. Failure of the heater results in an excessive

quantity of tritium added to the TPS system, resulting in overpressurization and release of tritium to a TPS glovebox. The tritium release is confined within the tritium confinement boundary, which is described in detail in Section 6a2.2.

The protection in place to mitigate a release of tritium to the facility stack is the tritium monitor on the TPS gloveboxes pressure control and VAC/ITS process vent exhaust, which causes an isolation of the glovebox as part of the tritium confinement boundary.

TPS Scenario 5 – Release of Tritium into the IF due to TPS-NDAS Interface Line Mechanical Damage

A release of tritium directly to the IF may be caused by mechanical damage to the TPS-NDAS interface lines which results in a leak of tritium to the IF. A release of tritium to the IF results in higher dose to workers and to members of the public. The TPS-NDAS interface lines are in subgrade penetrations which reduces the likelihood of mechanical damage that results in a tritium leak and are protected from mechanical impact between the subgrade penetration and the TPS gloveboxes.

The majority of the length of the TPS-NDAS interface lines are routed in subgrade sleeves and are therefore protected from mechanical damage from external impacts. A small length of the TPS-NDAS interface lines from the point at which they emerge from the subgrade sleeves in the TPS room to the TPS glovebox isolation valves is protected from mechanical damage by external guards. Therefore, TPS-NDAS interface line mechanical damage is not credible.

Heavy Load Drop Scenario Descriptions

With respect to the SHINE facility, a heavy load is defined as a load that, if dropped, may cause radiological consequences that challenge the accident dose criteria described in Section 13a2.2. There are three scenarios that are specific to heavy load drops in the ~~SHINE facility~~IF. These scenarios are (1) a heavy load drop into an open IU cell, (2) a heavy load drop onto an in-service IU cell, and (3) a heavy load drop onto TPS equipment.

Heavy Load Drop Scenario 1 – Heavy Load Drop into an Open IU Cell

A crane mechanical failure or operator error during a lift may result in a heavy load drop into an open IU cell. The heavy load can damage the SCAS components and result in a release of radioactive material.

SHINE has applied the applicable guidance from NUREG-0612, Control of Heavy Loads at Nuclear Power Plants (USNRC, 1980), for control of heavy loads at the SHINE facility, as described in Subsection 9b.7.2. Therefore, a heavy load drop into an open IU cell is not credible.

Heavy Load Drop Scenario 2 – Heavy Load Drop onto an In-Service IU Cell.

A crane mechanical failure or operator error during a lift may result in a heavy load drop onto an in-service IU cell. The heavy load can damage the IU cell plug which results in damage to SCAS components and result in a release of radioactive material.

SHINE has applied the applicable guidance from NUREG-0612, Control of Heavy Loads at Nuclear Power Plants (USNRC, 1980), for control of heavy loads at the SHINE facility, as

- Administrative controls on maintenance and use of combustible materials
- Catchment pans for the high voltage power supplies

Exothermic Chemical Reaction

Exothermic chemical reaction scenarios are described in Subsection 13a2.1.10.

Internal Flooding

Postulated internal flooding scenarios in the IF do not result in radiological consequences, as described in Subsection 13a2.1.11.

Dynamic Effects

Dynamic effects are not present at the ~~SHINE~~main production facility, as described in Subsection 13a2.1.11.

Human Intervention Interactions

As described in Subsection 13a2.1.11, human intervention interactions as accident scenario initiating events are described in other sections in this chapter as applicable.

13a2.2.11.4 Damage to Equipment

No damage to equipment occurs due to system interaction events since the TRPS initiates an IU Cell Safety Actuation or IU Cell Nitrogen Purge as needed prior to exceeding any design limits.

13a2.2.11.5 Radiation Source Terms

Because the postulated system interactions do not exceed any design limits or cause damage to the PSB, there is no radiation source term.

13a2.2.11.6 Radiological Consequences

Because the postulated system interactions do not exceed any design limits or cause damage to the PSB, there are no radiological consequences to workers or the public. Accident consequences resulting from system interactions that are referenced to other subsections in Chapter 13 are evaluated in those subsections.

13a2.2.12 FACILITY-SPECIFIC EVENTS

The majority of the evaluated facility-specific events do not have radiological consequences. The events which do have radiological consequences are related to the release of tritium into the facility from the neutron driver assemblies or from the tritium purification system. Three potential locations for the release of tritium were analyzed to determine the dose consequences and necessary controls. The results of the analysis are presented in this subsection.

15.2 FINANCIAL ABILITY TO OPERATE THE SHINE FACILITY

The SHINE facility is licensed as a Class 103 facility in accordance with 10 CFR 50.22, for commercial and industrial facilities. The costs of owning and operating the facility are devoted to commercial activities. SHINE has requested an Operating License (OL) for a term of 30 years. The SHINE facility produces medical isotopes, primarily molybdenum-99 (Mo-99). Mo-99 is the precursor of the diagnostic imaging isotope technetium-99m (Tc-99m), which is used in medical procedures worldwide.

Financial reports and certified financial statements are submitted annually in accordance with 10 CFR 50.71(b). The total annual operating costs for each of the first five years of operation of the SHINE facility have been estimated. Operating costs will be funded from the expected revenues associated with the sale of Mo-99 and other radioisotopes produced by the facility. SHINE expects that this revenue will be more than the operating costs incurred. The information below demonstrates that SHINE has reasonable assurance of obtaining the funds necessary to cover estimated operation costs for the period of the license.

15.2.1 ESTIMATE OF OPERATING COSTS

Table 15.2-1 provides the budgetary estimate of operating costs for the first five years of operation of the SHINE facility. The estimated costs presented in Table 15.2-1 are divided into two primary categories: costs of goods sold (COGS) and organizational expenses. The bases for the estimated operational costs of the facility for the first five years are discussed below as they relate to these categories.

The COGS is comprised of three key elements:

- Production personnel costs are based on an estimate of the number of employees required for the ~~production~~SHINE facility. This estimate includes personnel performing duties related to operations, engineering, radiation protection, and maintenance, as well as supervisory and management personnel. The production personnel cost estimate includes salary and benefits.
- Irradiation and processing costs include maintenance, replacement, and consumable costs associated with neutron driver assembly system (NDAS) main components, low-enriched uranium (LEU), and consumable supplies. As described in Table 15.2-1, the first year costs under this category are significantly lower than later years, as expected, based on minimal first year replacement projections.
  - For NDAS main components, SHINE has a binding contract with Phoenix, LLC that specifies the costs of NDAS main components on a firm-fixed basis. The contract with Phoenix, LLC serves as the basis for this operating cost estimate.
  - The LEU cost estimate is based on the total amount of LEU expected to be consumed within the SHINE facility and information provided during discussions with the U.S. Department of Energy/National Nuclear Security Administration Production Office and Y-12 National Security Complex in Oak Ridge, Tennessee.
  - Consumables consist of chemicals and materials used to produce, process, or refine medical isotopes or target solution, including tritium. This category also includes disposable or frequently replaced materials and chemicals that are used in facility operations or systems.

ENCLOSURE 2
ATTACHMENT 2

SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL TECHNOLOGIES, LLC OPERATING LICENSE APPLICATION RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

2800-12-01, REVISION 5
EMERGENCY PLAN
PUBLIC VERSION

71 pages follow

REVISION LOG

Revision #	Description of Changes
0	Original Issue
1	Updated document numbering to current standard, and update document format to current template. Updated Proprietary and Security-Related markings; Organizational Chart; and references. Revised document name to remove “Preliminary”. Removed list of acronyms and corrected acronym usage. Incorporated RAIs 12.7-9
2	Major Rewrite. Revised to meet requirements for Operating License Application submittal. This revision contains open items being tracked via IMR 2018000044.
3	Close open items
4	Update emergency action levels and chemical inventory appendix. Editorial updates throughout.
5	Incorporate responses to requests for additional information (RAIs) EP-1 through EP-7. Move backup ESC location from resource building to storage building. Update EALs to reflect dose levels from Revision 5 of Reference 12.14. Editorial changes throughout.

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1 INTRODUCTION

1.1 Purpose

The purpose of the SHINE Medical Technologies, LLC. (SHINE) emergency plan is to describe the essential elements of advance planning and necessary provisions for coping with and mitigating the consequences of emergencies within and beyond the SHINE site boundary. The plan is primarily focused on situations that may cause or threaten to cause radiological hazards that could affect employee or public health and safety. The plan also includes provisions for coping with other on-site emergency situations commensurate with their severity.

1.2 Scope

This emergency plan applies to the SHINE facility.

This plan was written to conform with 10 CFR 50, Appendix E, following the guidance of:

- Regulatory Guide 2.6, Revision 2, Emergency Planning for Research and Test Reactors and Other Non-Power Production and Utilization Facilities;
- ANSI/ANS-15.16-2015, Emergency Planning for Research Reactors;
- ANSI/ANS-8.23-2007, Nuclear Criticality Accident Emergency Planning and Response; and
- NUREG-0849, Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors.
- NUREG-1520, Revision 2, Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility

1.3 Overview

The emergency plan includes descriptions of the facility and organizations, and of emergency classifications, responses, recovery processes, and preparedness.

SHINE management is committed to ensuring this emergency plan is established, exercised and maintained.

Emergency personnel may deviate from actions described in the plan for unusual or unanticipated conditions at the direction of the Emergency Director. Reasonable actions that depart from license conditions or technical specifications may be authorized by a senior licensed operator in accordance with 10 CFR 50.54(x) and (y) if immediately needed to protect the public health and safety, and no action consistent with license conditions and technical specifications that can provide adequate or equivalent protection is immediately apparent.

1.4 SHINE Facility

The SHINE facility is owned and operated by SHINE Medical Technologies, LLC, and is located at 4021 South US Highway 51, Janesville WI, 53546.

The SHINE facility includes the following structures (see Figure 1):

- Main production facility
- Resource building
- Material staging building

- Storage building
- N2PS structure

The SHINE facility involves the use of a non-reactor based, subcritical fission process for the purpose of manufacturing medical isotopes. The SHINE facility contains irradiation units (IUs), each with a target solution vessel (TSV) with a licensed fission power of 125 kWth, located in the irradiation facility (IF) area of the main production facility. Also located in the IF are rooms and cells housing off-gas handling equipment, cooling equipment, tritium purification equipment, and an area for servicing neutron drivers.

The radioisotope production facility (RPF) area of the main production facility contains a hot cell bank (the "supercell"); below-grade vaults containing tanks, other process components, and storage space; two laboratories; and areas for waste-handling, cooling, and other equipment. The remaining areas of the facility, the control room area and the administrative annex area, contain the control room, electrical equipment, additional auxiliary equipment, and other miscellaneous areas. The general layout of the main production facility is provided in Figure 2.

1.5 Site Description

The SHINE site consists of an approximately 91-acre parcel in the City of Janesville, 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 4 miles to the south. The SHINE site is accessed from U.S. Highway 51.

The figures provided in Appendix 1 depict major features of the SHINE site and surrounding area:

- Figure 1 contains the site boundary, fences, gates, roads and parking lots on site, on-site structures and tanks, and U.S. Highway 51.
- Figure 2 shows the general arrangement layout of the main production facility, which includes the following four areas:
    - Irradiation facility (IF)
    - Radioisotope production facility (RPF)
    - Control room area
    - Administrative annex area
- Figure 3 provides an aerial view of the area surrounding the SHINE site, including the location of on-site structures and sensitive facilities near the SHINE site (0-1 mile), including churches, parks, residences, airstrips, and educational facilities. Farms are distributed throughout the one-mile radius of the SHINE site. There are no medical facilities within one mile of the SHINE site.
- Figure 4 shows a general area map, constructed from U.S. Geological Survey (USGS) topographical quadrangles (7.5 minute series), and includes the SHINE facility site boundary.
- Figures 5 through 8 show the individual USGS topographical quadrangles (7.5 minute series) containing or adjacent to the SHINE site.

1.6 Facility Activities and Materials

The licensed activities and other major activities conducted at the SHINE facility include:

- Preparation and irradiation of uranyl sulfate target solution; and

- Extraction, purification and packaging of medical isotopes from irradiated target solution inside hot cells.

The SHINE facility contains radioactive and hazardous materials that are part of the overall medical isotope production process. Appendix 2 provides the types, quantities and locations of radioactive and hazardous materials normally on the SHINE site.

1.7 Facility Emissions

The SHINE main production facility contains a facility vent stack at a height of 67 ft and a flow rate of approximately 26,200 cfm. The stack uses high efficiency particulate air (HEPA) filters and single stage high efficiency gas adsorption (HEGA) filter equipment for emission control. A stack release monitor provides information on radiation released from the facility stack.

1.8 Community Right to Know

SHINE certifies that the responsibilities under the Emergency Planning and Community Right To Know Act (EPCRA) of 1986 (Title III, Public Law 99-499) in accordance with 10 CFR 70.22(i)(3)(xiii) will be met.

1.9 Accident Summary

The following general types of accidents may require the implementation of protective actions:

- Failure of the primary system boundary leading to a spill of target solution inside an irradiation unit (IU) cell.
- Malfunction of the TSV off-gas system (TOGS) leading to a gaseous release of fission products inside an IU or TOGS shielded cell.
- Failure of one or more neutron drivers leading to a release of gaseous tritium inside an IU cell.
- Failure of tritium-containing equipment leading to a release of gaseous tritium inside the tritium purification system (TPS) room or the IF general area.
- Malfunction of isotope extraction equipment leading to a spill of target solution or other radioactive material inside the supercell.
- Leak or spill of target solution or other radioactive material into a tank vault or pipe trench, or other shielded location.
- Fire in a process vessel vent system (PVVS) carbon guard bed or carbon delay bed.
- Unshielded criticality accident in the uranium storage or target solution preparation areas.

Additional information on potential facility accidents can be found in Chapter 13 of the SHINE Final Safety Analysis Report (FSAR).

Measures and equipment used to respond to and detect accidents and to detect releases are described in Section 9.

2 DEFINITIONS

2.1 **Emergency action levels (EALs):** Specific instrument readings or observations, radiological dose or dose rates, or specific contamination levels of airborne, waterborne, or surface-deposited radioactive materials that may be used as recognized conditions that result in actions such as a) establishing emergency classes and b) initiating appropriate emergency measures.

2.2 **Emergency:** An emergency is a condition that calls for immediate action, beyond the scope of normal operating procedures, to avoid an accident or to mitigate the consequences of one.

2.3 **Emergency classes:** Emergency classes are classes of accidents grouped by severity level for which predetermined emergency measures should be taken or considered. In order of increasing severity, the emergency classes applicable to this plan consist of 1) Notification of Unusual Event, 2) Alert, and 3) Site Area Emergency, consistent with ANSI/ANS-15.16-2015.

2.4 **Emergency plan:** An emergency plan is a document that provides the basis for actions to cope with an emergency. It outlines the objectives to be met by the emergency procedures and defines the authority and responsibilities to achieve such objectives.

2.5 **Emergency plan implementing procedures (EPIPs):** EPIPs are documented instructions that detail the implementation actions and methods required to achieve the objectives of the emergency plan.

2.6 **Emergency planning zone (EPZ):** Area for which emergency planning is performed to assure that prompt and effective actions can be taken to protect the public in the event of an accident. The SHINE EPZ is the operations boundary.

2.7 **Emergency response:** Actions taken from the time of identification of a suspected, imminent, or actual accident or event to stabilization of the event, including the assumption that an accident has occurred, response to the emergency, and actions to begin subsequent recovery operations.

2.8 **Hostile action:** An act towards a facility or its personnel that includes the use of violent force to destroy equipment, take hostages, and/or intimidate the licensee to achieve an end.

2.9 **Immediate evacuation zone:** The area surrounding a potential accident location that must be evacuated without hesitation if an alarm signal (e.g., criticality accident alarm or radiation area alarm) is activated.

2.10 **Non-essential personnel:** Those personnel not needed for the continuing existence or functioning of the Emergency Response Organization (ERO). They are personnel not required to fill certain positions in the ERO. Identification of non-essential personnel is circumstance-oriented as determined by the Emergency Director.

2.11 **Off-site:** The geographical area that is beyond the site boundary.

2.12 **On-site:** The geographical area that is within the site boundary.

2.13 **Operations boundary:** The area within the site boundary where the shift supervisor has direct authority over all activities. The area within this boundary has prearranged evacuation procedures known to personnel frequenting the area. The controlled access area fence and the perimeter walls of the main production facility, the material staging building, the storage building, and the resource building are the SHINE operations boundary.

2.14 **Protective actions:** Actions to be taken to prevent or minimize exposure to radiation, radioactive materials, and other hazardous materials following a release.

2.15 **Radiologically Controlled Area (RCA):** An area where access is controlled by SHINE to limit exposure to radiological hazards.

2.16 **Site boundary:** The site boundary is that boundary, not necessarily having restrictive barriers, surrounding the operations boundary wherein the Emergency Director may directly initiate emergency activities. The area within the site boundary may be frequented by people unacquainted with the facility operations. The SHINE site boundary is the property line of the SHINE site. The site boundary is synonymous with the (owner) controlled area.

2.17 **Technical staff:** Personnel with specific skills and experience who can assist in the implementation of the requirements defined in this plan. Such personnel may include, but are not limited to, criticality safety, health and safety, and facility process support personnel. Technical staff includes, but is not limited to, engineering, radiation protection and maintenance personnel.

3 ORGANIZATION AND RESPONSIBILITIES

3.1 Emergency Response Organization

The Emergency Response Organization (ERO) is responsible for taking actions in an emergency to avoid an accident or to mitigate the consequences of one. The ERO is staffed with trained and qualified ERO personnel. ERO members attend formal initial and continuing training and participate in drills and exercises. The ERO consists of two groups: 1) the facility emergency organization and 2) the emergency support organizations.

Figure 9 illustrates the interrelationship between the facility emergency organization and the emergency support organizations within the total emergency response effort.

The facility emergency organization consists of SHINE staff members who are on-site at the time of the emergency or who may be called in to assist as required.

The emergency support organizations are those organizations and agencies that may be called upon for specific assistance based on the type of emergency. The roles of these agencies are described in Section 3.4. Agreement letters with these support agencies can be found in Appendix 3.

The ERO described in this section comprise the key positions of the recovery organization.

Additional information on ERO roles and responsibilities is provided in the EPIP addressing Emergency Response Organization Responsibilities.

3.2 Normal Facility Operating Organization

The initial response to any emergency is by the normal SHINE facility on-shift organization present at the site. Off-shift personnel may be called in to assist as required, as described in Section 7.

3.2.1 Normal Operating Organization

- Chief Executive Officer (CEO): The CEO is responsible for the overall management and leadership of the company.
- Chief Operating Officer (COO): The COO is responsible for overall company operations.
- Plant Manager: The Plant Manager is responsible for the overall operation of the facility.
- Operations: The facility operations personnel are responsible for the operation of the facility, and the safe, reliable, efficient plant operations.
- Security: The facility security personnel are responsible for the physical security of the facility.
- Engineering: The facility engineering personnel are responsible for providing technical expertise and support of facility operation and maintenance, and for controlling the physical facility configuration to ensure that facility operation, maintenance and configuration are maintained in accordance with the design basis. Engineering personnel are part of the facility technical staff and include criticality safety engineers, i.e., individuals with experience, training and qualification in criticality safety.

- Radiation Protection: The facility radiation protection personnel are responsible for handling and monitoring of radioactive materials. Radiation protection personnel are part of the facility technical staff.
- Maintenance: The facility maintenance personnel are responsible for performing maintenance on facility equipment in accordance with facility procedures, instructions and technical requirements.
- Chemistry: The facility chemistry personnel are responsible for sampling, analysis, and product quality control activities. They are considered part of the facility technical staff.
- Executive, support, administrative, and other personnel ("support personnel"): These individuals have various responsibilities involving procurement, licensing, quality, training, finance, etc., and may include personnel normally stationed off-site.

3.2.2 On-shift personnel, include, but are not limited to

- Shift supervisor: A senior licensed operator responsible for the safe operation of the facility.
- Licensed operators (including any additional on-shift senior licensed operators, if present): Responsible for ensuring licensed activities are conducted safely and in accordance with the facility license and procedures.
- Non-licensed operating staff: Responsible for conducting operations in the facility in accordance with procedures and under the direction of licensed operators.
- Security personnel: Responsible for the physical security of the facility.
- Radiation protection individual: At least one individual capable of monitoring radiation dose rates and contamination levels is present on each shift.

The organization for managing and operating the SHINE facility is provided in Figure 10.

3.3 Facility Emergency Organization

The facility emergency organization is initially staffed by on-shift personnel. Upon activation of the ERO, designated off-shift personnel will be notified to report to the Emergency Support Center (ESC), once it has been activated, or the control room if the ESC has not yet been activated.

Sufficient SHINE staff, with relevant expertise, comprise the facility emergency organization, such that SHINE is able to maintain a continuous around-the clock emergency response effort for as long as necessary.

The duties of the below listed ERO roles may be assumed by any of the individuals authorized for that role upon their arrival at the facility, and be passed from one individual to another, but only after being thoroughly briefed on status of the event and the currently proposed plan of action.

Individuals may delegate their actual duties, with the exception of the non-delegable responsibilities of the Emergency Director, but may not delegate the responsibility for their duties.

The facility emergency organization is shown in Figure 11.

3.3.1 Emergency Director

The Emergency Director is authorized to and responsible for directing and coordinating the overall emergency response. The role of the Emergency Director is initially filled by the on-shift shift supervisor. Only individuals who have received Emergency Director training are authorized to assume the Emergency Director responsibilities. In the event

the shift supervisor or the subsequent Emergency Director is absent from the facility or incapacitated, the Emergency Director responsibility will be assumed by the most senior operations department individual on-site, until a relief Emergency Director arrives at the facility. The Emergency Director has the following non-delegable responsibilities:

- Emergency event classification and decision to declare an emergency;
- Decision to activate the ERO;
- Decision to initiate on-site protective actions;
- Decision to notify off-site response authorities;
- Decision to request support from off-site organizations;
- Authorization of reentry into portions of the facility or site that may have been evacuated during the emergency;
- Authorization of volunteer emergency workers to incur radiation exposures in excess of normal 10 CFR 20 occupational limits; and
- Decision to terminate the emergency and initiate recovery actions.

The Emergency Director has the following additional, delegable, responsibilities:

- Activation of the ERO;
- Notification of off-site response authorities when a Notification of Unusual Event, Alert, or Site Area Emergency has been declared within 15 minutes of event classification;
- Notification of the NRC Operations Center within one hour of declaring the emergency;
- Assessment of damage to and status of the facility's capabilities to safely control radioactive material or hazardous chemicals associated with licensed activities;
- Prioritizing responses to concurrent emergencies; and
- Informing the ERO of planned emergency organization actions or changes.

