SHINE MEDICAL TECHNOLOGIES, INC.

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

PUBLIC VERSION

The NRC staff determined that additional information was required (Reference 1) to enable the continued review of the SHINE Medical Technologies, Inc. (SHINE) application for a construction permit to construct a medical isotope facility (References 2 and 3). SHINE responded to the NRC staff's requests via References (4) and (5). In the course of reviewing the SHINE responses provide via Reference (4), the NRC staff has determined that additional information is required to complete the review of the SHINE Preliminary Safety Analysis Report (PSAR) and Environmental Report (Reference 6). The following information is provided by SHINE in response to the NRC staff's request.

General Information Request

RAI G-2

Title 10 of the Code of Federal Regulations (10 CFR 50.34(a)(8)), requires that a PSAR include:

> *An identification of those structures, systems, or components of the facility, if any, which require research and development to confirm the adequacy of their design; and identification and description of the research and development program which will be conducted to resolve any safety questions associated with such structures, systems or components; and a schedule of the research and development program showing that such safety questions will be resolved at or before the latest date stated in the application for completion of construction of the facility.*

Based on the review of SHINE PSAR, NRC staff understands that there are structures, systems, and components that require additional research and development, and that this information will become available in SHINE's final safety analysis report (FSAR).

Specifically, in response to RAI G-1, SHINE described ongoing research and development activities to confirm the adequacy of system design, including irradiation and corrosion testing at Oak Ridge National Laboratory and precipitation studies of uranyl peroxide at Argonne National Laboratory. Based on a review of papers presented by Argonne National Laboratory at the 2014 Topical Meeting on Molybdenum-99 in Washington, D.C., the NRC staff understands that Argonne National Laboratory has additional ongoing and planned test programs related to radiolytic and fission gas generation, which could influence the design of the SHINE facility. However, these research programs have not been discussed in sufficient detail in the SHINE PSAR for the NRC staff to determine the extent of additional research and development required for structures, systems, and components of the SHINE facility.

Provide additional information describing all ongoing and planned research and development activities, including those related to radiolytic and fission gas generation at Argonne National Laboratory, which could impact the design of structures, systems, and components of the SHINE facility.

SHINE Response

10 CFR 50.34(a)(8) Research and Development Activities

SHINE is performing the following two required research and development activities to confirm the adequacy of system design:

- Irradiation and corrosion testing at Oak Ridge National Laboratory (ORNL) to study mechanical performance of materials; and
- Precipitation studies of uranyl peroxide in the target solution vessel (TSV) at Argonne National Laboratory (ANL).

These activities are described in detail in the SHINE Response to RAI G-1 (Reference 4).

National Lab Activities Not Associated with 10 CFR 50.34(a)(8)

The following additional activities are ongoing at the national labs and are expected to be used to assist in system development for SHINE, if meaningful results are obtained.

These additional activities are beneficial to SHINE if they are performed, but they are not required research and development activities required to confirm the adequacy of the SHINE design and are, therefore, not required to resolve any safety questions associated with structures, systems, or components at the SHINE facility. SHINE can design, construct, and operate the facility using existing experimental data, models, and conservative design margins without requiring the additional studies described below. The national lab work described below offers cost reduction benefits for SHINE and reduces in-house analysis/calculation needs.

A schedule is provided for each of the activities for the remaining work to be performed. Dates are in reference to the calendar year.

Mini-SHINE Experiments an ANL

ANL is performing a set of experiments to irradiate uranyl sulfate solution at nuclear and chemical conditions similar to the SHINE system. Sufficient data to support the design exists without completing these experiments, but results may be used for design improvements if they become available.

The irradiations involve the use of an electron linac directing a beam of electrons into a neutron-producing target. The neutron-producing target is contained within a uranyl sulfate solution (5 L in size for Phase 1 and 20 L in size for Phase 2). Low enriched uranium (LEU) is being used for the target solution. The neutrons cause fission in the uranium, yielding Mo-99 and other fission products.

The mini-SHINE experiment contains a recombination loop to recombine hydrogen and oxygen. Gas composition samples are also taken, and measurements of the hydrogen and oxygen release rates from solution will be made. However, SHINE notes that these measurements may not provide significant additional data beyond those measurements cited in the SHINE Response to RAI 4a2.2-2 (Reference 4) due to the lower fission to total energy ratio (i.e., fission to total energy fraction expected to be approximately 40 percent to 70 percent, resulting in lower G values than from a highly fissioning system) and the lower expected accuracy (i.e., accuracies of measurements of G values for ANL measurements are expected to be approximately 30 percent). However, new available measurements of hydrogen and oxygen release rates will be compared to expected values to the extent possible.

Following irradiation from the electron beam and a subsequent decay period, the solution is transferred to the extraction process, where the Mo-99 is extracted using similar extraction [Proprietary Information] column process as described in the SHINE PSAR. Following extraction [Proprietary Information] of the Mo-99, the solution is transferred to the purification process, where the LEU-modified Cintichem process is used to yield a product that meets the quality assurance standards of SHINE's customers. This process is also the same purification process as is expected to be used for SHINE. The SHINE extraction and purification steps have been demonstrated before. This experimental work will validate the overall system performance and provide additional operating experience for SHINE to streamline the startup process in the production facility.

This work may affect the following structures, systems, and components if meaningful results are obtained and SHINE chooses to use the results:

- TSV Off-Gas System (TOGS)
- Molybdenum Extraction and Purification System (MEPS)

Schedule:

- Performance of Phase 1 mini-SHINE: Q1 2015 to Q2 2015
- Installation of Phase 2 mini-SHINE: Q2 2015
- Performance of Phase 2 mini-SHINE experiments: Q3 2015
- Completion of mini-SHINE experiments: Q3 2015

<u>Nuclear System Transient Modeling Code at LANL</u>

LANL is writing a transient systems modeling code to analyze the coupled nuclear and thermal-hydraulics behavior of solution systems, including reactors and the SHINE accelerator-driven subcritical assembly. The transient systems model utilizes a neutronics model, a thermal-hydraulic model, gas production and release effects, and a gas recombiner system model. The code can calculate the steady state and transient behavior of aqueous nuclear systems.

LANL is validating code response versus solution reactor data to ensure the code matches the behavior of aqueous systems under a wide range of conditions (e.g., steady-state operation, slow transients, fast transients).

With inputs of the SHINE-specific parameters into the code (e.g., off-gas system volume, heat transfer surface area, geometry factors), the code will be used to perform the transient modeling for several of the accident and operational transients to be provided in the FSAR. (Other transients may be bounded by considering the worst case steady state conditions or by using other codes, such as RELAP.)

This modeling/code writing that is being performed at LANL is part of the normal design process, and it does not involve research into new calculation methods or performing new experiments.

This work may affect the following structures, systems, and components if meaningful results are obtained and SHINE chooses to use the results:

- Subcritical Assembly System (SCAS)
- TOGS

Schedule:

- Modify and extend transient modeling code to SHINE-specific parameters: Q1 2015 through Q2 2015
- Complete nuclear system transient modeling code: Q2 2015

<u>Computational Fluid Dynamics Simulations of TSV Best-Estimate Conditions at LANL</u>

LANL is working to perform computational fluid dynamics (CFD) simulations of the natural convection patterns of the uranyl sulfate solution in the TSV. While SHINE considers this normal engineering design work and not research and development, it is included here for completeness. Similar work would be performed during the normal design process if it was not being performed at LANL. Also, the results of the CFD models are not planned to be used for safety-related purposes, rather for best-estimate prediction of subcritical assembly operating conditions to determine product output.

The simulations are being performed to determine the normal operating temperature and void fraction in the TSV during operation. These simulations are used to predict facility output (capacity) for a given accelerator source strength. The CFD simulations are also being compared against the thermal-hydraulic experiment data from the University of Wisconsin - Madison (below) to validate the code behavior in this thermal--hydraulic regime.

This work may affect the following structures, systems, and components if meaningful results are obtained and SHINE chooses to use the results:

- SCAS
- TOGS

Schedule:

- Update CFD model and optimize solver settings: Q1 2015 through Q3 2015
- Issue report on completed CFD simulations of TSV best-estimate conditions: Q3 2015

Thermal-Hydraulic Experiments at University of Wisconsin – Madison

These experiments were completed, but are included in this response due to their relation to the CFD studies above. The University of Wisconsin – Madison performed experiments using a thermal-hydraulics test assembly [Proprietary Information]. Electric heaters and bubble injection were employed to replicate the power generation and gas production in the SHINE facility. The assembly was rectangular in nature, with two of the walls cooled by cooling water to simulate the TSV design.