3.3.2 Shift Supervisor

The shift supervisor acts as the initial Emergency Director upon declaration of an emergency. In the event the shift supervisor is absent from the facility or incapacitated, the most senior licensed operator will assume the shift supervisor responsibilities, in accordance with facility procedures. While acting as the Emergency Director, the shift supervisor will take immediate action during an emergency and will activate the ERO, as appropriate. Additionally, the shift supervisor has the following responsibilities, whether or not he or she is acting as the Emergency Director:

- Implementing immediate actions to respond to the emergency in accordance with facility emergency procedures;
- Directing and supervising the activities of the control room staff; and

- The responsibility for the safe operation of the plant in compliance with the facility NRC operating license, technical specifications, facility operating procedures and the requirements for their use. During an emergency, personnel may deviate from actions described in the plan for unusual or unanticipated conditions.

3.3.3 Emergency Communicator

The Emergency Communicator assists the Emergency Director in the execution of the Emergency Director's duties. The role of the Emergency Communicator is initially filled by an individual on-site, typically a member of the normal on-shift staff or on-site support personnel, appointed by the Emergency Director. A relief Emergency Communicator may be called in as part of the ERO activation, if required. The individuals authorized to assume the role of the Emergency Communicator are various SHINE personnel, including support personnel, who are designated to fill the roll, as described in the EPIP addressing Emergency Response Organization Responsibilities. In the event the Emergency Communicator becomes absent from the facility or incapacitated, the Emergency Director shall appoint another individual present at the facility to assume the role of Emergency Communicator until a relief Emergency Communicator arrives at the facility.

The Emergency Communicator is responsible for

- Exchanging information with off-site authorities responsible for coordinating and implementing off-site emergency measures, including transmitting dose projections and monitoring and surveying information;
- Relating information about the emergency situation to the news media and the public; and
- Ensuring a record of the events during and following the emergency is maintained.

3.3.4 Radiation Safety Coordinator

The Radiation Safety Coordinator is responsible for making radiological assessments and advising the Emergency Director, including responsibility for

- Making on-site and off-site dose assessments and projections;
- Recommending protective actions; and
- Identifying exposed personnel and determining their radiation dose.

The Radiation Safety Coordinator may collect on-site and off-site field monitoring data or monitor radiation dose rates and contamination levels if required. The role of the Radiation Safety Coordinator is initially filled by an on-site individual with radiation protection experience. A relief Radiation Safety Coordinator may be called-in as part of the activation of the ERO, if required. The individuals authorized to assume the responsibilities of the Radiation Safety Coordinator are radiation protection department personnel and members of the facility technical or operational staff with radiation protection experience. In the event the Radiation Safety Coordinator is absent from the facility or incapacitated, the Technical Support Coordinator will assume the responsibilities until a relief Radiation Safety Coordinator arrives at the facility.

3.3.5 Technical Support Coordinator

The Technical Support Coordinator is responsible for coordinating the technical response to the event, including

- Performing technical assessments of facility emergencies;
- Assisting the Emergency Director and Radiation Safety Coordinator in technical matters; and
- Coordinating the technical staff to augment the ERO on an as needed basis to support accident assessment and mitigation activities.

The individuals authorized to assume the responsibilities of the Technical Support Coordinator are members of the facility technical staff. In the event the Technical Support Coordinator is absent from the facility or incapacitated, the Radiation Safety Coordinator will assume the responsibilities until a relief Technical Support Coordinator arrives at the facility.

3.3.6 Criticality Safety Engineer

A criticality safety engineer is called-in upon activation of the ERO if a criticality event is suspected or confirmed, at the discretion of the Emergency Director or Technical Support Coordinator. The criticality safety engineer, when required, is responsible for

- Advising and assisting the Emergency Director in responding to the criticality accident; and
- Assisting the Radiation Safety Coordinator in conducting a radiological dose assessment appropriate for a criticality accident.

The criticality safety engineer role is filled by a designated, criticality safety qualified and trained facility engineer. If the criticality safety engineer is absent or incapacitated when required, the Radiation Safety Coordinator assumes the responsibilities until a relief criticality safety engineer arrives at the facility.

3.3.7 Security Personnel

Security personnel that are present at the facility when an emergency is declared will implement EPIPs appropriate to the event classification. In the event Security personnel become absent or incapacitated, additional Security personnel may be called-in, if required. Security personnel are responsible for

- Performing personnel Accountability, if required;
- Implementing access control of facility areas, at the direction of the Emergency Director, if required.

3.3.8 Operations Personnel

Operations personnel that are present at the facility when an emergency is declared will implement EPIPs appropriate to the event classification. In the event operations personnel become absent or incapacitated, additional operations personnel may be called-in, if required.

Operations personnel are responsible for

- Monitoring facility instrumentation and reporting results to the Emergency Director; and
- Implementing corrective actions at the direction of the Emergency Director.

3.3.9 Assessment Teams

Assessment Teams are comprised of facility operations, technical staff, or support personnel who have completed Assessment Team training, who may be called-in upon activation of the ERO by the Emergency Director, as required for the situation. Assessment Teams assist the Radiation Safety Coordinator in making radiological assessments by monitoring or collecting radiation dose rates and contamination levels. Assessment Team personnel assigned to perform duties related to monitoring or collecting radiation dose rates and contamination levels are trained and qualified to do so. In the event Assessment Team personnel become absent or incapacitated, additional Assessment Team personnel may be called-in, if required.

Assessment Teams are responsible for

- Collecting on-site and off-site field monitoring data;
- Monitoring radiation dose rates and contamination levels; and
- Assessing collateral damage to the facility.

3.3.10 Reentry and Damage Control Teams

Reentry and Damage Control Teams are comprised of facility operations, technical staff, or support personnel who have completed Reentry and Damage Control Team training, who may be called-in upon activation of the ERO by the Emergency Director, as required by accident conditions. Reentry and Damage Control Team personnel are trained in emergency response and reentry. Individuals may be assigned to both Assessment and Reentry and Damage Control Teams, depending on their experience, training and qualifications. In the event Reentry and Damage Control Team personnel become absent or incapacitated, additional Reentry and Damage Control Team personnel may be called-in, if required. Reentry and Damage Control Teams are responsible for

- Reentering an immediate evacuation zone during the emergency on a voluntary basis after being informed of the potential hazards and risks; and
- Performing actions associated with controlling and stabilizing emergency events in-progress, at the direction of the Emergency Director.

3.4 Emergency Support Organizations

In the event the decision is made by the Emergency Director to request support from off-site organizations, the following off-site support agencies and organizations would provide assistance as described below. Written agreements with these agencies can be found in Appendix 3. Local government agencies and organizations will be initially notified as described in Section 7 by contacting the Rock County 911 Communications Center. SHINE does not anticipate the need for Federal assistance.

3.4.1 Janesville Fire Department

- Fire Support

If off-site fire support is needed, the Rock County 911 Communications Center will dispatch Janesville Fire Department personnel. The nearest Janesville Fire Station is Station #2, approximately 2.5 mi from the SHINE facility. If additional fire equipment is needed, or if the Janesville Fire Department is unavailable, the Rock County 911 Communications Center will activate existing mutual aid agreements with neighboring communities for dispatch of fire equipment and personnel to the site. In instances where radioactive/hazardous materials are involved, the Emergency Director or designee will ensure information and assistance is provided to the responding off-site personnel.

Information specific to the SHINE facility is located in the Rock County 911 Communications Center's response information binder, which includes a prohibition on the use of firefighting foam inside the facility, due to criticality safety concerns.

- First Aid Support

  If immediate on-site first aid support is needed, the Rock County 911 Communications Center will dispatch Janesville Fire Department personnel. The Fire Department employs emergency medical technicians and individuals trained in first aid and qualified to provide immediate medical assistance required for radiological emergencies on-site.

- Ambulance Services

  Transportation of an injured person from the SHINE facility to an off-site medical facility will be provided by Janesville Fire Department ambulances and dispatched by the Rock County 911 Communications Center. In the event that the Janesville Fire Department ambulances are not available, the Rock County 911 Communication Center will activate existing mutual aid agreements with neighboring communities for dispatch of an ambulance to the SHINE site.

- Hazardous Materials Response

  If hazardous materials assistance is needed, the Janesville Fire Department Hazardous Material (HazMat) Response Team will be dispatched by the Rock County 911 Communication Center or by the local Fire Department Incident Commander.

3.4.2 Janesville Police Department

If law enforcement support is needed, the Rock County 911 Communications Center will dispatch law enforcement personnel. If needed, the Janesville Police Department will contact the Rock County Sheriff's Department or Wisconsin State Patrol, which maintain sheriff's deputies and State troopers in the Janesville area that can respond if additional resources are needed. Emergency law enforcement support may include the following:

- Providing traffic control;
- Controlling access to areas affected by the emergency;
- Assisting security personnel;
- Responding to emergencies at the facility, as necessary.

3.4.3 Hospitals

The following local hospital has medical services available and staff that are trained and prepared to handle radiological emergencies:

- SSM Health St. Mary's Hospital - 3400 East Racine Street - Janesville WI

Any radiation exposed or contaminated injured individuals from the site would be transported to the above facility for treatment.

3.4.4 Rock County Emergency Management

The Rock County Emergency Management organization is responsible for coordinating major emergencies, disaster response and recovery efforts in support of county and local governments. Rock County Emergency Management may provide additional resources to the response effort at its discretion.

3.4.5 State of Wisconsin

The State of Wisconsin has the general authority and responsibility to assist local units of government and local law enforcement agencies in responding to a disaster or the imminent threat of a disaster. The State of Wisconsin coordinates its response with Rock County Emergency Management as needed.

3.5 Maintaining Emergency Preparedness

The following individuals have roles related to maintaining emergency preparedness. Activities related to maintaining emergency preparedness are periodic or ongoing, and not required to be performed as part of the activation of the facility emergency organization. However, individuals responsible for maintaining emergency preparedness may also have roles in the facility emergency organization.

3.5.1 Operations Manager

The Operations Manager is responsible for

- Coordinating emergency preparedness planning;
- Reviewing and updating the emergency plan and procedures;
- Coordinating plans with other applicable organizations, and
- Ensuring that any written arrangements with off-site agencies are reviewed and renewed, as necessary.

The Operations Manager may delegate these responsibilities and authorities to any designated member of the Operations organization.

3.5.2 Criticality Safety Lead Engineer

The Criticality Safety Lead Engineer is responsible for

- Identifying potential criticality accident locations;
- Evaluating and characterizing potential criticality accidents, including making radiological dose predictions;
- Defining the immediate evacuation zone around the potential criticality accident locations; and
- Participating in the planning, conduct, and evaluation of exercises and drills.

These responsibilities may be delegated to any designated, qualified criticality safety engineer.

3.5.3 Radiation Protection Manager

The Radiation Protection Manager is responsible for

- Determining the instrumentation and equipment requirements for emergency response activities.
- Ensuring instrumentation and equipment is calibrated and maintained as required.

These responsibilities may be delegated to any designated member of the radiation protection organization.

3.5.4 Rock County Emergency Management

The Rock County Emergency Management organization is responsible for preparing response agencies, volunteer organizations, the private sector, and citizens to respond to and recover from disasters through planning and training.

4 EMERGENCY CLASSIFICATION SYSTEM

4.1 Basis for Emergency Classifications

The emergency plan provides for classification of emergencies into three standardized classes according to the severity of off-site radiological consequences: 1) Notification of Unusual Event, 2) Alert, and 3) Site Area Emergency, consistent with Table 1 of ANSI/ANS-15.16-2015. There are no credible accidents identified for the SHINE facility that would result in radiological levels exceeding the action levels for General Emergencies specified in Table 1 of ANSI/ANS-15.16-2015 at the site boundary. Therefore, the emergency plan does not include provisions for the General Emergency classification of event.

4.2 Emergencies Less Severe Than Notification of Unusual Events

SHINE recognizes emergencies of lesser consequences than the Notification of Unusual Event classification. These include physical occurrences within the facility requiring facility emergency organization response. The initial assessment of these events should indicate that it is unlikely that an off-site hazard will be created. Protective evacuations or isolations of certain areas within the facility may be necessary. Responses to these emergencies of lesser consequence than a Notification of Unusual Event are based on the recognition of immediate need for on-site staff to implement emergency measures to provide aid to affected persons or to mitigate the consequences of damage to equipment; coupled with assessing radiological monitors to determine if the possibility of a more serious emergency is present.

Situations of lesser consequence than Notification of Unusual Events that may warrant implementation of portions of this emergency plan or select EPIPs include:

1) Severe injuries to personnel;
2) Fires in the incipient stage or industrial safety hazards;
3) Transportation accidents less than one mile from the facility involving radioactive or licensed material;
4) Spills or releases of non-radioactive hazardous materials not associated with processing of licensed materials; or

5) Other situations that warrant precautionary activation of the ERO, at the discretion of the Emergency Director.

4.3 Notification of Unusual Event

A Notification of Unusual Event includes man-made events and natural phenomena creating a significant hazard potential that was previously non-existent. There is usually time available to take precautionary and corrective steps to prevent the escalation of the accident or to mitigate the consequences should it occur. No releases of radioactive or hazardous materials requiring off-site responses are expected.

Elements of the ERO will be activated or notified to increase the state of readiness as warranted by the circumstances.

Although the situation may not have caused damage to the facility, it may warrant preventive or mitigative actions or interruption of nonessential routine functions. Protective evacuations or isolation of certain areas of the facility may be necessary.

4.4 Alert

An Alert means events may occur, are in progress, or have occurred, that could lead to a release of radioactive material or hazardous chemicals incident to the processing of licensed materials; however, the release is not expected to require a response by an off-site response organization to protect persons off-site. Substantial modification of facility operating status is a highly probable corrective action. Protective evacuations or isolation of certain areas within the operations boundary or within the site boundary may be necessary.

4.5 Site Area Emergency

A Site Area Emergency means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material or hazardous chemicals incident to the processing of license material and that could require a response by off-site emergency response organizations to protect persons off-site.

A Site Area Emergency may be initiated when events such as major damage of primary boundaries containing radioactive or hazardous materials incident to the process of licensed material have occurred and actual or imminent failure of other physical barriers preventing releases have occurred and projected off-site radiological consequences exceed the action levels. Monitoring at the site boundary should be conducted to assess the need for off-site protective actions. Protective measures on site may be necessary.

5 EMERGENCY ACTION LEVELS

Emergency action levels (EALs) for the events described in the above emergency classes are found in Appendix 4.

These EALs have been established in terms of effluent monitors and other facility parameters from which the dose rates and radiological effluent releases at the site boundary can be projected.

EALs are used as criteria for determining the need for notification and participation of local agencies and the Commission. This emergency plan includes EALs that are used for determining when and what type of protective actions for the facility staff on-site to protect health and safety. The protective action guidelines are one rem whole body or five rem thyroid.

The SHINE safety analysis does not identify any events that could lead to a release of hazardous chemicals incident to the processing of license material that would require activation of the SHINE

emergency response organization to protect persons on-site, or that would require a response by an off-site response organization to protect persons off-site. For this reason, there are no EALs related to releases of hazardous chemicals incident to the processing of license material.

6 EMERGENCY PLANNING ZONES

There are no identified radiological emergencies at the SHINE facility that result in off-site plume exposure exceeding one rem whole body or five rem thyroid. Therefore, SHINE has identified an Emergency Planning Zone (EPZ) in accordance with the alternate method described in NUREG-0849 and ANSI/ANS-15.16-2015. The combined licensed power for all eight IU cells is less than 2 MW. Accordingly, the EPZ for the SHINE facility is the operations boundary.

7 ACTIVATION OF THE ERO AND NOTIFICATION

The activation of the Emergency Response Organization will be staged with the immediate activation of all or portions of the facility emergency organization, followed by the activation of emergency support organizations as required.

7.1 Activation and Notification of the Facility Emergency Organization

The shift supervisor or another individual authorized to assume the Emergency Director position shall implement the “Activation of the Emergency Response Organization” EPIP, when it is determined that conditions exist exceeding the EALs or if conditions warrant activation of the facility emergency organization in the opinion of the shift supervisor. Notifications of the emergency declaration will be made to on-site personnel and on and off-site ERO members in accordance with the EPIP addressing Activation of the Emergency Response Organization.

Emergency notification rosters are maintained in the control room and ESC, and in all controlled copies of the Emergency Plan Implementing Procedures Manual.

At the Notification of Unusual Event classification, select ERO personnel are notified and requested to either report to the facility or to remain available to respond, as the situation dictates.

At an Alert classification or higher, ERO personnel are notified for activation of the ESC.

7.2 Activation of the Emergency Support Organizations

The Emergency Director shall initiate the activation of the emergency support organizations upon the classification of a Site Area Emergency. The Emergency Director may activate all or part of the emergency support organizations for lower classes of emergencies in accordance with the EPIPs when off-site support is needed for the particular event, at the discretion of the Emergency Director.

The emergency support organizations are activated by calling the Rock County 911 Communications Center, in accordance with the EPIP addressing Activation of the Emergency Response Organization. This EPIP contains instructions for message authentication and to ensure the message was received.

7.3 Notification of Off-site Organizations

The Emergency Director ensures notifications are promptly made to off-site emergency response organizations as follows:

1) Local Agencies

A notification shall be made to the Rock County 911 Communications Center within 15 minutes of the emergency classification.

2) Nuclear Regulatory Commission (NRC)

An event will be reported to the NRC Operations Center immediately after notification of the appropriate local agencies, but not later than one hour after declaration of an emergency.

3) State Agencies

A notification will be made to the State of Wisconsin promptly after notification of the NRC Operations Center following the declaration of an emergency.

Follow-up notifications shall be made promptly whenever event conditions change significantly (e.g., event classification escalation, projected dose estimate changes), at the discretion of the Emergency Director, or at the request of an off-site organization.

Notifications are made in accordance with the EPIP addressing Notification and Communication, using concise, preformatted messages and standard reporting checklists to facility timely notification. The EPIP contains instructions for message authentication and to ensure the message was received.

Initial and follow-up notifications to off-site emergency response organizations including the NRC will contain the following information, to the extent known:

- Name, title, and telephone number of the caller;
- Location of the incident;
- Emergency class;
- Description of the emergency event;
- Date and time of incident initiation;
- Type and quantity of radionuclides or hazardous material released or expected to be released; and
- Impact of releases and recommended off-site emergency actions.

Rock County Emergency Management, contacted via the Rock County 911 Communication Center, has processes in place for prompt notification of the public if required, which include a backup method. The responsibility for activating public alert and notification systems remain with the appropriate governmental authorities.

The Emergency Communicator remains in periodic contact with off-site organizations via commercial telephone or other mutually agreeable mechanism to coordinate the emergency response and transmit updated dose projections, dose rates, contamination levels, or the results of field monitoring as necessary.

7.4 Activation of the Emergency Support Center

The ESC is activated at an Alert classification or higher. Activation for other events is optional, at the discretion of the Emergency Director. Activation of the ESC is described in the “Activation of the Emergency Response Organization” EPIP.

8 EMERGENCY RESPONSE

8.1 Responses Applicable to All Emergencies

8.1.1 Protective Action Guidelines

The Protective Actions for all classifications are based upon a guideline of one rem dose equivalent for whole body and five rem dose equivalent thyroid. Credible accidents at the SHINE facility do not result in off-site doses in excess of these guidelines.

8.1.2 Off-site Organization Responses

- Medical assistance shall be provided to injured personnel requiring more than first aid.
- Off-site fire support shall be requested to respond to all fires that progress beyond the incipient stage.
- Law enforcement shall be requested to respond to credible security events.

8.1.3 Voluntary Emergency Worker Exposures

The Emergency Director may authorize volunteer emergency workers to incur radiation exposure in excess of 10 CFR 20 limits, according to the following guidelines:

- Up to 10 rem TEDE for saving vital equipment
- Up to 25 rem TEDE for life-saving actions
- >25 rem TEDE for life-saving actions only for people fully aware of the risks involved

Individuals volunteering to receive doses in excess of 25 rem shall be briefed on the risks involved including the numerical levels of dose at which acute effects of radiation will be incurred and numerical estimates of the risk of delayed effects.

8.1.4 Provisions for Emergency Responders

- Use of Respirators: SHINE personnel use respiratory protection in any environment involving exposure to high level gaseous activity or oxygen deficient atmosphere, or where air quality is in doubt. In the presence of airborne particulates, emergency response personnel may be directed by the Radiation Safety Coordinator or radiation protection personnel to use full-face filter type respirators. The criteria for issuance of respiratory protection are described in 1100-09-03, Respiratory Protection Program.
- Use of Protective Clothing: Anti-contamination clothing, located in the facility dress out area and in the ESC is available for use by on-site personnel. The criteria for issuance of protective clothing are described in 1100-09-02, Radiation Protection Program.

8.1.5 Evacuation, Access Control, and Radiological Controls

Evacuation is the primary protective action anticipated for on-site personnel. Additional information related to evacuation is found in Section 8.6.

The Emergency Director may direct isolation and access control of facility areas to minimize exposures to radiation and the spread of radioactive contamination. Access control is implemented by site Security. Additional information on contamination control is found in Section 9.5.

8.1.6 Concurrent Emergencies

The ERO may implement more than one EPIP at any given time in order to respond to concurrent emergencies (e.g., fire, personnel injury or security incidents). The Emergency Director has the authority to prioritize emergency responses as necessary.

8.2 Emergencies Less Severe Than Notification of Unusual Events

8.2.1 Activation and Notification Actions

- The shift supervisor may activate the ERO, or portions of the ERO, if he or she feels conditions warrant activation.
- Off-site emergency response organizations may be contacted for assistance if required.

8.2.2 Additional Actions

Assessment, Corrective and Protective actions may be implemented in accordance with EPIPs, as required for the situation, at the discretion of the Emergency Director.

No radiological monitoring is anticipated to be required for this type of emergency, with the exception of transportation incidents. Personnel with portable survey equipment may be dispatched to assess the impact of transportation accidents involving licensed materials.

8.3 Notification of Unusual Event

8.3.1 Activation and Notification Actions

- The Emergency Director shall notify off-site organizations as described in Section 7.3.
- Facility emergency organization personnel are notified as described in Section 7.1. Personnel and requested to either report to the facility or to remain available to respond, at the discretion of the Emergency Director.

8.3.2 Assessment Actions

During emergencies involving airborne radioactivity, facility and surrounding area airborne radioactivity levels shall be determined by the stack release monitor and carbon delay bed effluent monitor, installed area radiation monitors and continuous air monitors, and portable monitoring equipment used by members of the ERO and communicated to the Emergency Director.

Assessment Team personnel may be dispatched to visually assess collateral damage to the facility caused by the event, or to monitor for potential releases inside or outside the facility.

The Emergency Director shall use this information and Appendix 4 to determine that the emergency is appropriately classified, and to determine release rates and contamination magnitudes, and to estimate projected exposures to on-site personnel.

8.3.3 Corrective Actions

Shutdown and/or isolation of affected or at-risk equipment or suspension of related activities should be considered by the Emergency Director. Physical barriers to contain radioactivity shall be maintained or implemented where necessary.

Specific corrective actions are provided in the EPIP addressing Emergency Classification and Initial Accident Assessment and the applicable Emergency Response EPIP.

8.3.4 Protective Actions

Protective actions may include instructing personnel to take shelter from severe natural phenomena, or evacuation of a room or small area of the SHINE facility.