The thermal-hydraulic experiments were used to determine the heat transfer coefficients and void fractions expected for this system over a range of power conditions. The heat transfer experiments are being modeled by the CFD simulations described above to validate the numerical accuracy of these codes in the thermal-hydraulic regime of interest.

This work is completed and does not have the potential to affect structures, systems, or components as described in the PSAR.

Design Support Work for Tritium Purification System at Savannah River National Lab

Savannah River National Laboratory (SRNL) is performing supporting design work for the Tritium Purification System (TPS). While SHINE considers this normal engineering design work and not research and development, it is included here for completeness. This work would be performed during the normal design process if it was not being performed at SRNL.

The work involves selecting and sizing components, performing design calculations, and other design activities due to their expertise with similar systems. Some limited testing work is being performed on pumps and integrated systems to ensure the expected gas flows and system response.

This work will continue during fiscal year (FY) 2015, with primary design responsibility being transferred to SHINE as SHINE moves into the detailed design phase.

This work may affect the following structures, systems, and components if meaningful results are obtained and SHINE chooses to use the results:

- TPS
- Neutron Driver Assembly System (NDAS)

Schedule:

- Continuation of SRNL design support work for the Tritium Purification System: Q1 2015 through Q3 2015
- Completion of SRNL design support work for the Tritium Purification System: Q3 2015

Uranium Concentration Measurement Techniques at LANL

LANL is investigating methods to measure the concentration of uranium in uranyl sulfate solutions. The investigations involve ultraviolet-visible spectroscopy (UV-Vis) and titration methods. The UV-Vis method is being compared against the “industry standard” titration method (i.e., Davies-Gray titration) to provide SHINE a more rapid yet accurate means for uranium concentration measurement. Work is being performed over a range of conditions, including impurities, to ensure that any potential interferences or non-linearities are properly characterized. If successfully characterized, the UV-Vis method for uranium concentration measurement is expected to be used, along with the Davies-Gray titration, in the final SHINE facility.

This work is not expected to affect the structures, systems, or components as described in the SHINE PSAR.

Schedule:

- Continue studies on accuracy, precision, and reliability of UV-Vis method: Q1 2015 through Q2 2015
- Complete report on uranium detection technique validation: Q2 2015

<u>Waste Stream Process Optimizations at ANL</u>

ANL is reviewing SHINE calculations regarding isotope partitioning in the radioisotope processing facility (RPF) to suggest process improvements to reduce waste generation and optimize the waste streams. These potential improvements involve modifications to the molybdenum extraction and purification steps and target solution cleanup processes. The modifications are not required, but may be pursued by SHINE depending on their simplicity and ease of implementation. The work may involve additional experiments to study how chemical or physical changes affect extraction [Proprietary Information] extraction ratios for different elements.

This work may affect the following structures, systems, and components if meaningful results are obtained and SHINE chooses to use the results:

- Uranyl Nitrate Conversion System (UNCS)
- MEPS
- Organic Liquid Waste Storage and Export System (OLWS)
- Aqueous Radioactive Liquid Waste Storage (RLWS)
- Radioactive Liquid Waste Evaporation and Immobilization (RLWE)
- Solid Radioactive Waste Packaging (SRWP)

Schedule:

- Continue waste stream process optimizations, including tests of potential changes to the target solution cleanup and molybdenum extraction and purification processes: Q1 2015 through Q3 2015
- Complete waste stream process optimizations: Q3 2015

Yield and Batch Sizes of the Molybdenum Purification Process

ANL is performing additional studies to verify the expected yield of the alpha-benzoin-oxime precipitation step in the molybdenum purification process under the expected SHINE curies levels per batch. Previous studies and confirmatory studies have been performed that verify the precipitation step will perform as expected and yield the expected level of Mo-99 product; however, ANL plans to perform a more comprehensive test to further reduce technical risk. Any process improvements found from these studies are not required to safely design, construct, and operate the facility, but may be pursued by SHINE to increase purified product yields depending on their simplicity and ease of implementation.

This work may affect the following structures, systems, and components if meaningful results are obtained and SHINE chooses to use the results:

- MEPS

Schedule:

- Perform confirmatory experiments on purification process yield and batch size: Q2 2015 to Q3 2015
- Complete report documenting experimental results: Q3 2015

CHAPTER 2 – SITE CHARACTERISTICS

The following questions of this chapter are based on a review of Chapter 2 of the SHINE PSAR (ADAMS Accession No. ML13172A263) using NUREG-1537, Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2, as well as SHINE's responses to a request for additional information dated September 19, 2014 (ADAMS Accession No. ML14296A192).

Section 2.2 – Nearby Industrial, Transportation, and Military Facilities

RAI 2.2-3

NUREG-1537, Part 2, Section 2.2, "Nearby Industrial, Transportation, and Military Facilities," states that the information contained in this section should be "complete enough to support evaluations of potential risks posed by these facilities to the safe operation and shutdown of the reactor during its projected lifetime."

SHINE PSAR, Section 2.2.3.1.3, "Toxic Chemicals," states, "[t]he control room is not safety-related. The control room operators are not required to operate safety-related equipment to ensure the safety of the public. Therefore, a toxic gas release is not a hazard to the facility."

While SHINE's response to RAI 2.2-1 provided information on the impact of an off-site toxic gas release on safety-related structures, systems, and components, additional information is needed for the NRC staff to evaluate the potential risk posed by a toxic gas release to the operators in the control room and the safe operation and shutdown of the facility.

Provide additional information describing why the control room would not become uninhabitable due to an accident on US-51 or I-90/39 involving the release of hazardous or toxic chemicals, such as those identified in PSAR Table 2.2-4, "Hazardous Chemicals Potentially Transported on Highways within 8 Km (5 Mi.) of the Project Site." Alternatively, should the control room become uninhabitable as a result of such an accident, provide additional information demonstrating that the operators will have sufficient time to shut down the facility prior to becoming incapacitated.

SHINE Response

The SHINE facility is designed such that an accident will not be initiated and there will be no radiological consequences in the event of a release of hazardous or toxic chemicals on U.S. Highway 51 (US-51) or Interstate 90/39 (I-90/39).

SHINE has evaluated the potential for an off-site toxic gas release within five miles of the site, similar to screening criteria found in Regulatory Positions 1.1 and 1.2 of Regulatory Guide (RG) 1.78 (Reference 7).

SHINE considered stationary sources and mobile sources expected to be transported on US-51, I-90/39, or on local railroads. The hazardous chemicals evaluated were primarily based on those chemicals identified in 2010 Tier II reports in Rock County, Wisconsin. The selection of mobile sources was based on: (1) the mobile sources of hazardous chemicals described in Table 2.2-4 of the PSAR; (2) stationary sources within five miles where deliveries or shipments could be transported on local roads; (3) large quantities of stationary sources elsewhere in the county where deliveries or shipments could be transported on major roads or rail lines; and (4) direct communication with select individual facilities regarding their types, quantities, and frequencies of shipments. Direct communication with individual facilities was also used to augment the stationary source information identified in the 2010 Tier II reports.

Chemicals were screened in several ways. Only chemicals with vapor pressures greater than 10 Torr at 100°F were considered for further evaluation, similar to the volatility screening criteria found in Section 3.2 of RG 1.78. Mobile sources were not considered if their shipment was not frequent (i.e., less than 10 shipments per year for truck traffic or 30 shipments per year for rail traffic), similar to the guidance found in Regulatory Position 1.2 of RG 1.78.

For the remaining chemicals, airborne dispersion was evaluated deterministically, using worst-case wind directions, and a temperature and wind speed with an annual exceedance probability of five percent, as recommended in Section 3.3 of RG 1.78. Only maximum concentration accidents, similar to those described in Section 3.2 of RG 1.78, were evaluated based on releases of the maximum expected amounts of chemicals. Maximum concentration-duration accidents were not evaluated because after shutting down the facility the operators do not need to take any other actions to assure facility safety. These deterministic evaluations were performed using ALOHA (Areal Locations of Hazardous Atmospheres), Version 5.4.4, an Environmental Protection Agency (EPA) chemical dispersion program.

Some mobile sources of chemicals were evaluated probabilistically, based on shipment or inventory information from local users of those chemicals, when the deterministic evaluation provided insufficient results. The acceptance criteria for releases evaluated in this manner is 10^{-6} releases per year, similar to the acceptance criteria described in Section 2 of RG 1.78.

The Control Room in this evaluation was assumed to have an air-exchange rate of 1.2 exchanges per hour, which is considered representative of a Control Room with construction features that are not as efficient for leakage control and without automatic isolation capabilities, similar to an example control room described in Appendix A of RG 1.78.

A two-minute exposure to National Institute for Occupational Safety and Health (NIOSH) Immediately Dangerous to Life and Health (IDLH) concentrations was used as the threshold for uninhabitability, similar to the toxicity limits described in Section 3.1 of RG 1.78. For chemicals with no defined IDLH limit, Protective Action Criteria (PAC) Level 2 limits were used, or the chemical was screened against qualitative toxicity information if no quantitative limits were available.

Of the chemicals evaluated, only an ammonia release could have a greater than 10^{-6} per year potential to result in an uninhabitable Control Room. For the closest ammonia release, the evaluation shows that the Control Room Operators would have sufficient time to shut down the facility (i.e., at least two minutes) by manually tripping the TSVs. This single action ensures:

- Target solution is drained to the criticality-safe dump tank(s);
- Decay heat from the target solution is removed via conduction through the dump tank(s) walls to the light water pool; and
- Hydrogen buildup in the primary system boundary is controlled via the TOGS.

These actions will maintain the target solution in a safe shutdown condition. There are no radiological consequences to the workers or the public due to an off-site toxic gas release that affects the facility.

Control Room Operators will be trained to detect and respond to abnormal conditions, including external events such as an off-site toxic gas release, and will have sufficient time to shutdown the facility, when necessary. The facility is designed so that safety systems necessary to maintain safe shutdown will perform the necessary functions even if Control Room Operators were to become incapacitated.

SHINE will update Subsection 2.2.3.1.3 of the PSAR in the Final Safety Analysis Report (FSAR) to include a description of the off-site toxic gas release analysis. SHINE will also update Table 2.2-4 of the PSAR in the FSAR to include the chemicals and corresponding quantities considered in the off-site toxic gas release analysis. An Issues Management Report (IMR) has been initiated to track the updates to Subsection 2.2.3.1.3 and Table 2.2-4 in the FSAR.

RAI 2.2-4

NUREG-1537, Part 2, Section 2.2, "Nearby Industrial, Transportation, and Military Facilities," states in part, "[t]he reviewer should focus on facilities, activities, and materials that may reasonably be expected to be present during the projected lifetime…."

a) *While SHINE's response to RAI 2.2-2(a) analyzed the increased number of takeoffs and landings due to the presence of the Airfest, additional information is needed on the Airfest performances and rehearsals in order for the NRC staff to determine the adequacy of SHINE's analysis of the impact of the Airfest to the SHINE facility. As the Federal Aviation Administration indicates in its Aeromedical Issues of Specific Aviation Operations (https://www.faa.gov/other_visit/aviation_industry/designees_delegations/designee_types/ame/tutorial/section2/aeromedical_issues/), aerobatic accidents tend to occur during performance, as opposed to during takeoffs and landings.*

   Provide either an expanded air show accident analysis that includes accidents that could occur during performances and rehearsals, or justification as to why an accident occurring during a performance or rehearsal would not adversely affect the SHINE facility.

b) *In response to RAI 2.2-2(b) SHINE provided information supporting the use of an aircraft accident probability of 10^{-5} per year as described in IAEA-TECDOC-1347; however, additional information is needed for the NRC staff to determine the adequacy of SHINE's use of an aircraft accident probability of 10^{-5} per year.*

   In the NRC's "Memorandum and Order, In the Matter of Private Fuel Storage L.L.C.," CLI-05-19, dated September 9, 2005, the Commission determined that 10^{-6} per year was the appropriate threshold probability for accident aircraft crash hazards for the Private Fuel Storage L.L.C. proposed independent spent fuel storage installation.

   In PSAR Section 2.2.2.5 "Evaluation of the Aircraft Hazard," SHINE used the methodology and data provided in the U.S. Department of Energy's (DOE) "Accident Analysis for Aircraft Crash into Hazardous Facilities," (DOE-STD- 3014-96). This DOE standard is "applicable to all facilities containing significant quantities of radioactive or hazardous chemical materials." Section A.2 of DOE-STD-3014-96 indicates that at least five United States institutions and federal government agencies, including the Food and Drug Administration, Environmental Protection Agency, DOE, NRC, and American National Standards Institute utilize a "one in a million" aircraft accident cutoff probability.

Provide additional information justifying the use of an aircraft accident probability of 10^{-5} per year as opposed to utilizing an aircraft accident threshold probability of 10^{-6} per year as supported by NRC precedent and DOE standards.

SHINE Response

a) An accident occurring during a performance or rehearsal would not adversely affect the SHINE facility because aerobatic activity would not be permitted by the Federal Aviation Administration (FAA) in a location or manner that could jeopardize the safety of the SHINE facility.

14 CFR 91.303 states:

> *"No person may operate an aircraft in aerobatic flight—*
>
> *(a) Over any congested area of a city, town, or settlement;*
> *(b) Over an open air assembly of persons;*
> *(c) Within the lateral boundaries of the surface areas of Class B, Class C, Class D, or Class E airspace designated for an airport;*
> *(d) Within 4 nautical miles of the center line of any Federal airway;*
> *(e) Below an altitude of 1,500 feet above the surface; or*
> *(f) When flight visibility is less than 3 statute miles.*
>
> *For the purposes of this section, aerobatic flight means an intentional maneuver involving an abrupt change in an aircraft's attitude, an abnormal attitude, or abnormal acceleration, not necessary for normal flight."*

Class E airspace for the Southern Wisconsin Regional Airport (SWRA) is defined in FAA Order JO 7400.9Y (Reference 8) as, "That airspace extending upward from 700 feet above the surface within an 8.9-mile radius of the Southern Wisconsin Regional Airport…" The SHINE site exists entirely within the lateral boundaries of the SWRA Class E airspace, and thus, aerobatic flight is prohibited in the vicinity of the SHINE site by 14 CFR 91.303(c).

However, 14 CFR 91.903 and 14 CFR 91.905 allow the FAA to issue waivers to 14 CFR 91.303 for the purposes of conducting airshows. Individuals who may be interested in conducting airshows at the SWRA would therefore be required to submit FAA Form 7711-2, Application for Certificate of Waiver or Authorization, in accordance with FAA Order JO 7210.3Y (Reference 9).

In determining where aerobatics will be performed within the geographic area specified on FAA Form 7711-2, the event organizer selects a site that will accommodate all the specific types of airshow demonstrations without detracting from safety or creating a hazard to any non-participants or spectators.

Volume 3, Chapter 6 of FAA Order 8900.1 (Reference 10) contains information for FAA personnel on whether to issue a FAA Form 7711-1, Certificate of Waiver or Authorization, to an applicant for an aviation event. Per the airshow airspace requirements described in Volume 3, Chapter 6 of FAA Order 8900.1, it is imperative that all areas adjacent to the airshow site containing homes, factories, major highways, traveled thoroughfares, or any occupied vessel, vehicle, or structure be carefully evaluated before making a final decision for site selection.

Based on FAA regulations, the location of the SHINE site will be taken into consideration when authorizing any future aviation events at the SWRA. Therefore, the results and conclusions presented in Subsection 2.2.2.5 of the PSAR will still be applicable should a future airshow be held at the SWRA during the operation of the SHINE facility, since an aviation event cannot be conducted in such a manner or location that would jeopardize the safety of the facility in the opinion of the FAA.

b) SHINE has performed an updated evaluation of the aircraft hazard using an aircraft accident threshold probability of 10^{-6} per year, as supported by NRC precedent and Department of Energy (DOE) standards. Therefore, justifying the use of an aircraft accident probability of 10^{-5} per year is not necessary. The updated analysis of aircraft hazard probabilities uses updated data inputs. The probability of an aircraft accident affecting the safety-related structures of the SHINE facility has been calculated using the methodology described below.