8.4 Alert

8.4.1 Activation and Notification Actions

- The Emergency Director shall notify off-site organizations as described in Section 7.3.
- ERO personnel are notified and the facility emergency organization is activated as described in Section 7.1.
    - The criticality safety engineer shall report to the facility for situations involving or suspected of involving a criticality hazard.
- The ESC is activated as described in Section 7.4.

8.4.2 Assessment Actions

During emergencies involving airborne radioactivity, facility airborne radioactivity levels shall be determined by the stack release monitor and carbon delay bed effluent monitor, installed area radiation and continuous air monitors, and portable monitoring equipment used by members of the ERO and communicated to the Emergency Director.

During emergencies involving criticality hazards, criticality accident alarm system (CAAS) instrumentation shall be monitored for event escalation criteria.

Assessment Team personnel may be dispatched to visually assess collateral damage to the facility caused by the event, or to monitor for potential releases inside or outside the facility.

The Emergency Director shall use this information and Appendix 4 to determine that the emergency is appropriately classified, and to determine release rates and contamination magnitudes, and to estimate projected exposures to on-site and off-site personnel.

8.4.3 Corrective Actions

Shutdown and/or isolation of affected equipment and suspension of related activities shall be considered by the Emergency Director. Physical barriers to contain radioactivity shall be maintained or implemented where necessary.

Specific corrective actions are provided in the EPIP addressing Emergency Classification and Initial Accident Assessment and the applicable Emergency Response EPIP.

8.4.4 Protective Actions

Protective actions may include evacuation of specific areas.

For emergencies involving criticality hazards, the Emergency Director shall order a precautionary evacuation of the affected area immediate evacuation zone for non-essential personnel.

Personnel shall be instructed to evacuate or take shelter from severe natural phenomena, security events, or other severe incidents, as appropriate.

The Emergency Director should consider evacuation of all non-essential personnel to outside the operations boundary.

8.5 Site Area Emergency

8.5.1 Activation and Notification Actions

- The Emergency Director shall notify off-site organizations as described in Section 7.3.
- ERO personnel are notified and the facility emergency organization is activated as described in Section 7.1.
    - The Criticality Safety Engineer shall report to the facility for situations involving or suspected of involving imminent or actual uncontrolled criticalities.
    - Assessment Teams shall report to the facility for Site Area Emergencies.
- Emergency support organizations are activated as described in Section 7.2.
- Emergency support organizations will consider precautionary notification of the public near the site, in accordance with their internal processes.
- The ESC is activated as described in Section 7.4.
- Assembly and Accountability for the site is initiated, as described in Sections 8.6.2 and 8.6.3, unless doing so would adversely affect site personnel (e.g., severe weather or security threats).

8.5.2 Assessment Actions

Facility and site boundary airborne radioactivity levels shall be determined by the stack release monitor and carbon delay bed effluent monitor, installed area radiation monitors and continuous air monitors, and portable monitoring equipment used by members of the ERO and communicated to the Emergency Director.

During emergencies involving criticality events, CAAS instrumentation shall be monitored for event status, and the criticality safety engineer shall evaluate the consequences of the criticality accident, including those from radioactive and nonradioactive hazardous materials that might be released as a result of the accident.

Assessment Team personnel may be dispatched to visually assess collateral damage to the facility caused by the event, and should be dispatched to monitor for potential releases outside the facility and at the site boundary.

The Emergency Director shall use this information and Appendix 4 to determine release rates and contamination magnitudes and to estimate projected exposures to on-site and off-site personnel.

8.5.3 Corrective Actions

Shutdown and/or isolation of all irradiation units and suspension of all activities involving target solution and or other radioactive material shall be directed by the Emergency Director. Physical barriers to contain or mitigate radioactivity releases shall be maintained or implemented where possible.

Emergency support organizations mobilize to the site and/or set up an incident command center to respond to the emergency.

Specific corrective actions are provided in the EPIP addressing Emergency Classification and Initial Accident Assessment and the applicable Emergency Response EPIP.

8.5.4 Protective Actions

Protective actions may include evacuation of specific areas of the SHINE facility.

For emergencies involving criticality events, the Emergency Director shall order an evacuation of the affected area immediate evacuation zone.

Personnel shall be instructed to evacuate or take shelter from severe natural phenomena, security events, or other severe incidents, as appropriate.

Non-essential personnel shall be evacuated off-site unless doing so would adversely affect personnel leaving the site (e.g., severe weather or security threats).

8.6 Evacuation, Assembly and Accountability

8.6.1 Evacuation

Various classes of emergency events may require evacuation of personnel. Evacuation is the primary protective action anticipated for on-site personnel. When an evacuation is initiated, all personnel within the immediate evacuation zone shall evacuate without hesitation by planned evacuation routes to established assembly stations.

All areas within the operations boundary have established immediate evacuation zones and evacuation routes. Sufficient exits from the immediate evacuation zones exist to enable rapid and unobstructed evacuation of personnel. Immediate evacuation for personnel protection shall take precedence over contamination control or security considerations. Evacuation routes are planned to minimize the total risk considering all potential hazards, including chemical, industrial, and radiation.

The public address system, and/or audible alarms and flashing lights are used to initiate area or facility evacuations. In the event of an evacuation, visitors are the responsibility of the facility employee being visited. A register of visitors is kept by Security and is available to the Emergency Director.

Evacuation is followed by Assembly and Accountability (see Section 8.6.2 and 8.6.3).

Radiation levels shall be monitored in occupied areas adjacent to the immediate evacuation zone and periodically at the assembly station after initiation of the emergency response. Collected information shall be provided to the Radiation Safety Coordinator. If this monitoring indicates that the dose rate exceeds 100 mrem/hour in areas that continue to be occupied, non-essential personnel shall be evacuated from those areas.

Evacuation zones, planned evacuation routes, and other detailed information are provided in the EPIP addressing Evacuation, Assembly, and Accountability.

8.6.2 Assembly

Assembly stations are those areas to where personnel shall report if an evacuation of any area of the facility has been called, or if a Site Area Emergency has been declared. Personnel are trained to report to their primary assembly area, and to listen for instructions provided by the ERO. If it is determined that the primary assembly area(s) is unfit for personnel, the Emergency Director may designate alternate assembly area(s) and direct personnel using appropriate communication systems. Assembly stations are clearly identified in the EPIP addressing Evacuation, Assembly, and Accountability and posted in the area.

Assembly stations consist of:

- Control room – primary assembly area for on-duty control room and Operations personnel
- Main production facility breakroom (primary ESC) – primary assembly area for ERO personnel
- Main production facility conference room – primary on-site assembly area for non-essential personnel
- Storage building office area (backup ESC) – alternate on-site assembly area
- SHINE Building One – contingency alternate off-site assembly area

Security personnel shall individually report their location(s) to the ERO, and then perform their Accountability duties as described in the EPIP addressing Evacuation, Assembly, and Accountability.

Personnel evacuating the facility will be monitored for contamination by the portal monitors as they exit the radiologically controlled area (RCA), or with portable friskers at assembly areas. Potentially contaminated personnel arriving at assembly areas will be segregated from non-contaminated individuals until they have been monitored. Additional decontamination information is described in Section 9.5.

SHINE has the capability of identifying quickly individuals who have received doses of 10 rads or more due to a criticality accident via reading of electronic dosimeters worn by personnel in the RCA.

The Radiation Safety Coordinator is responsible for identifying exposed personnel and determining their radiation dose, in order to ensure appropriate medical assistance is provided.

8.6.3 Accountability

The purpose of Accountability is to determine the locations of all personnel at the site and to muster emergency personnel at prearranged locations in the event of a Site Area Emergency. Accountability is also performed after Evacuation and Assembly, to ensure personnel are no longer located within evacuation zone(s). When Accountability of on-site personnel is determined to be necessary by the Emergency Director, all personnel on-site shall be accounted for and the names of missing individuals (if any) are determined and reported to the Emergency Director. Accountability is performed in accordance with the EPIP addressing Evacuation, Assembly, and Accountability.

As part of Assembly and Accountability, the Emergency Director may also direct isolation and access control of facility areas to minimize exposures to radiation and the spread of radioactive contamination.

8.7 Assessment Action Information

This section contains additional details on the Assessment Actions described in Sections 8.2, 8.3, 8.4 and 8.5.

8.7.1 Projections of Off-site Impacts

Facility emergency organization personnel make projections of off-site radiation dose based on field monitoring data or installed facility instrumentation, coupled with the results

of previously performed calculations. For all credible accidents, the worst-case projected accident consequences for off-site individuals are below 500 mrem for radiological releases and below protective action guidelines for hazardous chemicals incident to the processing of licensed materials. Therefore, dose projections using real-time meteorological information or specifically-designed computer codes are not required for the SHINE facility.

Instructions for completing off-site exposure estimates are found in the EPIP addressing Emergency Radiation Exposure Control.

Off-site dose projections will be made available to off-site emergency support organizations and NRC personnel following initial determination and following any significant changes to the predictions as described in Section 7.3.

8.7.2 Source Terms

Estimated radiological and chemical source term data are available in the EPIP addressing Emergency Radiation Exposure Control for use by the ERO.

Information from facility instrumentation readings, operations logs, and technical staff may be used to augment or update the source term data. If requested, source term information related to the emergency will be made available to appropriate off-site emergency response organizations and the NRC through the established communication lines.

8.7.3 On-site and Off-site Surveying

As part of the assessment process, Assessment Teams may be dispatched to collect samples, perform area radiation readings, and observe conditions throughout the facility and around the site boundary, in order to gather information about radiation dose rates and contamination levels. Assessment Teams report information to the Emergency Director or designee using hand-held radios, mobile phones, or directly by returning to the control room or ESC.

Radiation doses are measured by portable Geiger counters and handheld survey equipment.

Contamination levels are measured by portable air samplers via collecting samples for subsequent analysis in the on-site laboratory.

Hazardous chemicals incident to the processing of licensed materials, i.e., uranium particulate, are measured by portable alpha-emitter detection equipment. Other hazardous chemicals are detected by Geiger counters or air samplers due to their expected coincident with gamma radiation.

Instrumentation and equipment used for assessment is described in more detail in Section 9.4.

Monitoring outside the facility and at the site boundary shall be implemented within two hours of declaring a Site Area Emergency involving a potential or actual release. Monitoring should be continued periodically as necessary to monitor the progress of the event. Monitoring outside the facility may be implemented at the discretion of the Emergency Director for less severe emergency classifications.

Monitoring inside the facility is normally accomplished by installed equipment. Assessment teams may be dispatched to augment data obtained from installed equipment at the discretion of the ERO.

Although postulated accidents at the SHINE facility do not require off-site monitoring or protective actions, the capability for off-site monitoring using Assessment Teams and equipment is available, if required.

Field monitoring and assessments are performed in accordance with the EPIPs addressing Emergency Radiation Exposure Control and Damage Assessments.

8.8 Criticality Event Responses

8.8.1 Notification

The criticality safety engineer reports to the facility as part of the activation of the ERO for Alerts involving the discovery of a critical-mass quantity of special nuclear material in an unsafe geometry container or other condition that creates a criticality hazard; for Site Area Emergencies involving imminent or actual occurrences of an uncontrolled criticality; or whenever his or her assistance is deemed necessary at the discretion of the Emergency Director.

8.8.2 Reentry

All activities associated with reentry and rescue shall be coordinated and authorized by the Emergency Director.

Reentry shall be planned to minimize risks to personnel. The possibility of a continuing or recurring criticality accident shall be considered. Reentry during the emergency shall only be made by personnel trained in emergency response and reentry.

Reentry should be made only if a preliminary radiological survey indicates that the radiation levels are acceptable for reentry. Existing instrumentation or temporary sensors with remote readout may be used. All reentries shall be made with continuous radiation monitoring. Both neutron and gamma instruments should be used

Personnel who reenter the immediate evacuation zone during the emergency shall be informed of the potential hazards and shall choose to accept the associated risk. Reentry should be performed by more than one person, as part of a Reentry and Damage Control Team. If personnel need to be rescued, the rescue shall be planned so as not to expose rescuers to life threatening radiation doses. The requirements for voluntary emergency worker exposures described in Section 8.1.3 apply to all reentries during the emergency.

8.8.3 Stabilization

All activities associated with stabilization of a criticality event shall be coordinated and authorized by the Emergency Director. The Emergency Director may delegate authority to the criticality safety engineer, Technical Support Coordinator, or Radiation Safety Coordinator.

If the system remains critical and is possibly causing excessive damage or significant releases of radioactive material, an early reentry effort to disable the system may be permitted. The method for disabling the system shall be carefully planned and implemented to minimize risks to the Reentry and Damage Control Team.

The Criticality Safety Engineer shall determine if the system is subcritical and shall advise the ERO of methods to ensure stabilization of affected equipment and safe conditions for personnel. This might include placing the fissile material in a favorable geometry, diluting the fissile solution below a critical concentration, or using neutron absorbers to maintain subcriticality.

Neutron absorbers are available for use in shutting down or stabilizing a criticality event. Neutron absorbers are stored in the storage building. Prior to being selected for use, the effect of the neutron absorbers under accident conditions shall be evaluated by the criticality safety engineer. Consideration shall be given to material compatibility and to cases under which addition of the neutron absorber can increase system neutron multiplication.

9 EMERGENCY FACILITIES AND EQUIPMENT

Emergency facilities and equipment are available for emergency assessment, communications, first aid and medical care, and performing corrective and recovery actions.

9.1 Control Room

The control room is the centralized on-site location from which the facility is operated, and from which effective direction can be given and effective control can be exercised during an emergency. The control room is located within the safety-related area of the main production facility. It is equipped with instrumentation to supply information on the facility status and is continuously staffed with qualified licensed operators while the facility is operating. Available control room indications are further described in Sections 9.4.1, 9.4.4, and 9.4.5.

The control room is provided with communications equipment to communicate within and outside the facility, including commercial telephones, sound powered phones, base station radios, and the ability to broadcast on the public address system. Communications equipment is further described in Section 9.8. The control room contains a controlled copy of the EPIP Manual and current notification rosters.

Emergency response activities are coordinated from the control room until the ESC is activated.

9.2 Emergency Support Center (ESC)

9.2.1 Primary and Backup Locations

The ESC is an on-site facility from which effective direction can be given and effective control can be exercised during an emergency. The ESC is located to oversee operations in the control room and the facility, but it is separated from actual activities.

- The primary location of the ESC is the main production facility breakroom.
- The backup location of the ESC is the storage building office area.

Both locations for the ESC are equipped with communications equipment, including commercial telephones, a sound powered phone, a base station radio, and the ability to broadcast on the public address system. Communications systems are further described in Section 9.8.

Both locations for the ESC are adequately sized to seat at least six people, and contain the following supplies and equipment:

- A controlled copy of the EPIP Manual and current notification rosters;
- First Aid equipment;
- Handheld lights;
- Electronic dosimeters for use by emergency personnel; and

- A supply of anti-contamination clothing.

9.2.2 Contingency Location

If both ESC locations are unsuitable for use, the ESC may be relocated to SHINE Building One, located at 4027 South US Highway 51, Janesville, 53546.

9.3 Off-site Response and Coordination Facilities

The Rock County Emergency Operations Center, located at 3530 County Road F, Janesville WI 53545, is the facility used by Rock County Emergency Management. Rock County Emergency Management may use this facility at its discretion for coordinating responses to emergencies involving the SHINE site.

In the unlikely event that the emergency renders SHINE emergency facilities and equipment unusable, alternate facilities and equipment may be supplied by Rock County Emergency Management. Written letters of agreement pertaining to alternate facilities and equipment are found in Appendix 3.

9.4 Assessment Facilities and Equipment

This section describes the instrumentation, facility and equipment used to assess emergency events.

9.4.1 Installed Facility Radiological Instrumentation

This section describes installed instrumentation that provides information on radiological conditions. Unless specified otherwise, all indications are available inside the control room. Once the ESC is activated, information will be relayed to ESC staff via the communications systems described in Section 9.8.

- Criticality Accident Alarm System

  The criticality accident alarm system (CAAS) provides information on the occurrence of an actual criticality within the facility. The CAAS detectors are located in the RPF and are arranged so that each area within the RPF generally receives coverage from at least three detectors. The CAAS is powered by the facility redundant, safety-related uninterruptible power supply system (UPSS), which is expected to be available during any credible emergency event. The CAAS is described in FSAR Section 6b.3.2.

- Area Radiation Monitoring

  Detectors for monitoring direct radiation in occupied areas comprise the radiation area monitoring system (RAMS). RAMS detectors are located in the general areas of the IF and RPF. The RAMS is described in FSAR Section 7.7.3.

- Process Radiation Monitoring

  Safety-related detectors for monitoring radiation in the facility HVAC are located in the exhaust of each hot cell of the supercell, in the exhaust from the primary closed loop cooling system (PCLS) located in each IU cell, and in the general HVAC exhaust to the facility stack. These detectors comprise the radiation monitors of the engineered safety feature actuation system (ESFAS) and the target solution vessel reactivity protection system (TRPS). These monitors are described in FSAR Section 7.7.1.

- Process Tritium Monitoring

  Detectors for monitoring tritium levels within facility processes are provided in the tritium purification system (TPS). These safety-related tritium monitors provide signals to the safety-related facility control systems, and are described in FSAR Section 7.7.1.

- Airborne Contamination Monitoring

  Continuous air monitoring system (CAMS) detectors provide information on airborne alpha-beta and tritium contamination levels within the facility. CAMS detectors are located in the general areas of the IF and RPF. The CAMS is described in FSAR Section 7.7.4.

- Effluent Monitoring

  The stack release monitor (SRM) measures radiation levels in the main facility stack, and the carbon delay bed effluent monitor (CDBEM) monitors for noble gases at the exhaust of the process vessel vent system (PVVS) carbon delay beds to provide information on radiation levels in that flow path. The effluent monitors are described in FSAR Section 7.7.5.

- Criticality Accident Dosimeters

  Criticality dosimeters or instruments are located within the facility which, when recovered and evaluated, provide spectrum information and assist in reconstruction of a criticality incident. Information from criticality dosimeters is not available in the control room or in real time.

- Environmental Monitoring

  Information from installed environmental monitoring equipment is not available in the control room or in real time. Samples must be collected and analyzed in a laboratory.

  Four continuous air samplers are installed around the SHINE site boundary. Assessment Teams may collect samples from these locations for analysis at the on-site laboratory.

  Sixteen direct radiation monitors (i.e., TLDs or equivalent) are also installed around the SHINE site boundary. These monitors may be collected and analyzed at an off-site laboratory if required.

9.4.2 Portable Instrumentation and Equipment

Portable radiological monitoring equipment is primarily stored in the health physics office inside the main production facility . Supplies and equipment are also stored in the storage building.

Inventory lists, calibration schedules, and other detailed information for portable radiological monitoring equipment are contained in the EPIP addressing Emergency Equipment and Supplies. Equipment available for emergency use includes the following:

- Sampling kits
- Handheld lights
- Portable battery-powered radiation protection instruments (e.g., portable alpha-beta and alpha-beta-gamma probes and meters)

9.4.3 Laboratories

The SHINE facility contains two laboratories. Both laboratories are located inside the main production facility, within the radiologically controlled area. The laboratories include instrumentation for specific radionuclide identification and analysis. The laboratories have the following capabilities:

- Alpha-beta meters and counters
- Gamma spectrometer with high purity germanium (HPGe) detector
- Alpha spectrometer
- ICP-OES (elemental identification)
- ICP-MS (isotopic identification)
- Liquid scintillation counter (LSC)
- High-performance liquid chromatograph (HPLC))

9.4.4 Non-Radiological Monitors and Instrumentation

This section describes installed instrumentation that provides information on non-radiological conditions. Unless specified otherwise, all indications are available inside the control room. Once the ESC is activated, information will be relayed to ESC staff via the communications systems described in Section 9.8.

- Fire Detection

Fire detection and alarm systems are located throughout the main production facility and support buildings. The systems are designed, installed, located, inspected, tested, and maintained in accordance with NFPA 72, National Fire Alarm Code.

Fire detection consists of early warning air sampling smoke detection and gas monitoring system in general areas of the RCA, and smoke detection systems in other normally occupiable areas of the facility, in accordance with the facility Fire Hazards Analysis.

- Seismic Monitoring

The seismic monitoring system includes instrumentation, control cabinets and a dedicated computer for monitoring seismic activity in the safety-related portion of the facility. The seismic monitoring system provides event recording time histories for seismic events and provides indication of a seismic event to the process integrated control system for alarm in the facility control room. Data may be retrieved from the seismic monitoring system by either the dedicated computer or via the operator workstation in the facility control room.

- Weather Monitoring

The control room contains a weather band radio to assess potential meteorological threats to the facility.

9.4.5 Irradiation and Radioisotope Production Facility Process Monitoring and Instrumentation

The facility control room allows for monitoring and controlling the production facility processes. Indications described are available in the control room. Once the ESC is activated, information will be relayed to ESC staff via the communications systems

described in Section 9.8. The following indications are important for assessing the status of emergencies and determining appropriate event classification in accordance with EALs:

Variables associated with a breach of the primary system boundary:

- Target solution vessel (TSV) level
- TSV dump tank level

Variables used in determining and assessing the magnitude of radioactive material release external to the facility:

- Stack release monitor
- Carbon delay bed effluent monitor
- RVZ1 RCA exhaust radiation detectors
- RVZ2 RCA exhaust radiation detectors

Variables used in determining and assessing the magnitude of radioactive material release inside the facility:

- Radiation area monitors (RAMS)
- Continuous air monitors (CAMS)

9.5 Decontamination Facilities, Supplies, and Controls

This section contains information on decontamination and contamination control during emergencies.

Personnel are considered contaminated if they are found by direct frisk or use of a portal monitor to have contamination above background, as defined in the EPIP addressing Emergency Radiation Exposure Control. Equipment is considered contaminated if a survey of accessible surfaces results in contamination above background, as defined in the EPIP addressing Emergency Radiation Exposure Control.

9.5.1 Normal Controls and Facilities

During emergency conditions, normal facility contamination control practices, as discussed in radiation protection implementing procedures, will be adhered to as much as possible.

A decontamination room is located inside the main production facility at the main exit from the RCA. The decontamination room is used to decontaminate personnel for their own protection as well as to prevent spreading contamination to other areas. The decontamination room contains a sink, a shower, and a supply cabinet.

9.5.2 Emergency Controls and Supplies

Temporary decontamination areas can also be set up at various locations if necessary. Decontamination supplies (e.g., buckets, hoses, soap, brushes, etc.) for use in temporary decontamination areas are stored in the health physics office. Specific inventory lists are available in the EPIP addressing Emergency Equipment and Supplies.

When affected personnel must be transported, measures will be taken to prevent the spread of contamination. Such measures will include placing affected personnel in "clean" protective clothing or wrapping in blankets. The Emergency Director will ensure that the

emergency support organizations providing transportation and treatment are alerted if injured personnel are contaminated.

Potentially contaminated emergency vehicles will be surveyed before they are allowed to leave the site. SHINE is responsible for decontaminating contaminated vehicles. Off-site decontamination, if necessary, of equipment, facilities and personnel for the emergency support organizations will be accomplished by those organizations. Decontamination process details are found in the EPIP addressing Emergency Radiation Exposure Control.