In summary, the following three inputs contributed to the majority of the changes in the updated analysis:

1. The updated analysis uses the dimensions of the SHINE safety-related areas and vent stacks as described in Figures 1.3-3 and 1.3-5 of the PSAR. Previous aircraft hazard probabilities had been calculated using a larger preliminary building design.
2. The updated analysis uses an updated Terminal Area Forecast (TAF) Detail Report for the Southern Wisconsin Regional Airport (SWRA), issued February 2014, containing more recent aircraft operation data than was used to calculate previous aircraft hazard probabilities.
3. The updated analysis incorporates discussions with the Air Traffic Manager and staff at the Janesville Air Traffic Control Tower located at the SWRA regarding the number and types of aircraft operations at this airport. These discussions resulted in a change in the categorization of aircraft types using the SWRA.

SHINE will update Subsection 2.2.2.5 of the PSAR in the FSAR to include a description of the updated evaluation of the aircraft hazard, provided below. An IMR has been initiated to track the update to Subsection 2.2.2.5 in the FSAR. Subsections 2.2.2.1 through 2.2.2.4 of the PSAR do not require updates as a result of the updated evaluation of the aircraft hazard.

Evaluation of the Aircraft Hazard

<u>Evaluation of Airways</u>

The DOE provides a method for estimating the probability per year of an aircraft crashing into the facility. The methodology is outlined in DOE-STD-3014-96 (Reference 11) and uses crash rates for non-airport operations.

The non-airport crash impact frequency evaluation is determined from using the "four factor formula" provided in Equation 2.2-1 of the PSAR.

Tables B-14 and B-15 of DOE-STD-3014-96 provide $N_jP_jf_j(x,y)$ 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 also provide crash probabilities for unspecified locations in the continental United States (CONUS), and Table B-43 of DOE-STD-3014-96 provides a generic crash frequency for helicopters. Therefore, the CONUS average values and generic helicopter values are used for the SHINE facility and are provided in Table 2.2-4-1. The input values provided in Table 2.2-4-1 supersede the input values provided in Table 2.2-8 of the PSAR.

The effective plant area (A_j) for the safety-related structures of the SHINE facility depends on the length, width, and height of the facility, as well as the aircraft's wingspan, skid distance, and impact angle, as described in Equations 2.2-2, 2.2-3, and 2.2-4 of the PSAR. Table 2.2-4-1 provides the aircraft wingspan (WS), mean of the cotangent of the aircraft impact angle (cot(φ)), and aircraft skid distance (mean value) (S). The effective area input values provided in Table 2.2-4-1 supersede the effective area input values provided in Table 2.2-8 of the PSAR.

Table 2.2-4-1: DOE Input Values for CONUS Average

$N_jP_jf_j(x,y)$ Values

	$N_jP_jf_j(x,y)$ Value (1/mi^2)
Air Carrier	4.0E-07
Air Taxi	1.0E-06
General Aviation	2.0E-04
Small Military	4.0E-06
Military Helicopter	2.5E-05

Effective Area Input Values

	WS (ft)	**cot(φ)**	**S (ft)**
Air Carrier	98	10.2	1440
Air Taxi	59	10.2	1440
General Aviation	50	8.2	60
Small Military	110	10.4	447
Military Helicopter	79[a]	0.58	0

a) Wingspan is for Sikorsky CH-53E/MH-53E. DOE-STD-3014-96 only contained wingspan information for general aviation helicopters, which are generally smaller than military helicopters.

The total effective area (A_j) for the safety-related structures and the two stacks of the SHINE facility were calculated. Dimensions of the production facility used in the analysis include a width of 200 ft. 4 in, a length of 194 ft. 4 in., and a height of 57 ft. 8 in., as shown in Figures 1.3-3 and 1.3-5 of the PSAR. The dimensions for the off-gas stack were assumed to be 24 ft. 6 in. tall and 4 ft. 8 in. in diameter, and the dimensions of the boiler stack were assumed to be 49 ft. 3 in. tall and 1 ft. 8 in. in diameter.

The calculated effective area for the five aircraft types is provided in Table 2.2-4-2. The calculated effective areas provided in Table 2.2-4-2 supersede the calculated effective areas provided in Table 2.2-9 of the PSAR.

Table 2.2-4-2: Calculated Effective Areas (sq. mi.) by Aircraft Type Used for the Evaluation of Airways and Airports

Aircraft Type	Effective Area (sq. mi.)
Air Carrier	0.0378
Air Taxi	0.0315
General Aviation	0.0095
Small Military	0.0221
Military Helicopter	0.0028

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 2.2-4-5. The crash impact probabilities from airways provided in Table 2.2-4-5 supersede the crash impact probabilities from airways provided in Table 2.2-15 of the PSAR.

Evaluation of Airports

Only the SWRA and the Mercy Hospital Heliport are within 5 mi. (8 km) of the SHINE facility. No airport between 5 mi. (8 km) and 10 mi. (16 km) from the SHINE facility has greater than $200d^2$ (where d is the distance to the SHINE facility in km) aircraft operations per year. Based on this screening criterion (from Section 2.2.2 of NUREG-1537 (Reference 12)), only the SWRA and the Mercy Hospital Heliport need to be evaluated for the potential hazard posed by aircraft using these facilities. The Mercy Hospital Heliport is only used sporadically. The greater size of aircraft using the SWRA, greater number of operations at the SWRA, and the closer distance from the SHINE facility to the SWRA renders a separate analysis of the Mercy Hospital unnecessary because the probability contribution from Mercy Hospital is negligible.

Section 3.5.1.6 of NUREG-0800 (Reference 13) provides a method for estimating the probability of an aircraft crashing into the site from the operations at nearby airports. The method for calculating the probability per year of an aircraft crashing into the site due to airport operations at nearby airports is described in Equation 2.2-5 of the PSAR.

For the SWRA, the same calculated effective areas used for crash impact probabilities from airways are used to calculate the crash impact probabilities from airports. The calculated effective area for the five aircraft types is provided in Table 2.2-4-2. The calculated effective areas provided in Table 2.2-4-2 supersede the calculated effective areas provided in Table 2.2-10 of the PSAR.

The total operations at the SWRA used in the evaluation of the airport are based on the Federal Aviation Administration (FAA) Office of Aviation Policy and Plans (APO) TAF Detail Report, issued February 2014. The number of operations at the SWRA for each aircraft type is provided in Table 2.2-4-3. The number of operations provided in Table 2.2-4-3 supersedes the number of operations provided in Table 2.2-13 of the PSAR. The operations include both itinerant and local operations. The values provided in Table 2.2-4-3 are obtained from the maximum forecasted number of operations from 2014 through 2040 for non-military aircraft. A historical average of military operations from 1990 through 2013 is used to calculate crash impact probabilities from military operations. This method is used for military aircraft because the TAF Detail Reports did not forecast any growth from 2014 through 2040. The use of historical averages for military operations is more conservative than use of forecasted values, since the forecasted values are lower.

Table 2.2-4-3: Number of Operations per Year at Southern Wisconsin Regional Airport

Aircraft Type	Number of Operations
Air Carrier (Itinerant)	68
Air Taxi (Itinerant)	6,908
General Aviation (Itinerant)	23,469
Military (Itinerant)	390
Civil (Local)	22,253
Military (Local)	617

Based on communication with the SWRA and the Janesville Air Traffic Control Tower, the following information was obtained:

- 100 percent of the local civil operations are general aviation, which is considered to be small aircraft. In addition, air taxi operations are considered small aircraft per DOE-STD-3014-96.
- The percent of total operations on each runway:
  - Runway 14-32: 35 percent.
  - Runway 4-22: 50 percent.
  - Runway 18-36: 15 percent.
- The breakdown of operations on each runway are as follows:
  - Runway 14-32: 60 percent operations use Runway (RW) 32 and 40 percent operations use RW 14.
  - Runway 4-22: 60 percent operations use RW 4 and 40 percent operations use RW 22.
  - Runway 18-36: 50 percent operations use RW 18 and 50 percent operations use RW 36.
- Military operations are 1 percent small aircraft and 99 percent helicopters.

Based on this information, the operations on each runway, by type of aircraft, are provided in Table 2.2-4-4. The aircraft operation by type of aircraft on each runway data provided in Table 2.2-4-4 supersedes the data provided in Table 2.2-14 of the PSAR.

Table 2.2-4-4: Aircraft Operation by Aircraft Type on Each Runway

Aircraft Type	Runway Operations					
	RW 14	**RW 32**	**RW 4**	**RW 22**	**RW 18**	**RW 36**
Air Carrier	10	14	20	14	5	5
Small Non-Military	7,368	11,053	15,789	10,526	3,947	3,947
Small Military	1	2	3	2	1	1
Military Helicopter	140	209	299	199	75	75

The distance from the end of each runway to the SHINE facility center point is provided in Table 2.2-11 of the PSAR. The probability of a fatal crash per square mile per aircraft movement is provided in Table 2.2-12 of the PSAR, where the probabilities for general aviation crashes are applied to general aviation and local civil operations, and probabilities for air carriers are applied to air carrier and air taxi operations.

The crash impact probabilities for small non-military aircraft (i.e., general aviation itinerant operations, local civil operations, and air taxi itinerant operations), large non-military aircraft (i.e., air carriers), and military aircraft (i.e., small aircraft and helicopter) from airports are provided in Table 2.2-4-5. The crash impact probabilities from airports provided in Table 2.2-4-5 supersede the crash impact probabilities from airports provided in Table 2.2-15 of the PSAR.

Results of Evaluation of Airways and Airports

NUREG-1537 does not provide acceptance criteria to be used to evaluate the aircraft accident probability posed by nearby airports and airways. DOE-STD-3014-96 provides a screening value of 1E-06 per year, where the risk of an aircraft accident is considered acceptable if the frequency of occurrence is less than 1E-06 per year. The calculated crash probability for small non-military aircraft does not meet this criterion (2.6E-04). The safety-related structures of the SHINE facility are designed to withstand the impact of a small non-military aircraft (see Section 3.4 of the PSAR). The combined probability of all other aircraft crashes does meet this criterion (6.1E-07).

Table 2.2-4-5: Total Crash Probability

	Large Non-Military Aircraft	**Small Non-Military Aircraft**	**Military Aircraft**
Airport	2.9E-07	2.6E-04	1.5E-07
Airways	1.5E-08	1.9E-06	1.6E-07
Total	3.0E-07	2.6E-04	3.1E-07

CHAPTER 4 – IRRADIATION UNIT AND RADIOISOTOPE PRODUCTION FACILITY DESCRIPTION

The following questions of this chapter are based on a review of Chapter 4 of the SHINE PSAR (ADAMS Accession No. ML13172A265) using NUREG-1537, Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2, as well as SHINE's responses to a request for additional information dated September 19, 2014 (ADAMS Accession No. ML14296A192).

Section 4a2.2 – Subcritical Assembly

RAI 4a2.2-10

The ISG Augmenting NUREG-1537, Part 2, Section 4a2.2.1, "Reactor Fuel," Acceptance Criteria, states, in part, that the PSAR should consider "various phenomena that result in changes to the initial fuel composition and properties…[including] information on radiolytic gas formation" in the target solution.

While SHINE's response to RAI 4a2.2-2 provided a curve fit of gas generation data, as well as a discussion of the error and uncertainty in the curve fit, additional information is needed for NRC staff to determine the adequacy of the uncertainty of the radiolysis rate.

a) Discuss the uncertainty of the data used in the curve fit.

b) Discuss how the error in the curve fit would change if only the data close to the anticipated operational range of the target solution vessel were considered.

SHINE Response

a) As described in the SHINE Response to RAI 4a2.2-2 (Reference 4), published experimental data has been used to determine radiolysis rates for uranyl sulfate systems undergoing fission, as well as the uncertainty in those rates.

   Specific uncertainties were not provided with the reported radiolysis rates in the historical references; however, SHINE has performed research into the procedures and methods used to develop the data. Reference (14) describes in detail the method of analysis for the experiments which produced the data referenced in the SHINE Response to RAI 4a2.2-2. The data was obtained through neutron irradiation of precise preparations of test solutions, and included studies of the effects of uranium concentration, isotopic enrichment, temperature, anion accompanying the uranium, uranium oxidation state, pH, and added solutes.

   Measurements were taken by irradiating fused silica ampoules containing the solutions of interest, and performing careful degassing procedures prior to sealing. The energy deposition in each sample was measured using a manganese monitor, which was correlated to adiabatic calorimetric calibration measurements. The flux spectrum changes from each irradiation were assumed to be small (< one percent), second-order effects. Each reported data point (i.e., those data points used in the SHINE Response to RAI 4a2.2-2) was the average of from three to six individual determinations, and the results for each determination agreed within two percent or better.

The specific method of quantifying the formed radiolysis gases was through the Saunders-Taylor semi-micro technique, which is a combustion method using a platinum filament. Tests of this method show accuracy on the order of one percent (Reference 15).

Given the range of investigated parameters for determining sensitivity, and the reported reproducibility and accuracy in which the measurements were taken, SHINE estimates that the data used for the curve fit has an accuracy of approximately 5 to 10 percent. This estimated error agrees well with the spread of the data shown with the earlier curve fit.

Additional experimental results on radiolysis rates from fission in uranyl sulfate solutions may become available from ANL due to work currently being performed for the National Nuclear Security Administration (NNSA). This work is described in the SHINE Response to RAI G-2. If this data becomes available and is applicable to the SHINE system, SHINE will compare it to the previously cited data to the extent possible. However, SHINE notes that this data is expected to have less accuracy than the data in Reference (15), as described in the SHINE Response to RAI G-2.

Also described in the SHINE Response to RAI 4a2.2-2 is that the uncertainty in radiolysis measurements will be included in the design process. Beyond the quantified uncertainties in the radiolysis data, as described in the SHINE Response to RAI 4a2.2-2, SHINE will add additional margin to the radiolysis rates when sizing components to ensure that the system has sufficient recombination capacity at the highest potential generation rates. Assumed design margins for the TOGS are provided in the SHINE Response to RAI 4a2.8-1 (Reference 5).

Furthermore, the TOGS will contain hydrogen measurement capability. The expected hydrogen measurement locations are described in the SHINE Response to RAI 4a2.8-2 (Reference 5). This measurement capability will allow detection of the hydrogen concentration during operation to ensure that the system is operating as expected. As described in the SHINE Response to RAI 4a2.8-2, this hydrogen concentration measurement also results in an automatic trip of the TSV and neutron driver if higher than allowable hydrogen concentrations are reached.

b) SHINE performed an analysis of how the error in the curve fit would change if only the data close to the anticipated operation range of the TSV were considered. This analysis is provided in Appendix A of Attachment 1. The data with uranium concentrations close to the TSV concentration support the same error estimate of 15 percent described in the SHINE Response to RAI 4a2.2-2 (Reference 4).

   SHINE also notes that [Proprietary Information], as described in Table 4a2.2-1 of the PSAR. Excluding this data point would reduce the uncertainty of the data; however, it is left in for conservatism for the purposes of estimating uncertainty.

CHAPTER 11 – RADIATION PROTECTION PROGRAM AND WASTE MANAGEMENT

The following questions of this chapter are based on a review of Chapter 11 of the SHINE PSAR (ADAMS Accession No. ML13172A274) using NUREG-1537, Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2, as well as SHINE's responses to a request for additional information dated September 19, 2014 (ADAMS Accession No. ML14296A192).

Section 11.1 – Radiation Protection

RAI 11.1-9

As required by 10 CFR 50.34(a)(3)(i), the preliminary design information provided for the facility should include principal design criteria.

As specified in 10 CFR 20.1101(d): "[t]o implement the ALARA requirements of § 20.1101 (b), and notwithstanding the requirements in § 20.1301 of this part, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, shall be established by licensees other than those subject to § 50.34a, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions."

As stated, in part, in 10 CFR 20.1301, each licensee shall conduct operations so that the total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year.

SHINE PSAR Section 11.1.1.1, "Airborne Radioactive Sources," presents information on the public doses to the Maximally Exposed Individual (MEI). Consistent with the guidance in U.S. NRC Regulatory Guide 4.20, the effluent concentration values are compared with the effluent concentration limits in 10 CFR Part 20, Appendix B, Table 2 for showing compliance with the requirements of 10 CFR 20.1101(d). These concentration limits, however, only account for environmental pathway doses attributed to the inhalation pathway. Other environmental pathways, such as for radioiodine accumulation via the air-pasture grass-milk pathway, merit evaluation in the calculation of the total effective dose equivalent to individual members of the public. U.S. NRC Regulatory Guide 1.109 may be used as a reference for evaluating environmental pathway doses, as needed.