9.6 Personnel Monitoring Equipment

SHINE employees responding to a radiological emergency will use their normally assigned dosimetry (i.e., thermoluminescent dosimeter (TLD) badges or equivalent) to monitor beta and gamma exposure, plus any added high range or specialized dosimetry deemed necessary by the Emergency Director or Radiation Safety Coordinator.

Personnel entering areas with a potential for neutron radiation are verified to have or are supplied neutron dosimeters (e.g., thermoluminescent albedo dosimeters, electrochemically etched plastics (CR-39), or equivalent) prior to entering the area.

Personnel entering areas with a potential for a criticality accident are supplied personal criticality accident dosimeters (i.e., as specified in ANSI N13.3-1969 (R1981), “Dosimetry for Criticality Accidents”) prior to entering the area.

All personnel responding to the radiological emergency are given electronic dosimeters. Equipment for prompt on-site readout of electronic dosimeters is maintained in the health physics office.

Emergency support organization personnel are given dosimetry (gamma, beta, neutron, and/or criticality accident monitoring, and electronic dosimeters) prior to entering the affected area. A supply of emergency dosimetry is maintained in the health physics office and is readily available to emergency personnel. Details related to personnel dosimetry use during emergencies are found in the EPIP addressing Emergency Radiation Exposure Control.

Bioassay sample collection is used for assessing internal exposure, in accordance with the facility radiation protection procedures.

Exposure records are maintained in accordance with the normal facility radiation protection and records processes.

9.7 First Aid and Medical

9.7.1 On-site First Aid Assistance, Equipment and Supplies

First aid equipment is strategically located in the following areas, at minimum:

- Control room
- Main production facility breakroom (primary ESC)
- Storage building office area (backup ESC)
- Main production facility shipping/receiving dock

First Aid supply inventory information is found in the EPIP addressing Emergency Equipment and Supplies.

Facility emergency organization personnel are trained in basic first aid. Personnel who require care beyond first aid will be treated by emergency support organization personnel and transported to off-site medical facilities as necessary.

9.7.2 Off-site Medical Arrangements and Facilities

SHINE has made arrangements with the City of Janesville Fire Department and local hospitals to transport and treat personnel injured or exposed to radiation, including those who may be contaminated. Provisions for handling contaminated personnel are described in Section 9.5.

- The City of Janesville Fire Department has personnel who can provide emergency on-site first aid and transportation of affected individuals to off-site facilities for treatment.
- SSM Health St. Mary's Hospital - 3400 East Racine Street - Janesville WI

Additional details about arrangements and communications with off-site organizations are provided in Section 3.4 and in the EPIP addressing Notification and Communication.

9.8 Communications

This section describes the communications systems available for use by the ERO. Communications plans are contained in the EPIP addressing Notification and Communication, containing titles and alternates for those in charge at both ends of the communication links and the primary and backup means of communication.

9.8.1 Normal Commercial Telephones

The facility uses a commercial telephone communication system that provides for on-site two-way communication, paging and public address, and party-line-type voice communications. Stations for this system are located throughout the main production facility and outbuildings. These phones provide two-way normal communication between personnel within the SHINE campus and between the SHINE campus and off-site persons. Normal commercial telephones are the primary on-site and off-site communication system. The normal telephone communication system contains redundant servers and a battery backup.

9.8.2 Public Address

The public address (PA) system uses the telephone communication system to initiate public address announcements. The system also includes dedicated base transmitting units, which are designed to continue to function in the event of a failure of the phone system. Announcements can be made site-wide or to specific predefined zones. The public address system is audible in the following areas:

- Occupiable areas of the main production facility RCA
- Normally occupied areas of the main production facility and support buildings
- Hallways and corridors of the main production facility and support buildings
- Outdoor areas on the SHINE campus within the controlled access area fence

The PA system is a primary on-site communications system.

9.8.3 Sound Powered Phones

Sound-powered phones supplement the telephone system for on-site communications. The system uses portable sound-power telephones that can plug into local terminal jacks. The sound powered telephones are located in areas where critical operations and response activities are anticipated to occur. The sound powered telephones utilize the user's voice to create the necessary power for reliable and uninterrupted communications in the event of an emergency. The phones operate independent of any power source and are not affected by loss of power to the facility.

- Control room
- Main production facility breakroom (primary ESC)
- IF general area
- RPF general area

9.8.4 Radio

Handheld portable radios are available for use by facility emergency organization personnel as an additional on-site backup communication device. Handheld radios are powered by replaceable, rechargeable battery packs that maintain the ability to be independent of the facility power once charged. Base units are placed throughout the SHINE campus and communicate with the portable radios. Base stations are located at the following locations, at minimum:

- Control room
- Main production facility breakroom (primary ESC)
- Storage building office area (backup ESC)

The radio system also contains radios, antenna, battery backups, and amplifiers capable of communicating with the Janesville Wisconsin fire and police departments (emergency support organizations). Radios are a backup on-site communications system.

9.8.5 Mobile Telephones

An emergency mobile telephone is stored in the control room. Personal mobile telephones normally carried by SHINE personnel and emergency support organization personnel are also expected to be present in the facility. Mobile telephones serve as a backup on-site and off-site communications system.

9.9 Equipment Required to Maintain Safe Shutdown

The following facility equipment is relied upon to maintain a safe shutdown state:

- Target solution vessel off-gas system (TOGS)

  The TOGS is required to circulate gas within an irradiation unit to recombine hydrogen and oxygen generated from radiolysis. The TOGS is required to continue operating for five minutes after an irradiation unit has been shut down. The TOGS is described in FSAR Sections 4a2.1 and 4a2.8.

- Uninterruptible power supply system (UPSS)

  The UPSS provides power to the TOGS in the event normal power sources are lost. The UPSS also provides power to instrumentation and control systems and other systems used for monitoring facility status. The UPSS is described in FSAR Section 8a2.2.

- Nitrogen purge system (N2PS)

  The N2PS is required to prevent the accumulation of elevated levels of hydrogen in the irradiation units and in process tanks and vessels containing irradiated target solution. The N2PS is described in FSAR Sections 6b.2.3 and 9b.6.2.

10 RECOVERY

Recovery consists of those actions required to restore the facility and its impact on public health and safety to a safe status.

The Emergency Director determines when the emergency condition no longer exists, and Recovery can begin. The Emergency Director may secure from the emergency when conditions no longer meet an Emergency Action Level and it appears unlikely that conditions will deteriorate.

The Emergency Response Organization will also be the Recovery Organization. The Emergency Communicator will ensure that records of the event are compiled, evaluated, and retained.

10.1 Criteria

The criteria used to determine when reentry of the facility following an accident is appropriate are:

- Preliminary radiological survey indicates that the radiation levels are acceptable for reentry. Existing instrumentation or temporary sensors with remote readout may be used.
- Reentry personnel can perform the required activities within normal 10 CFR 20 exposure limits.
- Any fire, flood, earthquake, hazardous chemical release or similar emergency condition or threat to security no longer poses an immediate danger to reentry personnel or has been mitigated to an acceptably safe level.

The criteria used to determine when operation of the facility may be resumed following an emergency are:

- All applicable technical specifications and associated surveillance requirements are satisfied.
- Any fire, flood, earthquake, hazardous chemical release or similar emergency condition or threat to security no longer exists.
- Damage to affected facility structures, systems and components (SSC) designated for re-start has been repaired, and post maintenance tests and inspections have been completed satisfactorily, in accordance with normal facility procedures.
- Any SSC that cannot or will not be repaired, or where the repair will be deferred until a later date, have been appropriately isolated or abandoned, as applicable, and a technical justification (e.g., design change, technical report, etc.) of the acceptability of the existing condition has been prepared and approved in accordance with normal facility procedures.

10.2 Recovery Actions and Procedures

Recovery plans and procedures will be written and approved as needed. These procedures include those used to determine the necessary actions to reduce any ongoing releases of radioactive material or hazardous chemicals incident to the processing of licensed material and to prevent further incidents.

The recovery plans and procedures will be prepared by the facility technical staff, with input from the emergency support organizations, as applicable. Recovery plans and procedures will be evaluated and approved by an individual authorized to assume the role of the Emergency Director. Recovery plans and procedures will include elements such as stabilization actions, repair methods, and decontamination methods, as needed. The recovery plans and procedures will be compiled, kept and retained in accordance with the normal SHINE document control and records management processes.

SHINE has made the following provisions for accomplishing required restoration and recovery actions:

- The Emergency Director is assigned the responsibility for assessing the damage to and status of the facility's capabilities to safely control radioactive material and hazardous chemicals incident to the processing of licensed materials.
- Recovery assessments will be performed by Assessment Teams, using guidance contained in the EPIP addressing Damage Assessment.
- Normal processes for controlling personnel exposure, facility maintenance, and configuration control are in place.

11 MAINTAINING EMERGENCY PREPAREDNESS

The Operations Manager is responsible for maintaining emergency preparedness, including administration of the Emergency Plan training program.

11.1 Facility Emergency Organization Training

SHINE personnel with roles and responsibilities within the facility emergency organization receive initial training prior to being assigned those responsibilities, and receive annual refresher training, on the following topics:

- Emergency plan overview;
- Emergency procedure usage;
- Facility layout;
- Characteristics of a criticality event;
- Radiation safety;
- First aid; and
- Use of protective equipment and monitoring devices.

Team training, i.e., training of individuals together in groups consistent with their normal shift or assigned ERO team, is not required due to the small size of the total facility staff.

Initial training on the above topics is expected to take eight hours. Annual refresher training is expected to take four hours.

Additionally, individuals with authority to assume the roles described in Section 11.1.1 through 11.1.7 receive additional initial and annual refresher training in the specified topics below. Details on training requirements, including the expected number of hours for initial and annual refresher training for each topic, are contained in the EPIP addressing Emergency Organization Training.

11.1.1 Emergency Director

Individuals who have authority to assume the role of the Emergency Director receive additional training on the following topics:

- Emergency action levels and accident assessment;
- Notifications and communication with off-site organizations

Initial training on the above topics is expected to take four hours. Annual refresher training is expected to take two hours.

11.1.2 Control Room Staff

Individuals assigned to the control room staff, i.e., licensed operators, receive additional training on the following topics:

- Emergency action levels and accident assessment;
- Notifications and communication with off-site organizations

Initial training on the above topics is expected to take four hours. Annual refresher training is expected to take two hours.

11.1.3 Emergency Communicator

Individuals who have the authority to assume the role of the Emergency Communicator receive additional training on the following topics:

- Notifications and communication with off-site organizations

Initial training on the above topics is expected to take two hours. Annual refresher training is expected to take one hour.

11.1.4 Assessment Teams

Individuals assigned to Assessment Teams receive additional training on one or more of the following topics, depending on their particular role:

- Radiological monitoring;
- Damage assessment;
- Respirator use
    - Respirator training is administered in accordance with the normal respiratory protection program

Initial training on the above topics is expected to take two to four hours, depending on the individual's assigned duties. Annual refresher training is expected to take one to two hours.

11.1.5 Reentry and Damage Control Teams

Individuals assigned to Reentry and Damage Control Teams receive additional training on one or more of the following topics, depending on their particular role:

- Damage control and repair;
- Response to criticality accidents, including reentry and stabilization;
- Respirator use
    - Respirator training is administered in accordance with the normal respiratory protection program

Initial training on the above topics is expected to take two to four hours, depending on the individual's assigned duties. Annual refresher training is expected to take one to two hours.

11.1.6 Criticality Safety Engineer

Criticality safety engineers are trained qualified as part of the facility normal criticality safety program. In addition, criticality safety engineers receive training on their duties and responsibilities described in this Emergency Plan in the event of a criticality accident.

11.1.7 Security Personnel

Security Personnel receive initial and annual refresher training on access control, Assembly, and Accountability during emergencies.

Initial training is expected to take two hours. Annual refresher training is expected to take one hour.

11.2 Off-site Organization Training and Orientation

This section describes training, briefings, and orientation for off-site organizations.

11.2.1 Emergency Support Organization Training

Training is offered annually to off-site emergency support organization personnel in accordance with the EPIP addressing Emergency Organization Training. SHINE personnel will meet with each off-site assistance group to accomplish training and review items of mutual interest including relevant changes to the program. This training may include:

- Facility tours;
- Reentry procedures;
- Facility hazards;
- Information concerning facility access control (normal and emergency);
- Permitted manual fire suppression techniques;
- Potential accident scenarios;
- EALs;
- Notification procedures;

- Exposure guidelines;
- Personnel monitoring devices;
- Communications;
- Contamination control; and
- The off-site assistance organization role in responding to an emergency at SHINE, as appropriate.

11.2.2 Community Orientation

Radiological and SHINE facility orientation opportunities are offered biannually to other local services personnel (e.g., local news media, local government officials, etc.). The orientation may include:

- Emergency Plan purpose and/or brief overview;
- Facility tours; and/or
- Radiation safety overview.

11.3 General Site Personnel

This section describes training, briefings, and orientation related to the emergency response that are provided to individuals who may be on-site, including non-emergency response personnel.

11.3.1 SHINE Personnel

SHINE employees and other individuals with unescorted access to the facility, including those who are not assigned duties as part of the ERO, receive initial orientation training on the following topics:

- Emergency plan introduction
- Facility layout, evacuation, assembly, and accountability; and
- Facility alarm recognition.

Orientation training is expected to take two hours. The training emphasizes that emergency actions, including evacuation, should be performed in a manner to reduce risk of injury.

Additionally, SHINE employees and other individuals with unescorted access to the facility receive additional training:

- Individuals who are permitted to enter the RCA receive radiation safety training in accordance with normal Radiation Protection processes.
- Individuals who manage, work in, or work near facilities where the potential exists for a criticality accident receive criticality safety training in accordance with normal Criticality Safety processes.

11.3.2 Visitors

Visitors to the site are briefed that they shall ensure a facility employee being visited is aware of their location at all times and shall follow SHINE personnel instructions in the event of an emergency.

11.4 Drills and Exercises

Periodic drills and exercises are conducted to test the adequacy of EPIPs, to test emergency equipment and communications networks, and to ensure that ERO personnel are familiar with their duties. Drills are primarily on-site tests of one or more portions of the integrated capability of emergency response plans, equipment and organizations with off-site support functions being simulated. An exercise is a type of drill that is a full-scale test of the ERO, and off-site organizations are invited to participate. Drills and exercises are conducted in accordance with the EPIP addressing Drills and Exercises.

SHINE is committed to conducting exercises and drills in a manner that demonstrates the capability of the organization to plan and perform an effective response to an emergency.

11.4.1 Facility Emergency Organization Participation

Individuals who are assigned roles within the facility emergency organization are required to participate in at least one exercise or drill involving a combination of some of the principal functional areas of the ERO emergency response capabilities every two years to demonstrate task-related knowledge, and update and reinforce their previous response training.

Principal functional areas include the management and coordination of emergency response, accident assessment, event classification, notification of off-site authorities, assessment of the on-site and off-site impact of radiological releases, protective action recommendation development, protective action decision making, plant system repair and mitigative action implementation.

11.4.2 Planning and Controlling Drills and Exercises

Drills and exercises should be planned to demonstrate the following objectives:

- To test the capabilities of the emergency organizations and communication system and to reinforce emergency training.
- Resources are effectively used to control the site, mitigate further damage, control radiological releases, perform required on-site activities under simulated radiation or airborne and other emergency conditions, accurately assess the facility's status during an accident, and initiate recovery.
- Personnel protection measures, including controlling and minimizing hazards to individuals during fires, medical emergencies, mitigation activities, search and rescue, and other similar events, are implemented effectively and demonstrated via inclusion of these types of events in scenarios.
- On-site communications effectively support emergency response activities.
- The Emergency Communicator disseminates accurate, reliable, timely, and understandable information.
- Exercise and drill scenarios, as appropriate, emphasize coordination among on-site and off-site responses.

Exercises and drills shall be developed as written scenarios, and should be planned and controlled by personnel who are not direct participants (players) in the exercise. The technical staff shall participate in the planning of drills and exercises. Exercises shall have

defined objectives that specify the aspects of emergency response selected for testing or reinforcing.

Off-site organizations or governments, including city, county, and state agencies, shall be invited and allowed to participate in drills or exercises at their request.

Prior to the beginning of the exercise or drill, effective player, controller, evaluator, and observer pre-drill briefings are conducted. The pre-staging of equipment and personnel is minimized to realistically test the activation and staffing of emergency facilities.

During the exercise or drill, scenario data and messages provided by the controllers effectively maintain the timeline and do not interfere with the emergency organization's response to exercise scenario events, except when safety considerations are involved.

11.4.3 Drills

Drills are conducted annually, at minimum. The performance of an exercise fulfills this minimum requirement. The maximum interval between drills or between a drill and an exercise will not exceed 15 months. The maximum interval provides operational flexibility only and is not to be used to reduce frequency. The established frequency will be maintained over the long term.

The required annual drill shall test some combination of the principal functional areas of the ERO emergency response capabilities, and is conducted as an action drill. An action drill tests the integrated capability of the emergency plan, or a component thereof, and may include instruction periods to develop and maintain skills in a particular operation.

Drills may also be conducted to test a particular portion of the emergency plan, to consider accident management strategies or to instruct or train ERO personnel. One drill (or exercise) per year should include a realistic scenario involving a simulated criticality.

Additionally, evacuation drills shall be conducted at least annually. An evacuation may be included as part of the required annual drill or conducted separately. Evacuation drills should be scheduled to include all personnel who routinely work within the immediate evacuation zone. The drills shall be preannounced by written notice, posted signs, or public address announcement to minimize the possibility that accident or injury could result. A response to a false alarm can only be substituted for an evacuation drill if the required actions are observed or demonstrated.

11.4.4 Exercises

The on-site and off-site emergency plans shall be exercised every two years with full participation by each off-site authority having a role under the plans. The maximum interval between exercises will not exceed 30 months. The maximum interval provides operational flexibility only and is not to be used to reduce frequency. The established frequency will be maintained over the long term.

Off-site emergency support organizations shall be invited to participate in the planning, conduct and execution of the full participation exercise. If any off-site organizations or governments refuse to participate, their participation is not required in accordance with 10 CFR 50.47(c)(1). In such cases, an exercise shall be held with the facility emergency organization and such governmental entities as elect to participate in the emergency planning process.

11.5 Operational Readiness

The following activities are conducted in order to maintain operational readiness of the ERO and emergency equipment and supplies.

11.5.1 Communications

Communication checks are conducted quarterly with off-site emergency support organizations to verify the functionality of initial notification points, including backup communications systems, in accordance with the EPIP addressing Notification and Communications.

Communication checks are conducted annually with the NRC in accordance with the EPIP addressing Notification and Communications.

Emergency telephone numbers contained in rosters and emergency response telephone directories are verified and updated as part of the communication checks.

11.5.2 Equipment and Supplies

Portable instrumentation and equipment described in Section 9.4.2 will be functionally tested quarterly, and inventoried, maintained and calibrated at least annually, in accordance with the EPIP addressing Equipment and Supplies.

First Aid supplies and equipment described in Section 9.7.1 will be inventoried annually, in accordance with the EPIP addressing Equipment and Supplies.

11.6 Critiques

Exercises, drills, and training that provide performance opportunities to develop, maintain, or demonstrate key skills must provide for formal critiques in order to identify weak or deficient areas that need correction. Any weaknesses or deficiencies that are identified in a critique of exercises, drills, or training must be corrected. Critiques for exercises and drills should involve observers, controllers and representative participants. Critiques are performed in accordance with the EPIP addressing Critiques and Performance Improvement. Deficiencies that are identified are entered into the Issue Management system, and corrective actions will be taken, as necessary. If updates to the emergency plan or EPIPs are required as a result of the critiques, they will be processed in accordance with the EPIP addressing Revising the Emergency Plan and EPIPs and the normal Document Control processes.

11.7 Emergency Plan and Procedure Use and Maintenance

SHINE maintains procedures for implementing the requirements of the emergency plan. A list of EPIPs is found in Appendix 5. Controlled copies of the emergency plan and EPIPs are retained in the normal electronic SHINE Document Control system and controlled hard copies of the EPIP Manual are stored in the control room, primary ESC and backup ESC.

SHINE maintains emergency procedures for each area in which licensed special nuclear material is handled, used, or stored to ensure that all personnel withdraw to an area of safety upon the sounding of a CAAS alarm. This information is found in the “Criticality Emergency Response” EPIP.

Copies of current EPIPs are retained in accordance with the normal Records Management process for the life of the facility, and copies of and revised or superseded EPIPs are retained for at least three years.

The emergency plan and EPIPs are annually reviewed for accuracy by the Operations Manager, or designated member of the facility emergency organization. The emergency plan, EPIPs and

agreement letters are reviewed by those responsible every two years. Emergency action levels (Appendix 4) are reviewed with local governmental authorities on an annual basis.

The emergency plan and EPIPs are reviewed, revised, updated, approved and distributed in accordance with the EPIP addressing Revising the Emergency Plan and EPIPs and the normal SHINE Document Control process. This EPIP implements the requirements of 10 CFR 50.54(q) and Appendix E to Part 50, Section IV.B.2.