In order for the NRC staff to determine the adequacy of SHINE's conduct of operations and implementation of ALARA requirements, additional information is needed on the total effective dose equivalent to individual members of the public, considering all environmental pathways, to demonstrate compliance with 10 CFR 20.1301.

Provide design basis dose calculations for the MEI, considering all age groups and all applicable pathways, examining, in particular, the closest recipients in each of the sixteen (16) meteorological sectors. The environmental pathway dose assessment should include, but not necessarily be limited to, the cow and goat milk from the two dairy operations noted in PSAR Section 11.1.7.2.3.

SHINE Response

SHINE will provide a response to RAI 11.1-9 by March 20, 2015.

CHAPTER 12 – CONDUCT OF OPERATIONS

The following questions of this chapter are based on a review of Chapter 12 of the SHINE PSAR (ADAMS Accession No. ML13172A275) using NUREG-1537, Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2, the SHINE Preliminary Emergency Plan, Revision 0, dated September 25, 2013 using NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors," and SHINE's responses to a request for additional information dated September 19, 2014 (ADAMS Accession No. ML14296A192).

Section 12.7 – Emergency Planning

RAI 12.7-35

NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors," Section 3.0, "Organization and Responsibilities," Evaluation Item 1.b., states that the emergency plan should describe "[t]he reactor's emergency organization, including augmentation of the reactor staff to provide assistance for coping with the emergency situation, recovery from the emergency, and maintaining emergency preparedness."

On September 19, 2014, NRC staff requested additional information on the actions to be taken by operators when an emergency is declared. Specifically, in RAI 12.7-4, SHINE was asked to "describe the actions the on-shift operators will take if they cannot ensure their activities can be placed in a safe condition before reporting to the on-site assembly area."

SHINE's response to RAI 12.7-4 did not address the actions of the on-shift operators, such as the Shift Supervisor, Senior Facility Operator, and Facility Operator, when an emergency is declared.

In order for the NRC staff to determine the adequacy of SHINE's emergency organization, additional information is needed on the actions of the on-shift operators when an emergency is declared.

Describe the actions the on-shift operators, to include the actions the Shift Supervisor, Senior Facility Operator, and Facility Operator, as applicable, will take if they cannot ensure their activities can be placed in a safe condition before reporting to the on-site assembly area.

SHINE Response

[Security-Related Information]

An IMR has been initiated to track the inclusion of the above description in the SHINE Emergency Plan.

APPENDIX 12C – QUALITY ASSURANCE PROGRAM DESCRIPTION

The following questions of this chapter are based on a review of Appendix 12C in Chapter 12 of the SHINE PSAR (ADAMS Accession No. ML13172A275) using ANSI/ANS-15.8-1995, "Quality Assurance Program Requirements for Research Reactors" and SHINE's responses to a request for additional information dated September 19, 2014 (ADAMS Accession No. ML14296A192).

Appendix 12C Section 1 – Introduction

RAI 12C.1-3

As required by 10 CFR 50.34(a)(7), each applicant for a construction permit to build a production or utilization facility must include, in its preliminary safety analysis report, a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Regulatory Guide 2.5, Revision 1, states that the general requirements for establishing and executing a quality assurance program for the design, construction, testing, modification, and maintenance of research and test reactors in the American National Standards Institute/American Nuclear Society Standard (ANSI/ANS) 15.8-1995 provide an acceptable method for complying with the program requirements of 10 CFR 50.34, "Contents of Applications; Technical Information."

Section 12.9, "Quality Assurance," of the SHINE PSAR states that the "SHINE QA-1, Quality Assurance Program Description (QAPD), is based on ANSI/ANS 15.8-1995 (R2005) (ANSI/ANS, 1995), 'Quality Assurance Program Requirements for Research Reactors,' with guidance from Regulatory Guide 2.5, Revision 1." However, it is not clear to what extent ANSI/ANS 15.8-1995 has been applied to the development of the SHINE QAPD for the facility.

SHINE's response to RAI 12C.1-1 stated, in part, "Regulatory Guide 2.5 states that ANSI/ANS-15.8-1995 (R2013) provides an acceptable method of complying with the program requirements of 10 CFR 50.34, and was used by SHINE for developing the QAPD for the entire facility."

a) Clarify whether SHINE has verified that ANSI/ANS-15.8-1995 is sufficient for use in the development of the SHINE QAPD.

b) Clarify if the "SHINE QA-1" referred to in the first paragraph of Section 12.9 of the SHINE PSAR is, in fact, SHINE QAPD document number 2000-09-01.

SHINE Response

a) SHINE has revised the Executive Summary of the SHINE Quality Assurance Program Description (QAPD) to state, "SHINE has determined that ANSI/ANS 15.8-1995 is appropriate to use in the design of the facility even though this standard was written for research reactors." Revision 5 of the SHINE QAPD is provided as Attachment 2.

b) The "SHINE QA-1" referred to in the first paragraph of Section 12.9 of the PSAR is the SHINE QAPD (document number 2000-09-01). SHINE changed the naming convention of the QAPD from SHINE-QA-1 to 2000-09-01 in Revision 3.

SHINE will update Section 12.9 of the PSAR in the FSAR to refer to the current naming convention of the SHINE QAPD. An IMR has been initiated to track the update to Section 12.9 in the FSAR.

RAI 12C.1-4

ANSI/ANS-15.8-1995, Section 1.3, "Definitions," defines safety-related items as: "Those physical structures, systems, and components whose intended functions are to prevent accidents that could cause undue risk to the health and safety of workers and the public, or to the research reactor's programs; and to control or mitigate the consequences of such accidents."

The SHINE Quality Assurance Program Description (QAPD), "Executive Summary" and Section 1, "Introduction," the last paragraph, state that SHINE utilizes a definition of safety-related systems, structures, and components (SSCs) for the Quality Level 1 SSCs. Further, Section 1.3, Definitions, of the QAPD states that definitions for use at SHINE are located in a stand-alone document and are under document control.

SHINE's response to RAI 12C.1-2 stated, in part: "SHINE Administrative Procedure (AP) 2000-10-01 (Reference 23) is the stand-alone document referred to in Section 1.3 of the SHINE QAPD. Other than the definition of safety-related, the definitions located in the SHINE AP are consistent with those provided in Section 1.3 of ANSI/ANS-15.8-1995 (R2013)."

In reference to SHINE's response to RAI 12C.1-2, clarify what definition for "safety-related" is provided in SHINE AP 2000-10-01 and where it is included in the SHINE QAPD. Also, provide additional information discussing why it is acceptable to maintain key definitions that are used in the SHINE QAPD, in a stand-alone administrative procedure.

SHINE Response

The following SHINE definition for safety-related structures, systems, and components (SSCs) is provided in SHINE Administrative Procedure (AP) 2000-10-01 (Reference 16) and revised Section 1.3 of the SHINE QAPD:

"***safety-related SSCs*** *– those SSCs that are relied upon to remain functional during normal conditions and during and following design basis events to assure:*

1. *The integrity of the primary system boundary;*
2. *The capability to shutdown the target solution vessel (TSV) and maintain the target solution in a safe shutdown (SSD) condition;*
3. *The capability to prevent or mitigate the consequences of accidents which could result in potential exposures comparable to the applicable guideline exposures set forth in 10 CFR 20;*
4. *That the potential for an inadvertent criticality accident is not credible;*
5. *That acute chemical exposures to an individual from licensed material or hazardous chemicals produced from licensed material could not lead to irreversible or other serious, long-lasting health effects to a worker or cause mild transient health effects to any individual located outside the owner controlled area; or*
6. *That an intake of 30 mg or greater of uranium in soluble form by any individual located outside the owner controlled area does not occur.*"

SHINE has revised Section 1.3 of the SHINE QAPD to include applicable ANSI/ANS-15.8-1995 (R2013) (Reference 17) definitions. The definitions included in the SHINE QAPD are consistent with those provided in Section 1.3 of ANSI/ANS-15.8-1995 (R2013), with the following exceptions:

1. Modified the definition of commissioning by replacing the word “reactor” with “irradiation facility;”
2. The definition of experiment is not listed in the SHINE QAPD, as SHINE does not plan on conducting experiments as defined in ANSI/ANS-15.8-1995 (R2013);
3. Modified the definition of management by replacing the word “research reactor” with “SHINE;”
4. The definition of non-power reactor, research reactor, and test reactor are not listed in the SHINE QAPD, as these terms are not applicable to SHINE; and
5. The definition of safety-related items has been modified for applicability to SHINE, as described above.

Implementing procedures will provide the steps and define the approvals necessary to make changes to the definitions at SHINE. While SHINE believes this will adequately control a definition, to avoid confusion, in addition to the AP, the applicable ANSI/ANS-15.8-1995 (R2013) definitions have been placed in Section 1.3 of the SHINE QAPD.

Revision 5 of the SHINE QAPD is provided as Attachment 2.

Appendix 12C Section 2.1 – Organization

RAI 12C.2.1-5

ANSI/ANS-15.8-1995, Section 2.1, “Organization,” states, in part, that “[p]ersons responsible for ensuring that appropriate controls have been established, and for verifying that activities have been correctly performed, need 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.”

The SHINE QAPD Section 2.1, Subsection “Chief Operating Officer (COO)” states that “[a]uthority is also provided to access necessary work areas and encourages managers and employees to identify problems, initiate, recommend or provide corrective action and ensure corrective action implementation.”

SHINE’s response to RAI 12C.2.1-1 stated: “The COO delegates sufficient responsibility and authority to direct reports to ensure that appropriate controls have been established and for verifying that activities have been correctly performed. The COO also provides authority to direct reports to access necessary work areas. Direct reports to the COO are provided in Enclosure 1 of the SHINE QAPD. The COO encourages managers and employees to identify problems; initiate, recommend, or provide corrective action; and ensure corrective action implementation.”

In reference to SHINE's response to RAI 12C.2.1-1, clarify if the COO is the individual ultimately responsible for the implementation of the SHINE QAPD.

SHINE Response

Section 2.1 of the SHINE QAPD states the following, in parts:

> *"The CEO (level 1 management) is responsible for the overall management and leadership of the company. The CEO is also responsible for all technical and administrative support activities provided by SHINE and suppliers. The CEO provides direction to the COO, CFO, VP of Business Development and Chief Technology Officer 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 and delegates the necessary responsibility and authority to his direct reports to ensure quality is achieved and maintained by those who have been assigned the responsibility for performing the work and quality achievement is verified by persons not directly performing the work."*
>
> and
>
> *"The COO (level 1 management) reports to the CEO and is responsible for all operational aspects of the company including safety, quality, environmental stewardship, regulatory affairs, security, plant management, information technology and supply chain management. The COO is responsible for all external operations of SHINE, including supplier organizations. The COO is responsible for integrating all quality requirements as defined in the QAPD across the internal and external organization and reports to the CEO on all matters concerning quality."*

Based on the above, the Chief Executive Officer (CEO) has the overall responsibility for the SHINE Quality Assurance Program. The Chief Operating Officer (COO) is responsible for all operational aspects of SHINE and for integrating all quality requirements, which includes implementation.

Revision 5 of the SHINE QAPD is provided as Attachment 2.

Appendix 12C Section 5 – Decommissioning

RAI 12C.5-1

ANSI/ANS-15.8-1995, Section 5, "Decommissioning," states: "The quality assurance requirements for a facility during the decommissioning phase are addressed by the appropriate sections of this standard, and American National Standard for Decommissioning of Research Reactors, ANSI/ANS-15.10-1994 [4]."

The SHINE QAPD, Section 5, "Decommissioning," states: "The quality assurance requirements for the SHINE facility during the decommissioning phase are addressed by the appropriate sections of ANSI/ANS-15.8-1995 (R2013) and ANSI/ANS-15.10-1994."

SHINE's response to RAI 12C.5 stated, in part: "As stated in ANSI/ANS-15.8-1995 (R2013) (Reference 13), the quality assurance requirements for the SHINE facility during the *decommissioning phase are addressed by the appropriate sections of ANSI/ANS-15.8-1995 (R2013) and ANSI/ANS-15.10-1994 (Reference 24).”*

In reference to SHINE’s response to RAI 12C.5, ANSI/ANS-15.8-1995 does not state that it contains quality assurance requirements for the SHINE facility during the decommissioning phase. Provide additional information on what quality assurance requirements apply during the decommissioning phase, or alternatively include a statement in the SHINE QAPD indicating that the SHINE QAPD will be revised in the future to address the requirements for the decommissioning phase.

SHINE Response

SHINE has revised Section 5 of the SHINE QAPD to state that the section will be updated at a later date. In addition, the term “decommissioning” has been removed from Section 1.1 and Section 1.2 of the SHINE QAPD. Revision 5 of the SHINE QAPD is provided as Attachment 2.

Appendix 12C Enclosure 2 – Graded Approach to Quality

RAI 12C.E2-5

The SHINE QAPD Enclosure 2 – Graded Approach to Quality, states, in part: “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.” It also further states: “QL-2 will include the non-safety related quality activities performed by the licensee, that are deemed necessary by SHINE to ensure the manufacture and delivery of highly reliable products and services to meet or exceed customer expectations and requirements.”

SHINE’s response to RAI 12C.E2-3 stated: “The quality assurance requirements contained in the SHINE QAPD are applicable to nonsafety-related (NSR) activities and SSCs. SHINE will use the Graded Approach to Quality and the requirements in the SHINE QAPD to the extent necessary to ensure that NSR activities and SSCs meet or exceed customer expectations and requirements.”

(a) Clarify the meaning of the phrase “to the extent necessary” in SHINE’s response to RAI 12C.E2-3;

(b) Clarify whether QL-2 classification is applicable to all or only selected non-safety related SSCs and activities; if QL-2 is applicable to selected non-safety related SSCs and activities, describe the process used to identify those SSC and activities to which QL-2 classification applies; if QL-2 is considered to be a voluntary application of the SHINE QAPD requirements to selected non-safety related SSCs and activities, explain how this approach fits the framework of the graded approach to quality (“commensurate with the safety significance,”) as defined in the first sentence of Enclosure 2.

SHINE Response

(a) SHINE recognizes that it is not necessary to apply the same degree of control to all items in the facility. The use of the phrase “to the extent necessary” means variation in the degree of application. This position is consistent with the Foreword of

ANSI/ANS-15.8-1995 (R2013), which presents the interpretation of the phrase "as necessary."

For example, certain nonsafety-related SSCs may be co-located with Seismic Category I systems. The co-located nonsafety-related SSCs are supported in accordance with II over I criteria. These criteria avoid any unacceptable interactions between the safety-related systems and the nonsafety-related SSCs. Seismic Category I systems are safety-related, QL-1, and would receive the full measure of the SHINE QAPD. The quality measures applied to the nonsafety-related SSCs would be to the extent necessary to assure they are supported in accordance with II over I criteria, and could include measures such as design control, control of purchased items and services, and identification and control of items.

(b) The QL-2 classification is applicable to all nonsafety-related SSCs and activities, and is applied by SHINE to ensure the manufacture and delivery of highly reliable products and services to meet or exceed customer expectations and requirements. SHINE will use a graded approach and apply the requirements of the SHINE QAPD to the extent necessary, as described in Part a of the SHINE Response to RAI 12C.E2-5, above. SHINE design control and procurement procedures will consider the function of the nonsafety-related SSC or activity, the relative importance of that function, whether there are any codes, standards, or other requirements that apply, and then determine the appropriate quality measures. For example, the engineering specification procedure will require that the person creating a specification consider the functions of a nonsafety-related SSC and determine which quality measures, if any, should be applied to the specification for the nonsafety-related SSC.

CHAPTER 19 – ENVIRONMENTAL REVIEW (ER)

The following questions of this chapter are based on a review of Chapter 19 of SHINE's Environmental Review (ADAMS Accession Nos. ML13172A307 and ML13172A309) using NUREG-1537, Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2, as well as SHINE's responses to a request for additional information dated September 19, 2014 (ADAMS Accession No. ML14296A192).

Section 19.1 – Introduction of the Environmental Report

RAI 19.1-1

The ISG augmenting NUREG-1537, Part 1, Section 19.1.2, "Regulatory Provisions, Permits, and Required Consultations," and 10 CFR 51.45(d) state that an applicant should list and summarize the status of all applicable federal, state, local, and other regulatory requirements, permits, and consultations that would be required for the proposed facility to be constructed and operated.

In Section 19.2 of the environmental report, SHINE summarized the status of all applicable federal, state, local, and other regulatory requirements, permits, and consultations that would be required.