12 REFERENCES

12.1 1100-09-02, Radiation Protection Program

12.2 1100-09-03, Respiratory Protection Program

12.3 American National Standards Institute/American Nuclear Society, ANSI/ANS-15.16-2015, "Emergency Planning for Research Reactors," ANS, LaGrange Park, IL

12.4 American National Standards Institute/American Nuclear Society, ANSI/ANS-8.23-2007, "Nuclear Criticality Accident Emergency Planning and Response," ANS, LaGrange Park, IL

12.5 American National Standard Institute/American Nuclear Society, ANSI/ANS-8.21-1995, “Use of Fixed Neutron Absorbers in Nuclear Facilities Outside Reactors,” ANS, LaGrange Park, IL

12.6 American National Standard Institute/American Nuclear Society, ANSI/ANS-8.20-1991, “Nuclear Criticality Safety Training,” ANS, LaGrange Park, IL

12.7 U.S. Nuclear Regulatory Commission, "Emergency Planning for Research and Test Reactors," Regulatory Guide 2.6, Revision 2

12.8 U.S. Nuclear Regulatory Commission, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors," NUREG-0849, October 1983 (ML062190191)

12.9 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)

12.10 U.S. Nuclear Regulatory Commission, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content," NUREG-1537, Part 2, February 1996 (ML042430048)

12.11 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)

12.12 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)

12.13 Los Alamos National Laboratory; "A Review of Criticality Accidents," LA-13638, May 2000

12.14 CALC-2018-0048, Rev. 5, “Radiological Dose Consequences,” SHINE Medical Technologies

Appendix 1 FIGURES

Figure 1 – SHINE Facility Site Layout

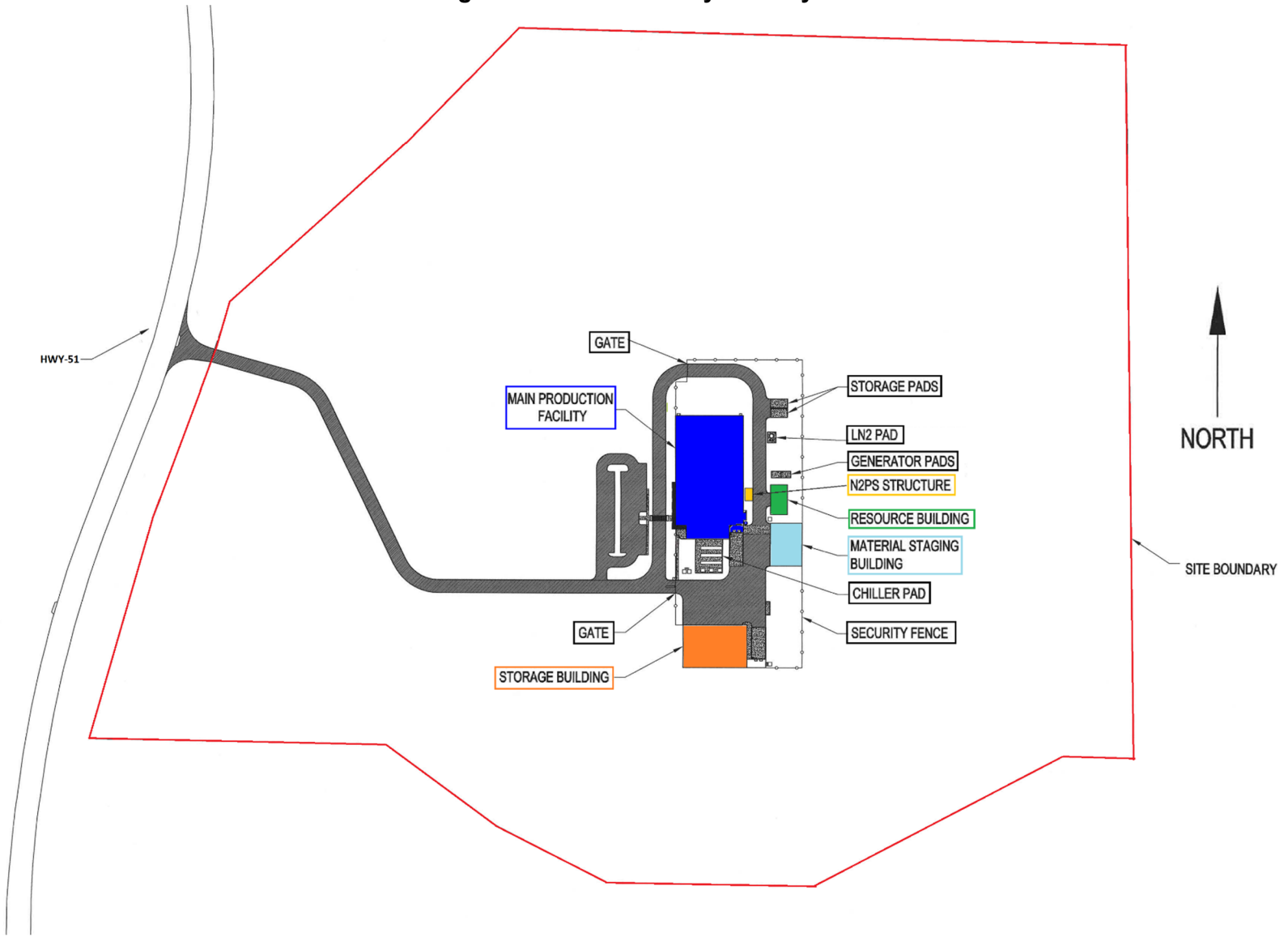


Figure 2 – SHINE Main Production Facility General Arrangement

SRI

Figure 3 – SHINE Site Buildings and Surrounding Area

Figure 4 – SHINE Site General Area Map

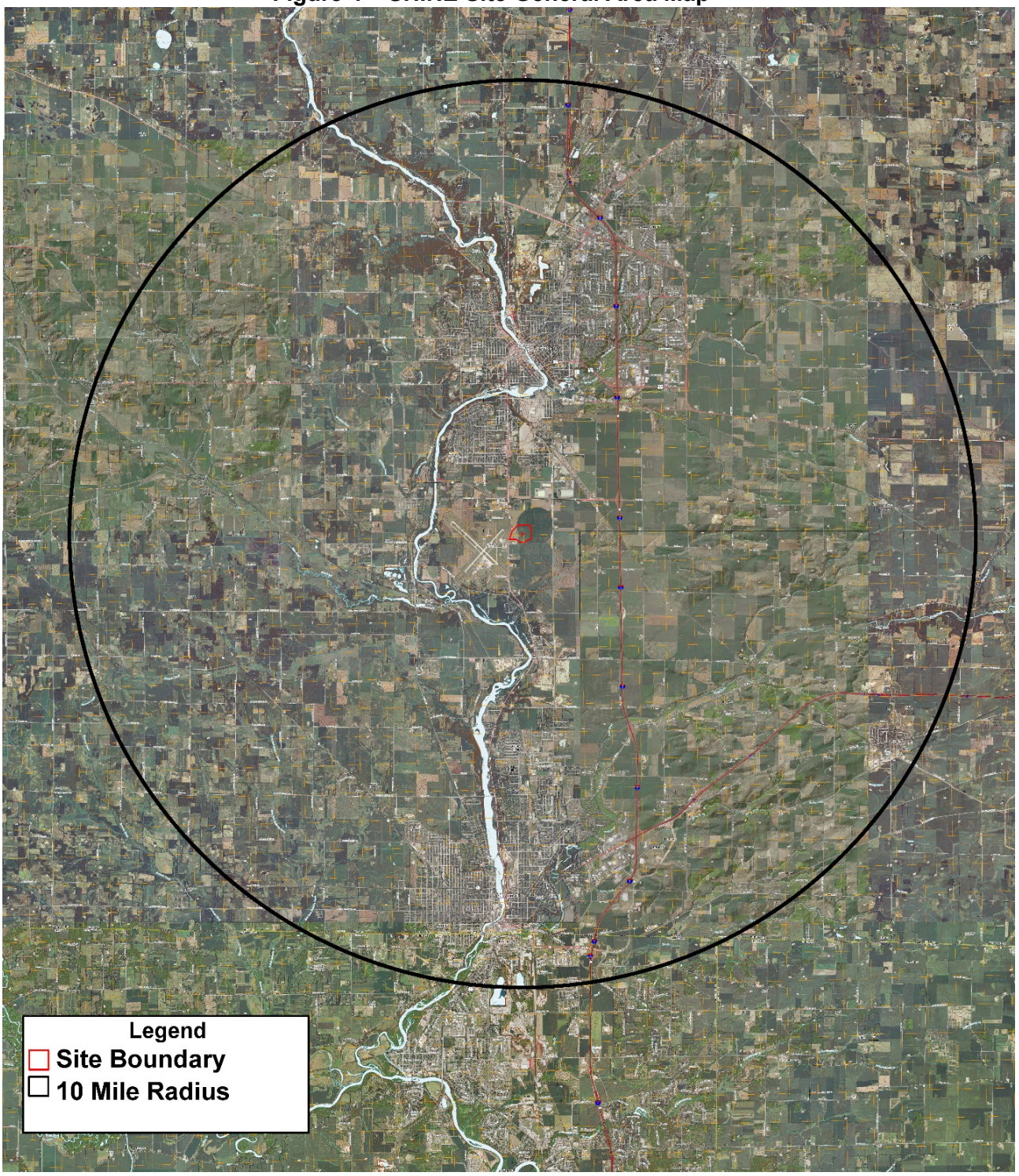


Figure 5 – U.S. Geological Survey Janesville West Quadrangle

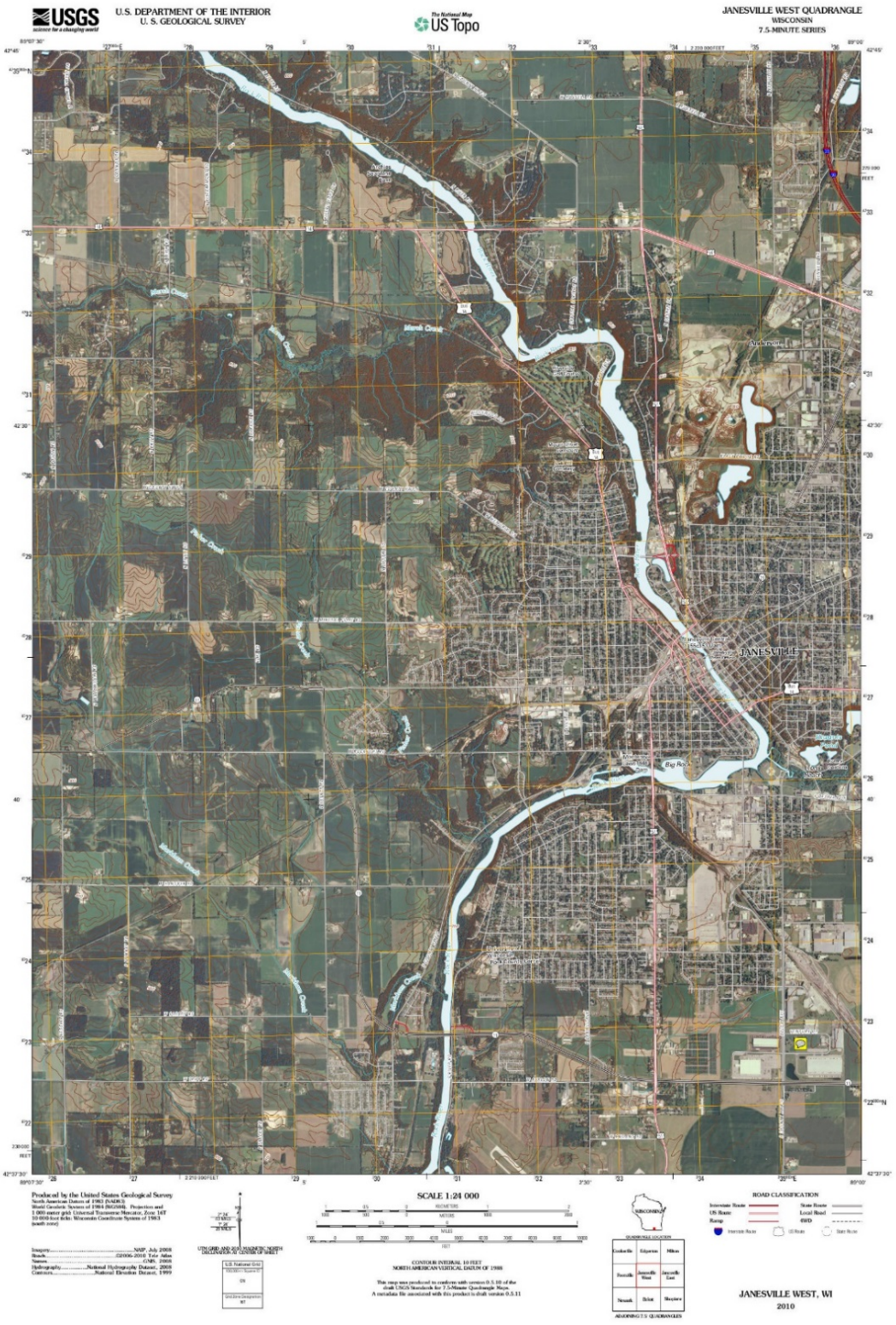


Figure 6 – U.S. Geological Survey Beloit Quadrangle

Figure 7 – U.S. Geological Survey Janesville East Quadrangle

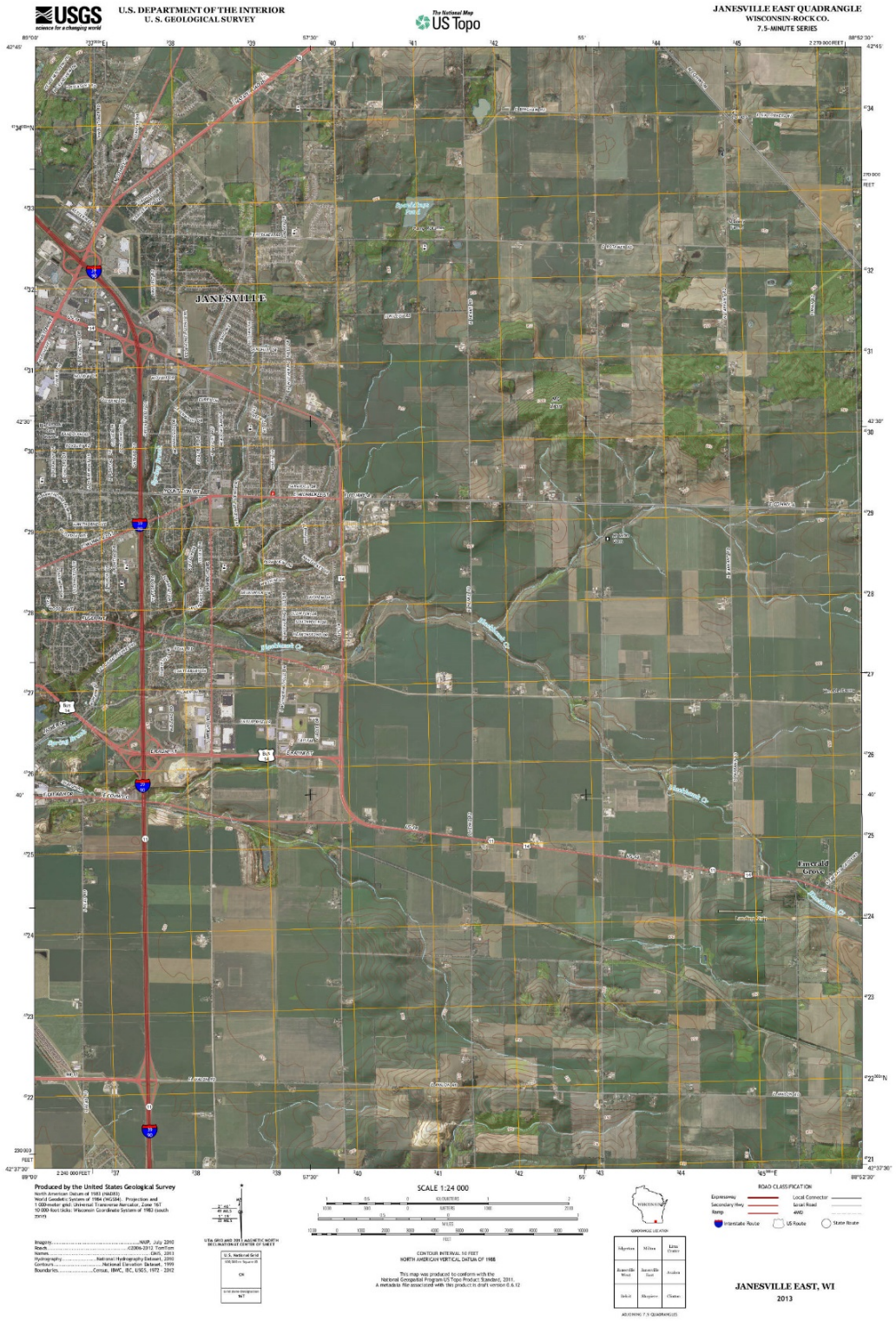


Figure 8 – U.S. Geological Survey Shopiere Quadrangle

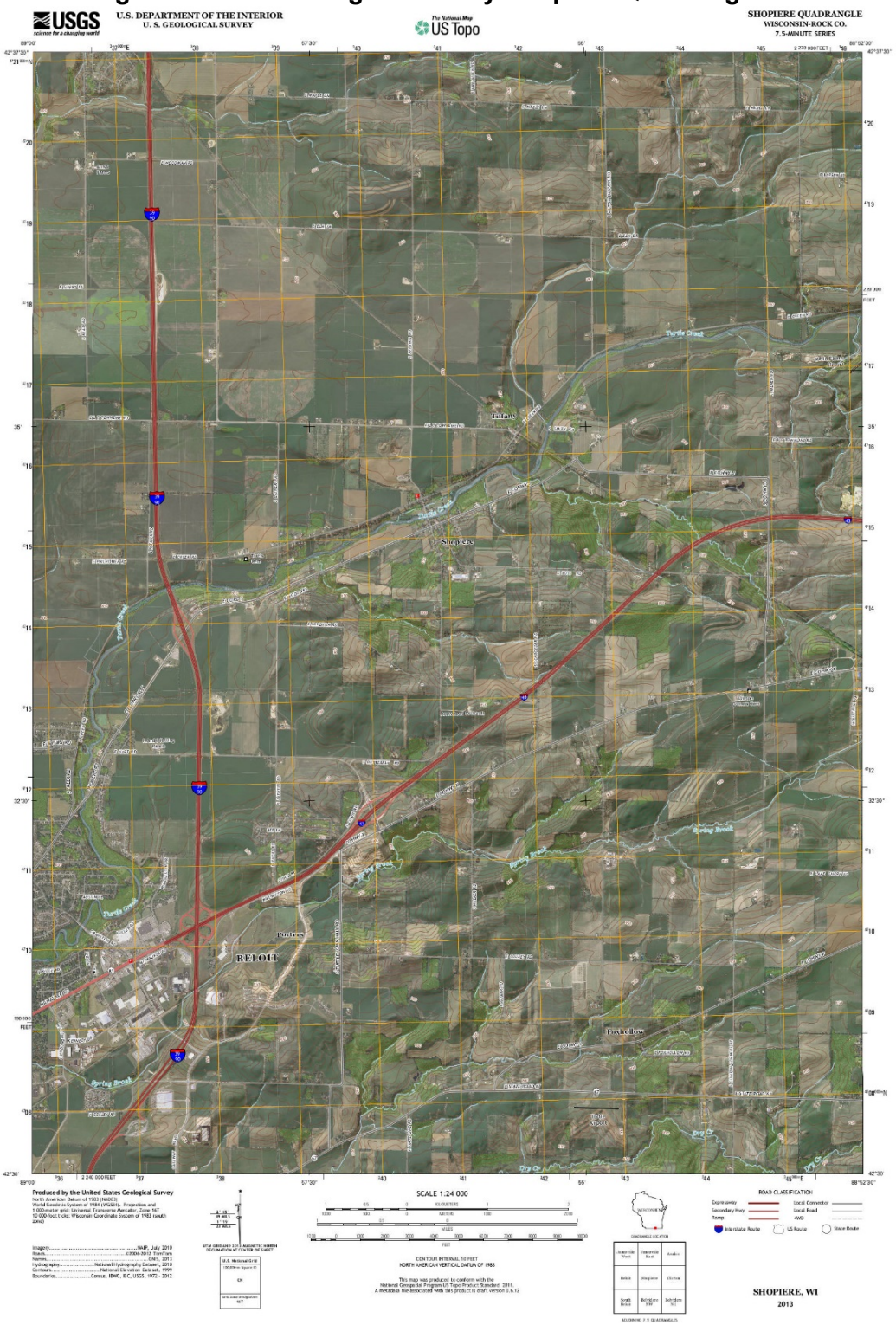


Figure 9 – Emergency Organization Interrelationships

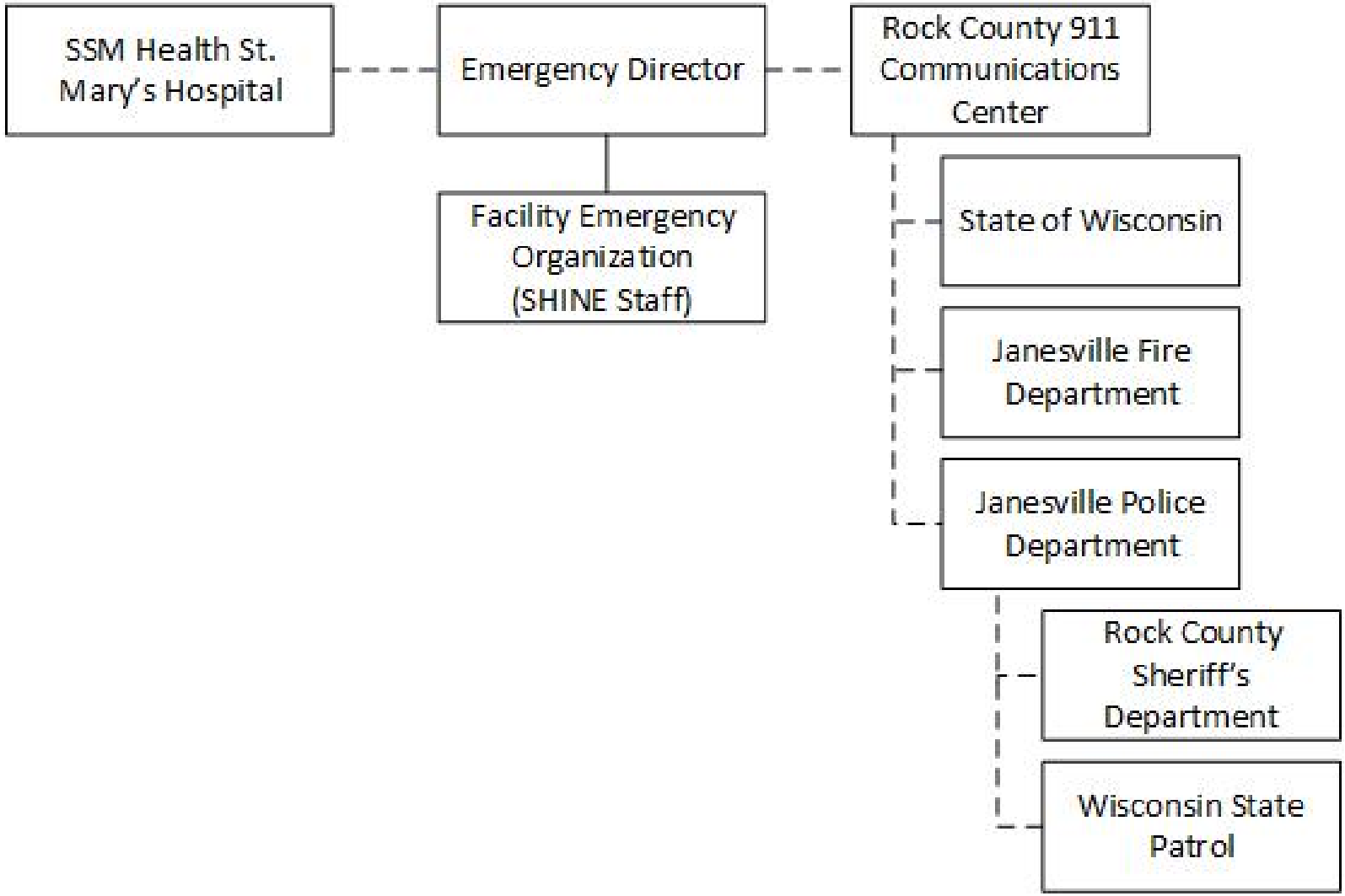


Figure 10 – SHINE Normal Facility Operation Organization Chart

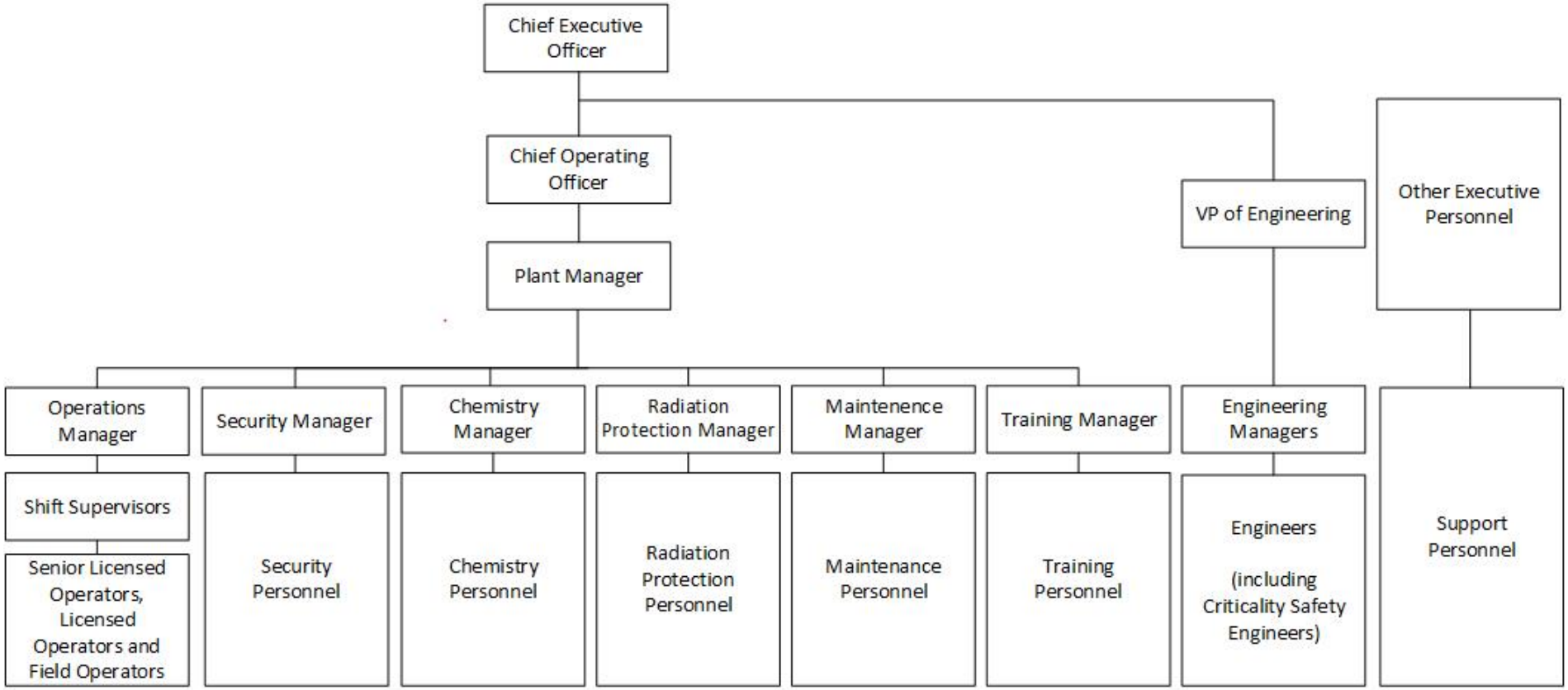
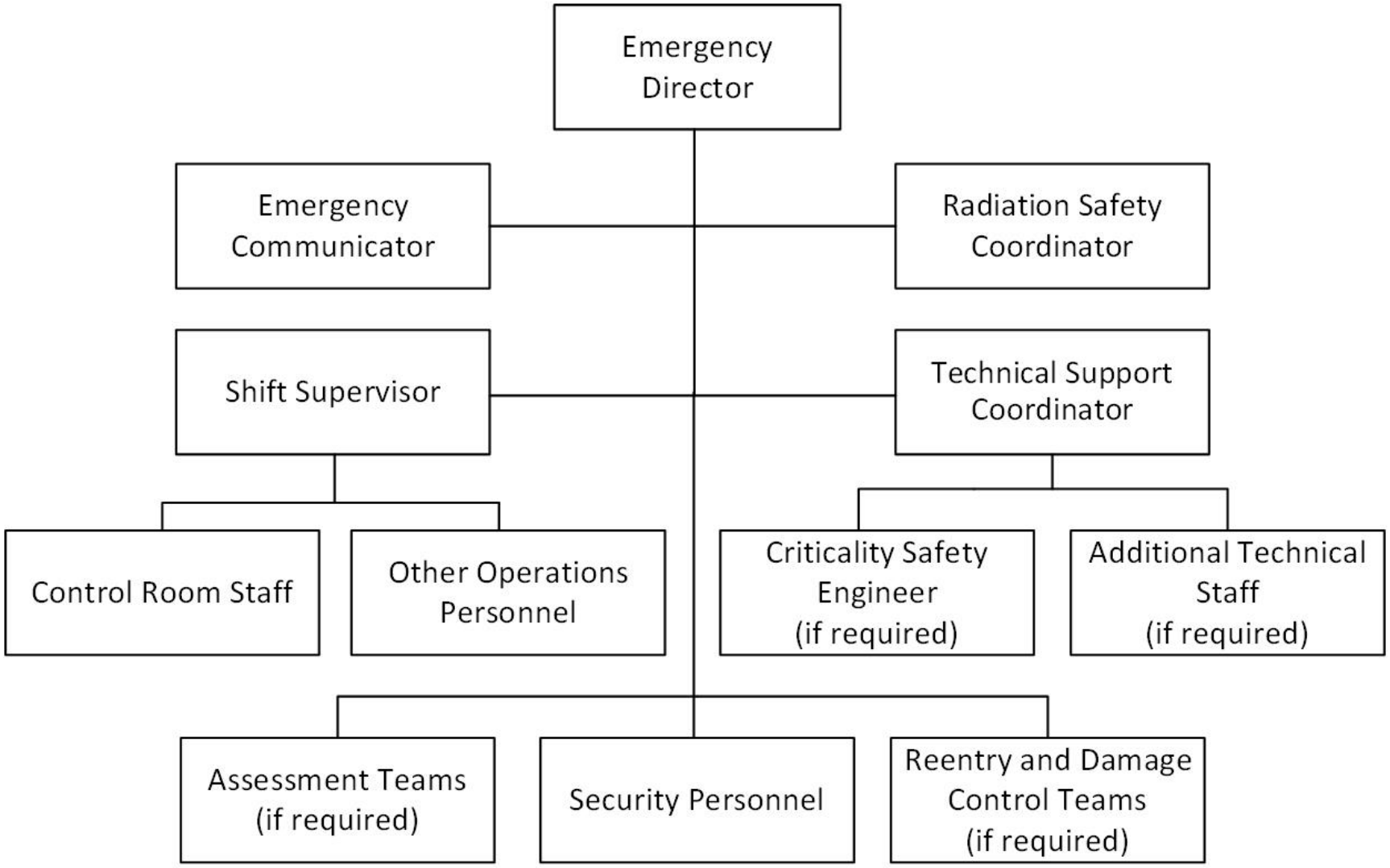


Figure 11 – SHINE Facility Emergency Organization



Appendix 2 RADIOACTIVE AND HAZARDOUS MATERIALS

Chemical Name	Hazard	Location	Approximate Maximum Site Inventory	Storage State
Alpha-benzoin oxime	Chemical	In process	1 kg	Liquid, In Process
		Liquid waste	2 kg	Liquid
		Chemical storage	1 kg	Solid Powder (two 250 g containers)
Ammonia (28 wt% in storage)	Radiological / Chemical	Liquid waste	21 kg	Liquid, In Process
	Chemical	Chemical storage	499 kg	Liquid (two 1000 L IBC)
[ ]PROP/ECI	Chemical	In process	5 kg	Liquid, In Process
		Liquid waste	2 kg	Liquid
		Chemical storage	10 kg	Solid (two 5 kg containers)
Hydrochloric Acid	Chemical	In process	1 kg	Liquid, In Process
		Liquid waste	1 kg	Liquid
		Chemical storage	4 kg	Liquid (two one-gallon containers)
Hydrogen Peroxide	Chemical	Facility chemical reagent system (FCRS)	178 kg	Liquid, In Process
		Chemical storage	668 kg	Liquid (two 1000 L IBC)

Chemical Name	Hazard	Location	Approximate Maximum Site Inventory	Storage State
Mineral Oil	Chemical	In pumps	172 kg	Liquid, In Process
		Chemical storage	360 kg	Liquid (two 55-gallon drums)
Molybdenum trioxide	Chemical	In process	1 kg	Liquid, In Process
		Liquid waste	1 kg	Liquid
		Chemical storage	1 kg	Liquid (two one-gallon containers)
Nitric Acid (70 wt% in chemical storage)	Radiological / Chemical	Liquid Waste	126 kg	Liquid, In Process
	Chemical	FCRS	102 kg	Liquid, In Process
		Chemical storage	1979 kg	Liquid (two 1000 L IBC)
Potassium hexachlororuthenate	Chemical	In process	1 kg	Liquid, In Process
		Liquid waste	1 kg	Liquid
		Chemical storage	1 kg	Solid powder (two 250 g containers)
Potassium permanganate	Chemical	In process	1 kg	Liquid, In Process
		Liquid waste	3 kg	Liquid
		Chemical storage	1 kg	Solid powder (two 250 g containers)
Rhodium chloride	Chemical	In process	1 kg	Liquid, In Process
		Liquid waste	1 kg	Liquid
		Chemical storage	1 kg	Solid powder (two 250 g containers)

Chemical Name	Hazard	Location	Approximate Maximum Site Inventory	Storage State
Silver Nitrate	Chemical	FCRS	1 kg	Liquid, In Process
		Chemical storage	1 kg	Crystal Powder (two 250 g bottles)
Sodium Iodide	Chemical	In process	1 kg	Liquid, In Process
		Chemical storage	1 kg	Solid (two 250 g bottles)
Sodium Hydroxide	Chemical	FCRS	60 kg	Liquid, In Process
		Chemical storage	1541 kg	Liquid (two 1000 L IBC)
Sodium Sulfite	Chemical	In process	1 kg	Liquid, In Process
		Liquid waste	3 kg	Liquid
		Chemical storage	2 kg	Solid (two 250 g bottles)
Sulfuric Acid	Radiological / Chemical	In Process	61 kg	Liquid, In Process
		Liquid waste	579 kg	Liquid
	Chemical	FCRS	95 kg	Liquid, In Process
		Chemical storage	3599 kg	Liquid (two 1000 L IBC)
Sulfur Hexafluoride	Asphyxiant / Chemical	IU Cells	1440 kg	Gas, In Process
		Storage	360 kg	Compressed Gas (Two 180 kg containers)
Nitrogen (Liquid)	Asphyxiant / Chemical	Storage	18,000 gal	Liquid, Outdoors, Bulk Storage Tank
Nitrogen (Compressed Gas)	Asphyxiant / Chemical	Storage	500 ft^3 at 3000 psig	Gas, N2PS Structure, Storage Tubes

Chemical Name	Hazard	Location	Approximate Maximum Site Inventory	Storage State
Uranium Metal	Chemical	Uranium storage	620 kg	Solid Pieces ~20% enrich. (Maximum storage container size 7.8 kg)
	Radiological	In process	[ ]PROP/ECI	Neutron multipliers natural enrich. (8 IU)
Uranium Oxide	Chemical / Radiological	Uranium storage	732 kg	Solid Powder (Maximum storage container size 5.04 kg)
Uranyl Peroxide	Chemical	In process	43 kg	Solid, In Process (intermediate compound)
Uranyl Sulfate	Radiological	In process	1058 kg	Liquid, In Process (Maximum in a single target solution prep tank is [ ]PROP/ECI)
	Radiological	Waste	254 kg	Liquid, In Process
Tritium	Radiological	In Process	30 g	Gas, In Process
Hydrogen	Flammable	In Process	60 g	Gas, In Process

Appendix 3 AGREEMENT LETTERS

This appendix contains letters of agreement that SHINE has obtained with off-site organizations for support of the Emergency Plan.

ROBERT D. SPODEN
ROCK COUNTY SHERIFF
BARBARA J. TILLMAN
CHIEF DEPUTY

May 18, 2018

Catherine Kolb, P.E.
Project Integration Manager
SHINE Medical Technologies, Inc.
4021 South US Highway 51, Janesville WI 53546

RE: Letter of Support

To whom it may concern:

This is to advise that the Rock County Sheriff's Office - Emergency Management Bureau is prepared to assist the above-mentioned facility in the event emergency services are required. All requests for fire, emergency medical services (EMS) or law enforcement should be reported through 911. For non-emergencies, County Emergency Management staff can be contacted during normal business hours (Monday - Friday, 7:30 AM to 4:00 PM) at 608-758-8440.

Additionally, our office can be contacted through the 911 Communications Center at 608-757-2244. The 911 Communications Center is operational 24-hours a day, seven days a week and has the ability to contact Emergency Management staff during non-business hours.

The Rock County Sheriff's Office - Emergency Management Bureau is available to assist in the event of an emergency or for drills, trainings and exercises. Since your emergency plan is on file at our office, please continue to provide any updates or changes.

If you have any questions, please contact me at [redacted]

Thank you.

Sincerely,

[redacted]

Sergeant Shena Kohler, [redacted]
County Director of Emergency Management

200 EAST U. S. HIGHWAY 14
JANESVILLE, WISCONSIN 53545-9601
PHONE: (608)757-8000 FAX: (608)757-7997

SSM Health | St. Mary's Hospital JANESVILLE

July 25, 2018

Catherine Kolb, PE
Project Integration Manager
SHINE Medical Technologies, Inc.
4021 South US Highway 51, Janesville WI. 53546

Letter of support

To whom it may concern:

This is to advise that SSM Health-St Mary's Hospital Janesville, located at 3400 East Racine Street, Janesville WI., is prepared to assist SHINE Medical Technologies Inc. in accordance with section 3.4.3 and section 9.7.2 of the current Emergency Plan revision in our files.

SSM Health St. Mary's Hospital Janesville may be contacted at the following phone numbers:

Emergency Preparedness Administrator.	608-373-8129
Emergency Department	608-373-8101
Switchboard	608-373-8000

If there are any questions, please contact me at [redacted]

Thank you

Robert Swenarski CHEC, WCEM
Emergency Preparedness Administrator
EMS Liaison/EOC Safety Officer
[redacted]

Appendix 4 EMERGENCY ACTION LEVELS

Classification	Category	Event	Emergency Action Levels
Notification of Unusual Event	Security	Threat to Security	Credible report from facility personnel or local authorities of a bomb threat, civil disturbance, or other security threat directed toward the facility.
Alert	Security	Security Event	Ongoing security event, including the threat of an imminent hostile action, that a) Threatens or compromises site security; b) Risks the safety of site personnel; OR c) Potentially degrades the level of safety of the facility.
Site Area Emergency	Security	Hostile Action	1) Hostile action at the facility, OR 2) Imminent or actual loss of physical control of the facility.
Alert	Criticality	Criticality Hazard	Discovery of a critical-mass quantity of special nuclear material in an unsafe geometry container or other condition that creates a criticality hazard.
Site Area Emergency	Criticality	Uncontrolled Criticality	Imminent or actual occurrence of an uncontrolled criticality, indicated by a) Valid actuation of the criticality accident alarm system (CAAS); OR b) Credible report from facility personnel.
Notification of Unusual Event	Fire	Prolonged Fire	Fire in the main production facility or the material staging building not extinguished within 15 minutes of control room notification of the fire or receipt of a control room fire alarm.

Classification	Category	Event	Emergency Action Levels
Alert	Fire	Fire Potentially Affecting Radioactive Material or Safety-Related SSCs	1) Fire in a carbon delay bed, indicated by a carbon monoxide level of 42 ppm in the affected bed. *Results in up to 36 mrem TEDE in 1 hour, 36 mrem TEDE in 24 hours, and 36 mrem CDE thyroid (approximated from TEDE) in 24 hours at site boundary* 2) Explosion or fire within the safety-related area of the main production facility or within the material staging building, with the potential to affect radioactive material OR cause damage to safety-related SSCs that provide a barrier to the release of radioactive materials.
Site Area Emergency	Fire	Fire Compromising Radioactive Material or Safety-Related SSCs	1) Fire in a carbon guard bed, indicated by a temperature of 150°C in the affected bed *Results in up to 81 mrem TEDE in 1 hour, 81 mrem TEDE in 24 hours, and 831 mrem CDE thyroid in 24 hours at site boundary* 2) Fire within the safety-related area of the main production facility or within the material staging building a) Involving radioactive material; b) Causing visible damage to safety-related SSCs that provide a barrier to the release of radioactive materials; OR c) Causing loss of the safety function of a safety-related SSC that provides a barrier to the release of radioactive materials.

Classification	Category	Event	Emergency Action Levels
Notification of Unusual Event	External	Severe Natural Phenomena or External Event	1) Tornado confirmed by direct observation by facility personnel or credible report from local authorities of a tornado in the immediate vicinity of the facility. 2) Seismic event, confirmed by at least two of the following: a) Seismic event alarm in control room b) Earthquake felt in the facility c) A “response event” for the SHINE site location, reported by the U.S. Geological Survey National Earthquake Information Center 3) Uncontrolled flooding inside the main production facility or the material staging building. 4) Aircraft crash on-site. 5) Other severe external event or natural phenomena on-site that creates a significant hazard potential, as determined by the Emergency Director.

Classification	Category	Event	Emergency Action Levels
Alert	External	External Event Potentially Affecting Radioactive Material or Safety-Related SSCs	1) Tornado strike of the main production facility or the material staging building. 2) Seismic event, meeting the criteria of an NOUE seismic event, that jeopardizes the function of safety-related SSCs that provide a barrier to the release of radioactive materials, OR potentially affects radioactive material. 3) Aircraft crash into the main production facility or the material staging building. 4) Uncontrolled flooding within the main production facility or the material staging building that jeopardizes the function of safety-related SSCs that provide a barrier to the release of radioactive materials, OR potentially affects radioactive material. 5) Other severe external event or natural phenomena affecting the facility that jeopardizes the function of safety-related SSCs that provide a barrier to the release of radioactive materials, OR potentially affects radioactive material, as determined by the Emergency Director.
Site Area Emergency	External	External Event Compromising Radioactive Material or Safety-Related SSCs	Credible report or observation by facility personnel of any of the Alert-Level External Events a) Actually compromising the integrity of radioactive material; b) Causing visible damage to safety-related SSCs that provide a barrier to the release of radioactive materials; OR c) Causing loss of the safety function of a safety-related SSC that provides a barrier to the release of radioactive materials.

Classification	Category	Event	Emergency Action Levels
Notification of Unusual Event	Radiological Release	Equipment Malfunction	Failure of primary system boundary and release of target solution into the IU cell in Modes 2, 3 or 4, indicated by a. Evidence of PSB failure (IU Cell Safety Actuation signals OR RVZ1e radiation monitoring > 5x background), AND b. Elevated radiation levels or airborne contamination levels in the IF (factor of 10 over normal levels), as indicated by facility RAMS, CAMS, or portable instruments. *Results in up to 0 mrem TEDE in 1 hour, 21 mrem TEDE in 24 hours, and 21 mrem CDE thyroid in 24 hours at site boundary*
Alert	Radiological Release	Equipment Failure or Release within the Facility	Elevated radiation levels or airborne contamination levels WITHIN a site building that indicate severe loss of control (factor of 100 over normal levels), as indicated by facility RAMS, CAMS, or portable instruments.

Classification	Category	Event	Emergency Action Levels
Site Area Emergency	Radiological Release	Severe Equipment Accident or Release to Environment	1) TOGS or PSB gas headspace pressure boundary failure during Mode 2, 3 or 4 with pressurized release (N2PS actuation), indicted by a) Evidence of pressure boundary failure (N2PS actuation signals OR RVZ1e radiation monitoring > 5x background), AND b) Elevated radiation levels or airborne contamination levels in the IF (factor of 100 over normal levels), as indicated by facility RAMS, CAMS, or portable instruments. *Results in up to 2 mrem TEDE in 1 hour, 121 mrem TEDE in 24 hours, and 953 mrem CDE thyroid in 24 hours at site boundary* 2) Elevated radiation levels or airborne contamination levels OUTSIDE the main production facility that indicate a significant release to the environment (factor of 100 over normal levels), as indicated by portable instruments.

Classification	Category	Event	Emergency Action Levels
Notification of Unusual Event	Other	Other Unusual Events	Other conditions exist that warrant precautionary activation of the ERO, at the discretion of the Emergency Director.
Alert	Other	Other Alerts	Other conditions that warrant activation of the ERO, at the discretion of the Emergency Director.
Site Area Emergency	Other	Other Site Area Emergencies	Other conditions that warrant activation of off-site emergency response organizations or precautionary notification of the public near the site, at the discretion of the Emergency Director.

Appendix 5 EMERGENCY PLAN IMPLEMENTING PROCEDURE (EPIP) LIST

The following is a topical list of Emergency Plan Implementing Procedures (EPIPs).

- Emergency Response Organization Responsibilities
- Emergency Classification and Initial Accident Assessment, addressing
    - Notification of Unusual Event
    - Alert
    - Site Area Emergency
- Activation of the Emergency Response Organization
- Notification and Communication
- Emergency Radiation Exposure Control, including
    - Exposure Projections
    - Radiological Monitoring
    - Emergency Dosimetry
    - Emergency Exposure Authorization
    - Emergency Contamination Control
- Evacuation, Assembly, and Accountability
- Emergency Equipment and Supplies
- Damage Assessments
- Emergency Organization Training
- Exercises and Drills
- Critiques and Performance Improvement
- Revising the Emergency Plan and EPIPs
- Emergency Response, including
    - Security Event Response
    - Severe Natural Phenomena and External Event Response
    - Fire Response
    - Criticality Emergency Response
    - Radiological Release Response
    - Hazardous or Toxic Chemical Spill or Release Response
    - Equipment Malfunction, Failure or Severe Accident Response

ENCLOSURE 2
ATTACHMENT 3

SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL TECHNOLOGIES, LLC OPERATING LICENSE APPLICATION
RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

2000-09-01, REVISION 16
QUALITY ASSURANCE PROGRAM DESCRIPTION (QAPD)

27 pages follow

REVISION LOG

Revision #	Description of Changes
0	Original Issue
1	**Added the following definitions**: boiling, gas management system barrier, neutron moderator, primary system boundary, primary cooling system, recombiner, radiolytic gas release, subcritical target, target solution vessel, target solution barrier, target solution. **Modified the following definitions**: basic component, finding, safety-related items **Deleted the following definition**: certificate of compliance **Provided minor editorial changes.**
2	Updates from the Final Interim Staff Guidance Augmenting NUREG-1537, part 1. Minor editorial and formatting changes.
3	Revision to address clarification and changes based on RAI responses. Removal of IROFS and modification of the QLs.
4	Additional clarifications on RAI responses and adding definitions.
5	Clarification for safety-related definition and minor edits
6	Revision to the definitions of QL-1 and QL-2, and additional clarification resulting from RAI responses.
7	Revised the management level for the Plant Manager and removed ANSI/ANS-15.1 management levels from those management positions outside of Plant Operations.
8	Revise reference section (6) to remove canceled document (2000-10-01, “Glossary of Terms”) and Glossary reference from section 1.3. Addition of safety-related activities definition to section 1.3. Update cover page document approval format to reflect current template.
9	Revised to reflect: changes in the organization; update to the Policy statement; added procedure implementing procedure table; consistency with FSAR submittal.
10	Revised definition of safety-related. Added position description of Chief Technology Officer (CTO). Moved/Modified language from The CEO, COO and the VPRA/QA duties and placed it in section 2.1. Revised definitions of QL-2 and 3.
11	Revised to reflect changes in: the organization in Section 2.1, the Organization Chart in Enclosure 2, and the number and title of the implementing procedure for Section 2.15 in Enclosure 3
12	Responsibility for the SHINE Document Control and Records Management program moved from VPRA/Q to COO and DoS. Update SHINE and Baker procedure references in Enclosure 3.
13	Change SHINE Medical Technologies, Inc. to SHINE Medical Technologies, LLC in the Executive Summary. Update and correct SHINE and Baker procedure references in Enclosure 3.
14	Remove QL-3 from the document, remove CTO role from and add Deputy to COO to Section 2.1, update organizational chart, and correct

	typographical errors. Added the following SHINE implementing procedures to Enclosure 3: 1200-01-01 Design Package, 1200-01-04 Technical Reports, 1200-09-04 Design Control Program; and changed 1200-01-10 Design Control to 1200-01-10 Design Criteria Documents, added Baker to follow 1200-01-06 to 2.3.6. Clarified Director of Construction description.
15	Remove Deputy COO from the body and organizational chart.
16	Engineering Support and Auxiliary Systems, and the Director of Engineering Support and Auxiliary Systems reporting to the VP of Engineering; modifying the programmatic responsibility for Document Control and Records Management from the Director of Engineering Support to the Chief Operating Officer. Editorial corrections throughout document.

TABLE OF CONTENTS

EXECUTIVE SUMMARY

This Quality Assurance Program Description (QAPD) provides the SHINE Medical Technologies, LLC (SHINE) quality assurance program (QAP) for safe and reliable production of ^{99}Mo and other radioisotopes for medical use and is specific to SHINE. Title 10 of the Code of Federal Regulations (CFR), § 50.34(a)(7) requires each applicant for a construction permit to build a production or utilization facility to include, in its Final Safety Analysis Report (FSAR), a description of the QAP to be applied to the design, fabrication, construction, and testing of the structures, systems, and components (SSCs) of the facility. Furthermore, 10 CFR § 50.34(b)(6)(ii) requires that each applicant for a license to operate a facility include, in the FSAR, a description of the managerial and administrative controls to be used to assure safe operation.

NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors", Section 12.9, "Quality Assurance", recommends the applicant consider the guidance in Regulatory Guide 2.5, "Quality Assurance Program Requirements for Research and Test Reactors", and ANSI/ANS-15.8, "Quality Assurance Program Requirements for Research Reactors". Regulatory Guide 2.5, Rev.1 states that ANSI/ANS-15.8-1995 provides an acceptable method of complying with the program requirements of 10 CFR § 50.34 and was used for

developing this QAPD. SHINE has determined that ANSI/ANS-15.8-1995 is sufficient for use in the development of the SHINE QAPD, which is to be applied to the design, fabrication, construction, and operation of the SHINE facility.

POLICY STATEMENT

SHINE shall design, procure, operate and maintain the SHINE facility in a manner that will ensure the health and safety of the public and workers and protect the environment. SHINE commits to operating in a planned, prudent, efficient, safe and cost-effective manner that is in compliance with the CFR, the applicable Nuclear Regulatory Commission (NRC) Facility Operating License, and the applicable laws and regulations of the state and local governments.

In addition, the management of SHINE believes that sound quality, safety, security, and environmental programs are essential to SHINE's success and is personally engaged in their implementation. Quality is owned by every SHINE employee. Quality cannot be achieved solely through inspection. It is achieved by employees with the knowledge, skills, experience, training and motivation to do the job right. Persons who manage, perform and verify work all contribute to an integrated, cost effective and efficient quality management system to produce a quality product.

The SHINE QAP is the QAPD provided in this document and the associated implementing documents. They provide control over SHINE activities that affect the quality of safety-related nuclear plant SSCs and include all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in service. The QAPD is the top-level document that establishes the manner in which quality is to be achieved and presents the SHINE overall philosophy regarding the achievement and assurance of quality. Implementing documents assign more detailed responsibilities and requirements and define organizational interfaces involved in conducting activities within the scope of the QAP. SHINE uses the guidance and best practices from various industry standards to develop implementing procedures. SHINE applies a graded approach consistent with importance to safety and reliability.

Compliance with the QAPD and implementing documents is mandatory for personnel directly or indirectly associated with implementation of the SHINE QAPD.

1 INTRODUCTION

SHINE uses a new class of isotope generator that is compact and relatively inexpensive to generate a reliable supply of Mo-99 and other radioisotopes for medical applications. This technology does not use highly enriched uranium, nor does it require a nuclear reactor for production.

Although SHINE uses an accelerator for production, this technology requires licensing under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities". This QAPD addresses the requirements in 10 CFR § 50.34(b)(6)(ii) for a description of a QAP specific for SHINE. Regulatory Guide 2.5 and ANSI/ANS-15.8-1995 provide an acceptable method of complying with the quality assurance program requirements of 10 CFR § 50.34.

SHINE uses accelerator technology for neutron production and the sub-critical fission process and does not meet the definition of a nuclear reactor as identified in 10 CFR § 50.2, “Definitions”. Nonetheless, SHINE uses a definition of safety-related for systems, structures and components (SSCs) that is applied to the Quality Level 1 SSCs and uses a graded approach to quality for other SSCs. The graded approach to quality for this QAPD can be found in Enclosure 2.

1.1 Scope

SHINE addresses the requirements of 10 CFR § 50.34 for a description of the QAP in this controlled document. This QAPD and applicable implementing procedures apply specifically to SHINE. The procedures that implement the requirements in this document are found in the SHINE Information Management System.

The QAPD describes the administrative and engineered controls for ensuring compliance with requirements. It applies to the design, construction and operation of the SHINE facility.

1.2 Application

The quality assurance program applied by SHINE activities will be consistent with the importance of these activities to safety and reliability. Activities included in this quality assurance program are, as a minimum, those related to irradiation unit safety and protection system, material processing safety, criticality safety, engineered safety features, and applicable radiation monitoring systems, as identified in the Limiting Conditions for Operations sections of the Technical Specifications.

SHINE applies a graded approach to those items and activities that could affect the quality of safety-related structures, systems and components (SSCs) and other components not specifically designated as safety-related. A Quality Level (QL) matrix is used to ensure quality requirements are understood and specified for each SSC. Activities that could affect quality include siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, repairing, maintaining, modifying, inspecting, testing, and operating.

SHINE developed and implemented the QAP beginning with the design, siting and construction phase of the facility. This QAP focuses on the development of appropriate controls to ensure the facility is properly designed and fabricated to meet SHINE requirements. The majority of these controls provide documentation that attests to the facility quality to support an operating license.

Following facility construction and commissioning, the focus of this quality program shifts to establishing those controls that ensure proper and reliable facility operation. All of the program provisions established during the design and construction phase will remain in place but will change in level of implementation appropriate to support facility operations; each portion of Section 2, Design, Construction and Modifications, would be implemented only as necessary. The operating phase will impose additional requirements related to the conduct of operations. Additional program requirements are defined in Section 3.

1.3 Definitions

Definitions are listed to provide uniform interpretation of terms and phrases used.

certified operator – an individual authorized by the chartering or licensing organization to carry out the duties and responsibilities associated with the position requiring the certification.

commissioning – the process during which constructed irradiation facility structures, components, and systems are made operational and verified to meet design requirements.

corrective action – measures taken to rectify conditions adverse to quality, and where necessary, to prevent repetition.

document – any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.

licensed operator – see “certified operator”.

maintenance – those activities necessary to maintain operability or restore systems to within specified design limits. Maintenance consists of repair, rework, replacement, adjustment, cleaning, or other actions necessary to maintain an item in or restore an item to an acceptable condition.

management – management means those persons within the SHINE organization whose responsibility and authority includes the quality assurance program. The levels of management are as described in ANSI/ANS-15.1-2007.

modification – a change in the physical design or functional characteristics of a system, structure, or component.

procedure – a document that specifies or describes how an activity is to be performed.

quality – the degree to which an item or process meets or exceeds the user’s requirements and expectations.

quality assurance – those planned and systematic actions necessary to provide adequate confidence that the structure, system, or component will perform satisfactorily in service.

safety-related activities – those activities affecting the safety-related functions of SSCs, including siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, repairing, maintaining, modifying, inspecting, testing, and operating.

safety-related Items - Those physical 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.

shall, should and may – the word "shall" is used to denote a requirement; the word "should" to denote a recommendation; and the word "may" to denote permission, neither a requirement nor a recommendation.

2 DESIGN, CONSTRUCTION, AND MODIFICATIONS

This section provides the requirements for establishing, managing, conducting, and assessing the program of controls over the design, construction, and modification of the SHINE facility. SHINE

recognizes that the described controls are integral to the management of the licensed activity and do not necessitate the establishment of a separate program. This section will be implemented as applicable to the specific scope of work activities.

2.1 Organization

This section describes the SHINE organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAPD implementation. The organizational structure includes internal and external functions for SHINE including interface responsibilities for multiple organizations that perform quality-related functions. The organizational structure and assignment of responsibilities are defined and documented such that: (a) quality is achieved and maintained by those who have been assigned responsibility for performing work; and (b) quality achievement is verified by those not directly performing the work. SHINE Senior Management ensures that those responsible for ensuring appropriate controls have been established, and for verifying that activities have been correctly performed, have sufficient authority, access to work areas, and freedom to: (a) identify problems; (b) initiate, recommend, or provide corrective action; and (c) ensure corrective action implementation. Implementing documents assign more specific responsibilities and duties, and define the organizational interfaces involved in conducting activities and duties within the scope of the QAPD. Management gives careful consideration to the timing, extent and effects of organizational structure changes. The SHINE functional organization chart is provided in Enclosure 1.

Chief Executive Officer (CEO)
The CEO is responsible for the overall design, management and technical leadership of the company and is also responsible for all technical and administrative support activities provided by SHINE and suppliers. The CEO provides direction to the President & Chief Financial Officer (P&CFO), Chief Operating Officer (COO), Vice President of Regulatory Affairs and Quality (VPRA/Q), Vice President of Engineering (VPE), and Information Technology Manager (ITM) to fulfill the organization's responsibilities. The CEO reports to the Board of Directors with respect to all matters.

The CEO has overall responsibility for SHINE QA Program.

President & Chief Financial Officer (P&CFO)
The P&CFO is second-in-command at SHINE and acts for the CEO when the CEO is not in the office or otherwise not available. The P&CFO reports to the CEO and is responsible for all financial matters for SHINE. The P&CFO will oversee all compliance and recognition for government (federal and state) contracts and private grants. The P&CFO is also responsible for procurement and all external operations of SHINE, including supplier organizations.

Procurement Manager (PrM)
The PrM reports to the P&CFO and is responsible for overall company policy regarding the procurement of material, equipment, and services; establishes specific procedures for the contracting of services and the purchase and control of materials and equipment. The PrM is also responsible for integrating and implementing applicable requirements from the QAPD into the procurement process to ensure that suppliers meet SHINE requirements. Additionally, the PrM is responsible for the oversight of suppliers and the management

aspects associated with their execution of the design, fabrication, procurement, construction and operation of the SHINE facility.

Supplier Organizations
Supplier organizations are responsible for their portion of the execution of the design, fabrication, procurement, construction, and testing of SSCs for the facility. Such supplier organizations are responsible for identifying, implementing and verifying flow-down of quality requirements as applicable. They will participate in necessary assessments and inspections as specified in procurement documents.

Chief Operating Officer (COO)
The COO reports to the CEO and is responsible for Engineering Construction and the operational aspects of the company including safety, management, and training. The COO is also responsible for the development and implementation of the SHINE Document Control and Records Management programs as well as for matters regarding environment, safety, and health. The COO works closely with the Quality Assurance Manager (QAM) on matters involving adherence to safety requirements defined in the QAPD and other regulatory, state and local requirements.

Director of Engineering Construction (DoC)
The DoC is responsible for all aspects of facility construction, including modification activities, project management, structural design and field engineering. The DoC reports to the COO.

Plant Manager (PM)
The PM is responsible for the operation and management of SHINE's facilities. The PM is also responsible for establishing and managing the required training programs to support the organization, and for establishing and maintaining the programs and systems to ensure protection of the company's assets. The PM reports to the COO.

Operations Manager (OM)
The OM is responsible for safe, reliable, and efficient plant operations within the constraints of the operating license and regulatory requirements. This position is also responsible for the development and implementation of appropriate operational controls in accordance with the QAPD and other requirements. The OM reports to the PM.

Radiation Protection Manager (RPM)
The RPM is responsible for establishing and implementing the Radiation Protection (RP) program, monitoring worker doses, and calibration and QA of all health physics instrumentation. The RPM reports to the PM.

Training Manager (TM)
The TM is responsible for development, administration and overall management of the implementation of the various training processes and activities, including as required by regulations and the training for site and facility personnel. The TM reports to the PM.

Vice President of Regulatory Affairs and Quality (VPRA/Q)

The VPRA/Q reports to the CEO and is responsible for nuclear related licensing and quality activities. The VPRA/Q is responsible for the planning and execution of the licensing process for the design, construction and operation of the facility. The VPRA/Q is also responsible for the implementation of the SHINE Corrective Action program. The VPRA/Q is responsible for ensuring clear lines of communication between SHINE and the NRC. The VPRA/Q is responsible for integrating the quality requirements as defined in the QAPD across the internal and external organizations and reports to the CEO on matters concerning quality. The VPRA/Q is also responsible for all local, state and federal permits.

Quality Assurance Manager (QAM)

The QAM is responsible for Quality Assurance and Quality Control (QA/QC) processes and activities, including the development and verification of implementation of the QAPD described in this document. The QAM is responsible for assuring compliance to regulatory requirements and procedures through assessments and technical reviews; monitoring organizational processes to ensure conformance to commitments and licensing document requirements; for ensuring that contractors and suppliers providing quality services, equipment, parts, and materials to SHINE are meeting the requirements as defined in the QAPD. The QAM has sufficient independence from other priorities to bring forward issues affecting safety and quality and makes judgments regarding quality in all areas necessary regarding SHINE's activities. The QAM has the ability and responsibility to report to the CEO any quality issues which cannot be resolved at the VPRA/Q level. The QAM reports to the VPRA/Q.

Director of Licensing (DoL)

The DoL is responsible for implementing nuclear related licensing activities, including the planning and execution of the licensing process for the design, construction and operation of the facility. The DoL is responsible for communication between SHINE and the NRC. The DoL reports to the VPRA/Q.

Vice President of Engineering (VPE)

The VPE is responsible for nuclear, instrumentation and control and chemical process systems; the design of auxiliary equipment (mechanical, electrical and plumbing); and system testing. The VPE is also responsible for maintaining the safety analysis and is the design authority for the facility. The VPE reports to the CEO.

Director of Engineering Support and Auxiliary Systems (DoS)

The DoS is responsible for facility design configuration control, engineering support, and auxiliary systems. The DoS reports to the VPE.

Information Technology Manager (ITM)

The ITM provides technical expertise regarding electronic data systems, computer networks, and telecommunications and ensuring the technology necessary for implementation of the QAPD and implementing procedures is available. The ITM reports to the CEO.

2.1.1 Authority to Stop Work

All employees have the right and responsibility to stop work when they encounter an unsafe condition. Additionally, quality assurance and inspection personnel have the authority and the responsibility to stop work in progress which is not being done in accordance with approved procedures or where safety-related SSC quality may be jeopardized. This extends to off-site work performed by suppliers that furnish materials and services.

2.1.2 Quality Assurance Organizational Independence

Independence shall be maintained between the organizations performing the work or service and oversight performed by the quality organization (i.e., quality assurance and quality control).

2.2 Quality Assurance Program

This section describes the requirements for establishing, implementing, and managing the QAP for SHINE in accordance with the requirements in ANSI/ANS-15.8-1995, “Quality Assurance Program Requirements for Research Reactors”. This includes the managerial and administrative aspects of internal and external activities that affect quality of the SHINE facility and programs.

To achieve the goals of defining and effectively designing safety-related SSCs, SHINE implements the use of a graded approach to quality. The measures applied to a particular engineered or administrative control or control system may be graded commensurate with the reduction of the risk attributable to that control or control system. This approach to achieving levels of quality is described in this QAPD and related implementing documents.

The QAPD provides the basis for a planned and systematic approach to the cost- effective achievement of safety, quality and reliability. The primary method to ensure this is through the SHINE procedures. The SHINE procedures are delineated, managed and maintained by the VPRA/Q with support from all SHINE team members. See Enclosure 3 for a matrix of QAPD sections and their corresponding implementing procedures.

Delegated responsibilities may be performed under a contractor’s or supplier’s QAP, provided that they have been approved in accordance with the QAPD. Periodic assessments of their QAP are performed to ensure compliance with the SHINE QAPD and implementing procedures. In addition, routine interfaces with their personnel provide added assurance that quality expectations are met. Assessments may be planned and performed by SHINE qualified assessors or independent contractors or consultants as determined by the QAM.

Personnel assigned to implement elements of the QAPD shall be capable of performing their assigned tasks. SHINE establishes and maintains formal and informal indoctrination and training programs for personnel performing, verifying or managing activities within the scope of the QAPD to ensure that suitable proficiency is achieved and maintained. Sufficient managerial depth is provided to cover absences of incumbents. When required by code, regulation or standard, specific qualification and selection of personnel is conducted in accordance with those requirements as established in applicable SHINE procedures. Indoctrination includes the administrative and technical objectives and requirements of the applicable codes and standards and the QAPD requirements as necessary. Records of personnel training and qualification are to be maintained.

2.3 Design Control

This section describes the requirements for establishing, developing, implementing and documenting a process to control the design, design changes, and temporary modifications subject to the provisions of the QAPD. Procedures identify the process and include provisions for the control of design, development, verification, approval, release, status, distribution, revisions, review of calculations and other design documents, control of software and implementation of required rules, regulations, codes and standards. As part of the design control, the design review program has been developed to meet the requirements of ANSI/ANS-15.8-1995.

2.3.1 Design Requirements

Applicable design inputs, such as design bases, performance requirements, regulatory requirements, codes, and standards shall be identified and documented.

2.3.2 Design Process

Design interfaces shall be identified and controlled, and the design efforts shall be coordinated by the design organization among the participating organizations. Interface controls will include the assignment of responsibility and establishment of implementing documents among the interfacing design organizations for the review, approval, release, distribution and revision of documents involving design interfaces.

The applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application. Known problems affecting the standardized or previously proven designs, and their effects on other features, shall be considered. Deviations from the established and documented design inputs, including the reasons for the changes, shall be documented and controlled.

The design organization is responsible to ensure that the final design shall:

1. be relatable to design input by documentation in sufficient detail to permit design traceability and verification, and
2. identify assemblies and/or components that are part of the item being designed.

When a computer design program is used to develop portions of the facility design or to analyze a design for acceptability, that program shall be fully documented, validated and controlled to ensure the correctness of its output. When a design program must be developed, the program shall be controlled to ensure that it is fully documented and validated. Where changes to previously valid computer programs are made, documented revalidation shall be required for the change. Verification of design-unique computer programs shall include appropriate benchmark testing.

2.3.3 Design Verification

Independent design reviews shall be used to verify the adequacy of design by one or more of the following:

1. performance of design reviews,
2. use of alternate calculations,
3. performance of qualification tests, or

4. comparison of similar proven systems.

The responsible design organization shall identify and document the particular design verification method or methods used. Design verification will be performed by competent individuals or groups other than those who performed the design, but whom may be from the same organization. In all cases the design verification shall be completed prior to reliance upon the component, system, structure, or computer program to perform its function in operations.

In the event that qualification testing is needed to verify design, the use of qualification tests will be defined in a formal test plan that shall include appropriate acceptance criteria and shall demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions. Test results will be documented and evaluated by the responsible design organization to ensure that test requirements have been met.

2.3.4 Design Documents and Records

Design documents and records, which provide evidence that the design and design verification process were performed, shall be collected, stored and maintained for the life of the safety-related unit.

2.3.5 Commercial Grade Items

The use of commercial-grade equipment in safety-related applications shall be reviewed to ensure that it can adequately perform its intended function. Procedures shall be implemented to provide guidance on how to review and evaluate commercial grade items for suitability in applications covered by the QAPD. When a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

2.3.6 Change Control

Procedures shall be established to ensure that modifications to safety-related structures, systems, and components, or computer codes shall be based on a defined "as-exists" design. Changes to verified designs shall be documented, justified, and subject to design control measures commensurate with those applied to the original design. The control measures shall include assurance that the design analyses for the structure, system, component, or computer code are still valid. Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.

2.4 Procurement Document Control

Procedures shall be established to ensure that procurement documents will contain sufficient technical and quality requirements to ensure that the items or services satisfy the needs of SHINE. Procurement documents at all procurement levels shall identify the documentation required to be submitted for information, review, or approval by SHINE. At each level of procurement, the procurement documents shall provide for access to the supplier's plant facilities and records, for

inspection or assessment by SHINE, a designated representative or other parties authorized by SHINE.

SHINE procurement documents shall include SHINE's requirements for reporting and approving disposition of supplier's non-conformances associated with the items or services being procured. The procurement documents for safety-related items should prohibit the supply of sub-standard or counterfeit parts or materials.

2.5 Procedures, Instructions and Drawings

Activities affecting quality shall be performed in accordance with documented instructions, procedures, or drawings appropriate to the circumstances. These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished.

These documents shall be prepared to prescribe performance expectations and define the proper sequence and detail to accomplish the work. Copies of applicable and necessary procedures, instructions and drawings shall be available to the appropriate SHINE internal and external organizations to accomplish work in an efficient and safe manner. See Enclosure 3 for a detailed listing of implementing procedures.

2.6 Document Control

The preparation, issue, and change of documents which specify requirements that affect quality or prescribe activities affecting quality, shall be controlled to ensure that correct documents are used. The document control system shall be documented, and provide for:

1. identification of documents to be controlled and their specified distribution;
2. identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents; and
3. review of documents for adequacy, completeness, and correctness prior to approval and issuance.

Major changes to controlled documents shall be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated.

2.7 Control of Purchased Items and Services

The procurement of items and services shall be controlled to ensure appropriate procurement planning, source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, assessment and examination of items or services for acceptance upon delivery or completion.

2.7.1 Supplier Selection

The selection of suppliers shall be based on evaluation of their capability to provide items or services in accordance with requirements of the procurement documents.

2.7.2 Work Control

SHINE shall establish measures to control the supplier's performance to ensure that purchased items and services meet quality requirements. Controls may include test plans, review of supplier's submitted documents, arrangements for source surveillance or inspection, and other technical and administrative interfaces with the supplier in accordance with procurement documents.

2.7.3 Verification Activities

The supplier shall be responsible for the quality of his product and shall verify and provide evidence of that quality. Supplier-generated documents shall be controlled, handled, and approved in accordance with established methods. Means shall be implemented to provide for the acquisition, processing, and recorded evaluation of technical, inspection and test data against acceptance criteria. Based on complexity of the product and importance to safety, SHINE shall consider independently verifying the quality of a supplier's product through source surveillances, inspections, assessments or review of the supplier's non-conformances, dispositions, waivers and corrective actions.

2.7.4 Item or Service Acceptance

Acceptance of items or services provided to SHINE shall require a system to provide assurances that purchased items and services conform to procurement specifications. Methods used to accept an item or related service from a supplier shall be a supplier Certificate of Conformance, source verification, receiving inspection, post-installation test or a combination thereof. Receiving inspection shall be performed in accordance with established procedures and instructions, to verify by objective evidence such features as proper configuration, identification and cleanliness, and to determine any shipping damage, fraud or counterfeit.

2.8 Identification and Control of Items

When specified by codes, standards, or specifications that include identification or traceability requirements, the item identification and control process shall be capable of providing identification and traceability control. Items' identification shall be maintained from the initial receipt or fabrication of the items up to and including installation and use. Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed. Identification markings shall be applied through the use of materials and methods which provide clear and legible identification and do not detrimentally affect the function or service life of the item. Markings shall be transferred to each part of an identified item when the item is subdivided and shall not be obliterated or hidden by surface treatment or coatings unless substitute means are provided. Where specified, items having limited calendar or operating life shall be identified and controlled to preclude use of items whose shelf life or operating life is expired.

2.9 Control of Special Processes

Special processes include any in which the results are highly dependent on the control of the process or skill of the personnel. These are also those processes in which the specified quality cannot be readily determined by inspection or non-destructive testing of the product. Special processes shall be controlled by instructions, procedures, drawings, checklists, travelers or other

appropriate means. SHINE and its suppliers are responsible for adhering to the approved procedures and processes for performing the special process. The requirements of applicable codes and standards, including acceptance criteria for the process, shall be specified or referenced in the procedures or instructions that control the process. Records shall be maintained as appropriate for the currently qualified personnel, processes, and equipment associated with special processes.

2.10 Inspections

Inspections to verify conformance of an item or activity to requirements shall be planned, documented and performed. The inspection program shall apply to procurement, construction, modification, and maintenance. Inspection of items in-process or under construction shall be performed for work activities where product quality cannot be determined by inspection of the completed product. The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements. Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage or other characteristics as required to verify the quality and conformance of the item to specified requirements. Associated quality records shall be examined for adequacy and completeness. Only items that have passed the required inspections and tests shall be used, installed or operated. Measuring and Test Equipment (M&TE) used to perform inspections shall be identified in inspection documentation for traceability of inspection results.

Inspection results shall be documented. Acceptance of items shall be documented and approved by authorized personnel. Inspection shall be performed by persons other than those who performed the work being inspected, but may be from the same organization. Each person who verifies conformance of work activities for purposes of acceptance shall be qualified to perform the assigned inspection task. The need for formal training shall be determined and training activities conducted as required to qualify personnel who perform inspections and tests. On-the-job training shall be included, with emphasis on firsthand experience gained through actual performance of inspections. Records of inspection personnel's qualification shall be established and maintained by their employer.

2.11 Test Control

Formal testing shall be required to verify conformance of designated structures, systems or components to specified requirements and demonstrate satisfactory performance for service or to collect data in support of design or fabrication. Testing shall include prototype qualification tests, proof tests prior to installation and functional tests. Test results shall be documented and evaluated by a responsible authority to ensure that test requirements have been satisfied. Computer programs used for operational control shall be tested in accordance with an approved verification and validation plan and shall demonstrate required performance over the range of operation of the controlled function or process.

2.12 Control of Measuring and Test Equipment

Tools, gauges, instruments and other M&TE used for activities affecting quality shall be controlled and calibrated or adjusted, at specified periods to maintain accuracy within specified limits. Out-of-calibration devices shall be tagged or segregated, and not used until they have been

recalibrated. Records shall be maintained of calibration data traceable to the individual piece of M&TE. Calibration and control measures are not required when normal commercial equipment provides adequate accuracy.

2.13 Handling, Storage and Shipping

Handling, storage, and shipping of items shall be in accordance with work and inspection instructions, drawings, specifications, shipping instructions or other pertinent documents or procedures for conducting the activity.

2.14 Inspection, Test and Operating Status

The status of inspection and test activities shall be identified on the items or in documents traceable to the items, in order to ensure that required inspections and tests are performed and to ensure that items which have not passed the required inspections and tests are not inadvertently installed or operated.

2.15 Control of Non-Conforming Items and Services

Items that do not conform to requirements shall be controlled to prevent inadvertent installation or use. Controls on non-conforming items shall provide for identification, documentation, evaluation, segregation from like conforming items when practical, and disposition of non-conforming items. Non-conforming conditions shall be evaluated for further reporting to appropriate regulatory agencies. Non-conforming characteristics shall be reviewed, and recommended dispositions of non-conforming items proposed and approved, in accordance with documented procedures.

The disposition (use-as-is, reject, repair, or rework) of non-conforming items shall be identified and documented. Technical justification for the acceptability of a non-conforming item disposition “repair” or “use-as-is” shall be documented. Non-conformance to design requirements of items dispositioned “use-as-is” or “repair” shall be subject to design control measures commensurate with those applied to the original design. The as-built records shall reflect the accepted deviation. Repaired or reworked items shall be re-examined in accordance with applicable procedures and with the original acceptance criteria, unless the non-conforming item disposition has established alternate acceptance criteria.

2.16 Corrective Actions

Conditions adverse to quality shall be identified promptly and corrected as soon as practical. The corrective actions shall be in accordance with the design requirements unless those requirements were faulty. In the case of a significant condition adverse to quality, the cause of the condition shall be investigated, and corrective action taken to preclude recurrence.

2.17 Quality Records

A records system or systems shall be established at the earliest practical time consistent with the schedule for accomplishing work activities. The records system or systems shall be defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation. The records shall include as a minimum: inspection and test results, results of

quality assurance reviews, quality assurance procedures, and engineering reviews and analyses in support of designs or changes and modifications.

Some records shall be maintained by or for the plant owner for the life of the particular item while it is installed in the plant or stored for future use. Such records shall be classified in accordance with the following criteria:

1. those which would be of value in demonstrating capability for safe operation;
2. those which would be of value in maintaining, reworking, repairing, replacing, or modifying an item;
3. those which would be of value in determining the cause or results of an accident or malfunction of a safety-related item;
4. those which provide required baseline data for in-service inspections; or
5. those which would be of value in planning for facility decommissioning.

Other records shall be retained for a shorter period as determined by SHINE. The records shall be stored in a location or locations that prevent damage from moisture, temperature, and pestilence. Additional provisions shall be made for special processed records such as radiographs, photographs, negatives, microfilm and magnetic media, to prevent damage from excessive light, stacking, electromagnetic fields, temperature and humidity. Records maintained by a supplier shall be accessible to SHINE.

2.18 Assessments

SHINE will conduct periodic assessments of quality-affecting activities during design, construction, modification and operations to evaluate the effectiveness of the as-implemented quality program. Assessments shall be performed in accordance with written procedures or checklists. Assessment results shall be documented and should be reviewed by management personnel who have responsibility for the area assessed. Conditions requiring prompt corrective action shall be reported immediately to the appropriate management of the assessed organization.

Management of the assessed organization or activity shall investigate adverse findings, schedule corrective action (including measures to prevent recurrence) and notify the appropriate assessing organization in writing of action taken or planned. The adequacy of the responses shall be evaluated by the assessing organization. Assessment records include assessment plans, reports, written replies, and the record of completion of corrective action. Personnel selected for assessment assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be assessed. The assessor shall have the capability to communicate effectively, both in writing and orally.

3 FACILITY OPERATIONS

This section provides the elements of the QAP for conduct of operation at the SHINE facility. The requirements shall be applied to any equipment or operation as appropriate and consistent with its potential safety impact or program goals. Many of the program requirements are satisfied by existing documentation, or by procedures and activities required by other standards and

requirements of the chartering or licensing agency. Some requirements of the QAP for operations may also be found in other documents, such as the Training Program, Emergency Plan, Security Plan, Technical Specifications (see ANSI/ANS-15.1-2007) and the Radiation Protection Program (see American National Standard for Radiation Protection at Research Reactor Facilities, ANSI/ANS-15.11-2009). Such requirements do not need to be duplicated in the quality assurance program.

3.1 Organization

SHINE shall provide sufficient resources in personnel and materials to safely conduct operations. Planning should anticipate needs as appropriate for any task. The organization structure shall be defined as required by Technical Specifications.

3.2 Quality Assurance Program

SHINE shall establish a QAP by implementing a policy for the conduct of operations. The policy will assign personnel to implement the policy and identify the goals for operating the SHINE facility. Personnel assignments and progress toward achieving goals will be documented.

3.3 Performance Monitoring

SHINE shall monitor facility performance relative to the goals that will be used as performance indicators. SHINE shall document periodic observations of operations and identify and assess any deficiencies to ensure the execution of corrective actions that will prevent recurrence. If appropriate, trend analysis should be performed to indicate where improvements or lessons learned could be implemented. Violations of operating practices should be addressed and documented as appropriate.

3.4 Operator Experience

SHINE shall document the methods for maintaining operator experience. Operators should be responsible for maintaining experience in operating the SHINE facility. This may be achieved by routine operation of the SHINE facility and documentation of the activity. A method should be provided to make operators aware of important current information that is related to facility operations and individual job assignments. Operator training is addressed in American National Standard for the Selection and Training of Personnel for Research Reactors, ANSI/ANS-15.4-2016.

3.5 Operating Conditions

Pre-operations checklists shall be used to determine or verify required pre-operational conditions and readiness to operate. Operating equipment shall be periodically monitored to detect abnormal conditions or adverse trends. Operating conditions should be documented in an operations logbook or other record. The operator should notify the appropriate level of management of any abnormal situations.

3.6 Operational Authority

SHINE shall establish the method for conducting operations and the responsibility for each shift. Operating personnel shall conduct a comprehensive review of appropriate records and equipment before assuming responsibility for the facility. Operational authority may be transferred through a

documented turnover briefing and facility walk-through procedures. These procedures should include checklists to record items important to facility status.

3.7 Control Area

Operators shall be alert and attentive to the control console's indications, alarms, and other activities within the control area. Only persons specifically authorized or certified to operate the SHINE facility shall operate control area equipment. Trainees may operate equipment only when they are directly supervised by certified operators. Control area activities and access should be limited to ensure that the operators are attentive to control responsibilities. A procedure shall be in place for quick placement of the SHINE facility in a safe configuration if evacuation of the control area or site is necessary.

3.8 Ancillary Duties

Operators shall not be assigned ancillary duties to be performed during operations to the extent that these duties could interfere with the ability to monitor facility parameters and maintain control of the SHINE facility.

3.9 Emergency Communications

Operators shall be able to contact the appropriate level of management rapidly and shall have the means to notify all affected personnel promptly of operations or emergencies on-site.

3.10 Configuration Control

Equipment shall be identified that requires configuration control. SHINE is responsible for establishing and maintaining proper configuration and should authorize any changes to safety-related items. All configuration changes to safety-related items should be documented. Before placing equipment into operation, the system shall be properly calibrated or checked, as appropriate, and any deficiencies in the equipment or the current configuration of the system documented. This should also address methods for temporary modifications. SHINE facility maintenance that requires a change in the system shall be documented.

3.11 Lockouts and Tagouts

Locks and tags shall be placed on equipment when, for safety or other special administrative reasons, controls must be established. If there is potential for equipment damage or personnel injury during equipment operation, maintenance, inspection, or modification activities, or from inadvertent activation of equipment, a facility lockout/tagout procedure shall be implemented.

3.12 Test and Inspection

Tests shall be performed following system maintenance, design changes, or inspection that involves dismantlement of components or systems. A documented test plan shall be used to demonstrate that the component or system is capable of performing its intended function. The results of the test should be documented and retained in facility records as appropriate.

3.13 Operating Procedures

Operating procedures shall provide appropriate direction to ensure that the facility is operated normally within its design basis, and in compliance with technical specifications. Operating

procedures shall be written, reviewed, approved by appropriate management, controlled, and monitored to ensure that the content is technically correct, and the wording and format are clear and concise. The facility policy on use of procedures should be documented and clearly understood by all operators. The extent of detail in a procedure should depend on the complexity of the task; the experience, education, and training of the users; and the potential significance of the consequences of error. The process for making changes and revisions to procedures should be documented. A controlled copy of all operations procedures should be maintained in the control room or equivalent area.

3.14 Operator Aid Postings

Any posted information that aids operators in performing their duties should be current and correct. Management should review operator aids to determine that they are necessary and correct before approving their postings. Postings should be checked periodically for continued applicability.

3.15 Equipment Labeling

Equipment shall be labeled to help facility personnel positively identify equipment they operate and maintain. Information on labels should be consistent with information found in facility procedures, valve lineup sheets, piping and instrument diagrams or other documents. Labels should be permanent, securely attached, readable and have appropriate information.

4 APPLICABILITY TO EXISTING FACILITIES

The SHINE facility will be a newly constructed facility and this section does not apply.

5 DECOMMISSIONING

This section of the QAPD will be updated at a later date.

6 REFERENCES

6.1 American National Standard for Quality Assurance Program Requirements for Research Reactors, ANSI/ANS-15.8-1995.

6.2 American National Standard for the Development of Technical Specifications for Research Reactors, ANSI/ANS-15.1-2007.

6.3 American National Standard for the Selection and Training of Personnel for Research Reactors, ANSI/ANS-15.4-2016.

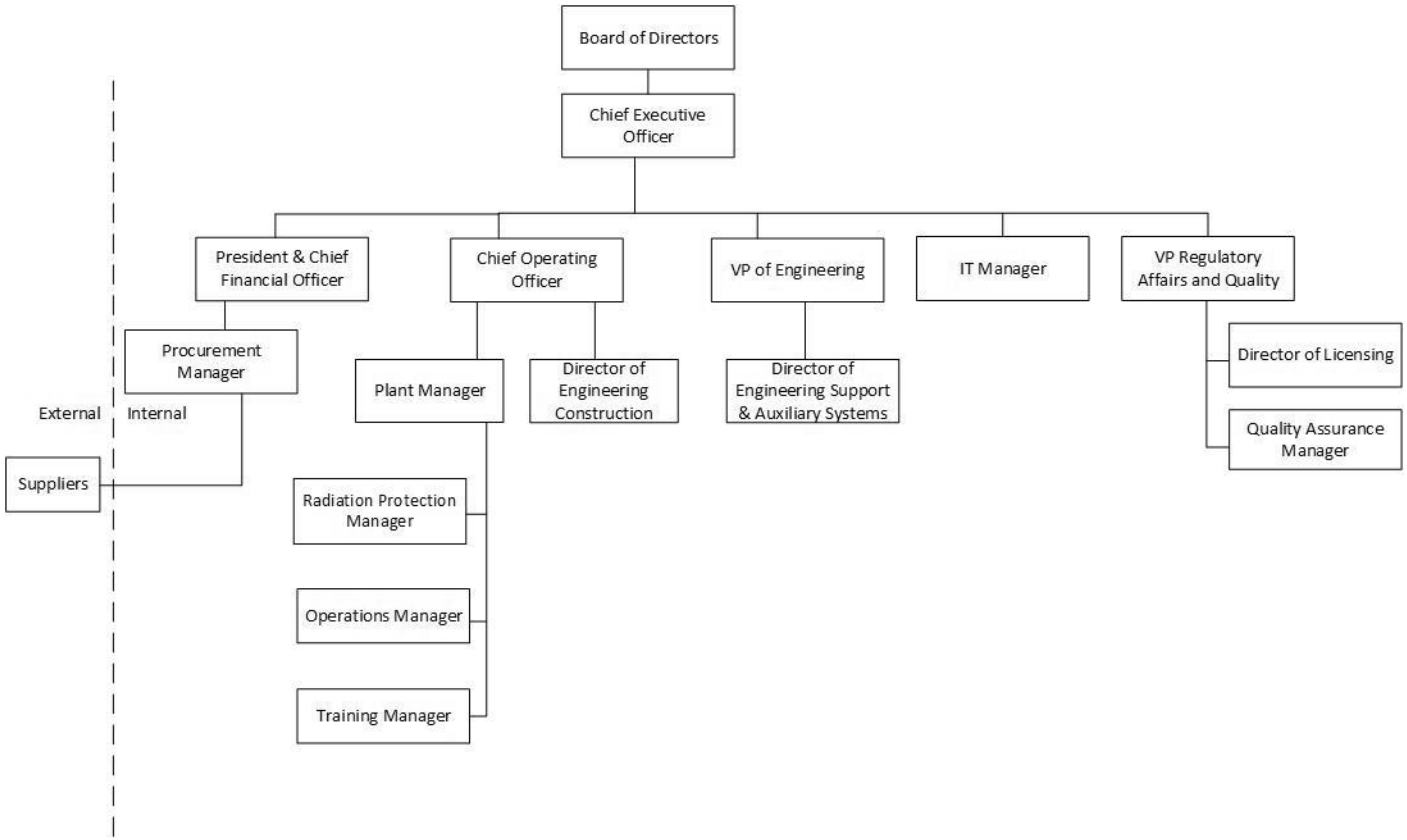
6.4 Appendix B to 10 CFR Part 20—Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage.

6.5 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.

6.6 NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content”.

6.7 Regulatory Guide 2.5, Rev.1, “Quality Assurance Requirements for Research and Test Reactors”.

ENCLOSURE 1 – SHINE FUNCTIONAL ORGANIZATIONAL CHART



ENCLOSURE 2 – GRADED APPROACH TO QUALITY

The graded approach to quality is a process by which the level of analysis, documentation, and actions necessary to comply with a requirement is commensurate with the safety significance. The graded approach permits the implementing organization to focus resources on those activities that are deemed, by qualitative analysis, to reduce the associated risks and hazards.

The activities and tasks are performed in accordance with approved implementing procedures.

QL-1 shall implement the full measure of this QAPD and shall be applied to safety-related SSCs and to safety-related activities.

QL-2 is applied to SSCs and activities that are intended to prevent unacceptable interactions between non-Seismic Category I SSCs and safety-related SSCs.

ENCLOSURE 3 – PROCEDURES THAT IMPLEMENT THE QAPD

QAPD Section	Subject	SHINE Implementing Procedures	Baker Implementing Procedures
2.1	Organization	QAPD, Section 2.1	01.01 Organization
2.1.1	Authority to Stop Work	0100-01-01 Stop Work	Baker QAPD, Section 5.1.3E
2.1.2	QA Organizational Independence	QAPD, Section 2.1.2	01.01 Organization
2.2	QA Program	QAPD, Section 2.2 2900-01-01 Training 1200-01-07 Classification of SSCs	02.01 General Co-worker Indoctrination and Training 02.02 Co-worker Qualification and Certification 02.03 Quality Assurance Program Description Procedure
2.3 2.3.1 2.3.2 2.3.3 2.3.4	Design Control Design Requirements Design Process Design Verification Design Documents and Records	1200-01-01 Design Packages 1200-01-02 Calculations 1200-01-03 Owner's Acceptance Review 1200-01-04 Technical Reports 1200-01-08 Drawings 1200-01-10 Design Criteria Documents 1200-01-13 Engineering Software Control and Quality Assurance 1200-01-15 Specifications for Structures, Systems, and Components (SSCs) 1200-09-01 Configuration Management 1200-09-04 Design Control Program	03.01 Design Interface
2.3.5	Commercial Grade Items	1600-01-02 Commercial Grade Dedication	07.02 Commercial Grade Dedication (CGD) of Items for Safety Related Applications
2.3.6	Change Control	1200-01-06 Design Change Control Process	Baker to follow SHINE 1200-01-06 Design Change Control Process
2.4	Procurement Document Control	1600-01-01 Procurement	04.01 Controlling Procurement Documents

QAPD Section	Subject	SHINE Implementing Procedures	Baker Implementing Procedures
2.5	Procedures, Instructions and Drawings	1200-01-08 Drawings 2100-01-01 Document Control	5.01 Controlling Instructions and Procedures
2.6	Document Control	2100-01-01 Document Control 2000-01-03 Good Documentation Practices 2000-01-12 Signatures and Review/Approval Process	06.01 Controlling Documents
2.7 2.7.1 2.7.2 2.7.3 2.7.4	Control of Purchased Items and Services Supplier Selection Work Control Verification Activities Item or Service Acceptance	2000-01-11 Supplier Qualification 1600-01-01 Procurement 1600-01-03 Request for Quotation (RFQ) 2000-01-13 QA Surveillances Receipt Inspection procedure to be developed for facility operations prior to OL issuance. Baker procedure used for construction.	07.01 Controlling Purchases of Items and Services
2.8	Identification and Control of Items	Procedure to be developed for facility operations prior to OL issuance. Baker procedure used for construction.	08.01 Identifying and Marking Material
2.9	Control of Special Processes	Procedure to be developed for facility operations prior to OL issuance. Baker procedure used for construction.	09.01 Controlling Special Processes
2.10	Inspection	Procedure to be developed for facility operations prior to OL issuance. Baker procedure used for construction.	10.01 Performing Inspections
2.11	Test Control	1200-01-13 Software Control and QA Procedure for non-software testing to be developed for facility operations prior to OL issuance. Baker procedure used for construction.	11.01 Controlling Tests
2.12	Control of Measuring and Test Equipment	Procedure to be developed for facility operations prior to OL issuance. Baker procedure used for construction.	12.01 Controlling Measuring and Test Equipment
2.13	Handling, Storage and Shipping	Procedure to be developed for facility operations prior to OL issuance. Baker procedure used for construction.	13.01 Handling, Storage, Cleaning, Packaging and Shipping of Items

QAPD Section	Subject	SHINE Implementing Procedures	Baker Implementing Procedures
2.14	Inspection, test and Operating Status	Procedure to be developed for facility operations prior to OL issuance. Baker procedure used for construction.	14.01 Identifying the Inspection, Test and Operating Status of Items
2.15	Control of Nonconforming Items and Services	2000-01-14 Control of Nonconforming Items.	15.01 Controlling Nonconforming Items
2.16	Corrective Actions	2200-01-01 Issues Management 2200-01-03 10 CFR 21 and 10 CFR § 50.55(e) Reporting 2200-01-05 Condition Evaluation 2200-01-06 Apparent Cause Evaluation 2200-01-07 Root Cause Evaluation	16.01 Corrective Action Program 16.02 Reporting Potential 10 CFR 21 & 10 CFR § 50.55(e) Issues to SHINE
2.17	Quality Records	2100-01-02 Records Management 2000-11-01 SHINE Quality Records Retention Policy	17.01 Controlling Quality Assurance Records
2.18	Assessments	2000-01-08 Assessments 2000-01-13 QA Surveillances	18.01 Performing Assessments 18.02 Performing Surveillances
3	Facility Operations	Procedures to be developed for facility operations prior to OL issuance.	Baker scope for construction only