For the permits identified in Table 19.1.2-1 of the environmental report, provide a timeline or status update for when SHINE expects to apply for and receive the permits. If relevant, provide a specific regulatory or other milestone on which a given permit may be dependent upon.

SHINE Response

The SHINE Response to Proposed Action Request #10 (Reference 18) provided an updated listing of permits and approvals required for construction and operation, initially provided as Table 19.1.2 1 of the PSAR. SHINE has further updated the listing of permits and approvals required for construction and operation, provided as Table 19.1-1-1, based on the current SHINE project schedule.

Table 19.1-1-1: Permits and Approvals Required for Construction and Operation

Agency	Regulatory Authority	Permit or Approval	Activity Covered	Expected Timeframe of Receipt	Status	Regulatory or Other Milestone Dependency
U.S. Nuclear Regulatory Commission	Atomic Energy Act 10 CFR 50.50	Construction Permit	Construction of the SHINE facility	Q3 2015	Preliminary Safety Analysis Report (PSAR) submitted Q2 2013	Final EIS and Record of Decision; safety evaluation report (SER) for the Construction Permit
	10 CFR 50.57	Operating License	Operation of the SHINE facility	Q1 2018		SER for the Operating License
	10 CFR 40	Source Material License	Possession, use, and transfer of radioactive source material	Q1 2018		
	10 CFR 30	By-Product Material License	Production, possession, and transfer of radioactive by product material	Q1 2018		
	10 CFR 70	Special Nuclear Material License	Receipt, possession, use, and transfer of special nuclear material	Q1 2018		
	National Environmental Policy Act (NEPA) 10 CFR 51	Environmental Impact Statement (EIS) in accordance with NEPA	Site approval for construction and operation of a radioisotope facility	Q3 2015	Environmental Review (ER) submitted Q1 2013	
Federal Aviation Administration (FAA)	Federal Aviation Act 14 CFR 77	Construction Notice FAA Form 7460-1	Construction of structures that potentially may impact air navigation	Q3 2015	FAA Form 7460-1 submitted in 2011; Determination of No Hazard received 11/2011; Determination of No Hazard extension received 04/2012; Determination of No Hazard expired 11/2014; Plan to re-submit FAA Form 7460-1 Q2 2015	
		Construction Notice FAA Form 7460-2	Construction of structures that potentially may impact air navigation	Q1 2017	Plan to submit FAA Form 7460-2 within 5 days of construction reaching its greatest height	When building reaches its highest planned height.
U.S. Environmental Protection Agency	Clean Water Act 40 CFR 112, Appendix F	Spill Prevention, Control and Countermeasure (SPCC) Plans for Construction and Operation	Storage of oil during construction and operation	Q3 2015	Baseline plan is to begin SPCC Plan development Q2 2015 and self-certify	
U.S. Department of Transportation (DOT)	Hazardous Material Transportation Act 40 CFR 107	Certificate of Registration	Transportation of hazardous materials	Q1 2018	Baseline plan is to submit DOT Form F 5800.2 Q1 2018	
Wisconsin Department of Natural Resources (WDNR)	Federal Clean Air Act Wisconsin Statutes Chapter 285 Wisconsin Administrative Code Chapter NR 406	Air Pollution Control Construction Permit	Construction of an air pollution emission source that is not specifically exempted	Q3 2015	Baseline plan is to submit Application for Type A Registration Construction Permit Q2 2015	
	Federal Clean Air Act Wisconsin Statutes Chapter 285 Wisconsin Administrative Code Chapter NR 406	Air Pollution Control Operation Permit	Operation of an air pollution emission source that is not specifically exempted	Q3 2015	Baseline plan is to submit Application for Type A Registration Operation Permit with Construction Permit Application Q2 2015	
	Federal Clean Water Act Wisconsin Statutes Chapter 283 Wisconsin Administrative Code Chapter NR 216	Construction Storm Water Discharge Permit	Discharge of storm water runoff from the construction site	Q3 2015	Baseline plan is to submit a Water Resource Application for Project Permits (WRAPP) to request coverage under a General Permit Q2 2015, at least 14 working days before construction begins	
	Federal Clean Water Act Wisconsin Statutes Chapter 283 Wisconsin Administrative Code Chapter NR 216	Industrial Storm Water Discharge Permit	Discharge of storm water runoff from the site during facility operation	Q1 2018	Baseline plan is to submit No Exposure Certification at least 14 working days prior to initiation operations, Q4 2017	

Agency	Regulatory Authority	Permit or Approval	Activity Covered	Expected Timeframe of Receipt	Status	Regulatory or Other Milestone Dependency
	Wisconsin Statutes Chapters 280 and 281 Wisconsin Administrative Code Chapter NR 809	Approval Letters	Construction by the City of Janesville of water and sanitary sewer extensions to the SHINE facility	Q3 2015	Permit to be requested by the City of Janesville	
	Wisconsin Statutes Chapter 291 Wisconsin Administrative Code Chapter NR 660, 662, and/or 666	Compliance with hazardous waste notification, record keeping, and reporting requirements	Generation of hazardous waste	Q1 2018	Baseline plan is to notify of decision to claim WDNR of Storage and Treatment Conditional Exemption (NR 666 Subchapter N) Q1 2018 or within 90 days of LLMW generation	
Wisconsin Department of Safety and Professional Services	Wisconsin Statutes Chapter 101 Wisconsin Administrative Code Chapters SPS 361 and 362	Building Plan Review	Compliance with state building codes; required before a local building permit can be issued for a commercial building	Q3 2015	Baseline plan is to submit Building Plan Q2 2015	Final building plan complete.
Wisconsin Department of Transportation	Wisconsin Statutes Chapter 85 Wisconsin Administrative Code Chapter Trans 231	Permit for Connection to State Trunk Highway	Construction of driveway connection to U.S. Route 51	Q3 2015	Baseline plan is to request permit simultaneously or before the submission of the Site Plan, Q2 2015	
	Wisconsin Statutes Chapter 85 Wisconsin Administrative Code Chapters Trans 231	Right of Entry Permit	Construction by the City of Janesville of utility extensions across U.S. Route 51	Q3 2015	Permit to be requested by the City of Janesville	
	Wisconsin Statutes Chapter 114 Wisconsin Administrative Code Chapter Trans 56	Variance from Height Limitation Zoning Ordinances	Construction of structures that exceed height limitations established for Southern Wisconsin Regional Airport	Q3 2015	It is not anticipated this variance will be needed based on the refined building and stack heights developed during Preliminary Design	
City of Janesville Community Development Department	City of Janesville Ordinance 18.24.050.A	Site Plan Approval (includes Building Site Permit for the Southern Wisconsin Regional Airport Overlay District)	Administrative approval of the site layout and plans for parking, lighting, landscaping, etc.	Q3 2015	Baseline plan is to submit Site Plan and building elevations Q2 2015	Final site plan complete.
	City of Janesville Ordinance 15.06.070	Storm Water Plan Approval (may be included in Site Plan Approval)	Administrative approval of grading and drainage plans	Q3 2015	Baseline plan is to submit Stormwater Management Plan with Site Plan Q2 2015	Final storm water plan complete.
	City of Janesville Ordinance 15.05.080	Erosion Control Permit (may be included in Site Plan Approval)	Administrative approval of erosion control plans	Q3 2015	Baseline plan is to submit erosion control plan with site plan Q2 2015	Final erosion control plan complete.
	City of Janesville Ordinance 13.16	Sanitary Sewer and Water Supply Facility Approvals	Administrative approval of construction, installation, and operation of connections to the municipal sewer and water supply systems	Q3 2015	Construction and installation approved via the Plumping Plan. For operation, baseline plan is to provide baseline monitoring report to Wastewater Treatment Plant at least 90 days prior to discharge Q4 2016	Final plans complete.
	City of Janesville Ordinance 15.01.100.A	Plumbing Plan Approval	Installation of plumbing systems	Q3 2015	Baseline plan is to submit Plumbing Plan with Building Plan Q2 2015.	Final plumbing plan complete.
	City of Janesville Ordinance 15.04.010.A	HVAC Plan Approval	Installation of heating, ventilation, and air conditioning systems	Q3 2015	Baseline plan is to submit HVAC Plan with Building Plan Q2 2015	Final HVAC plan complete.
	City of Janesville Ordinance 8.32.010	Fire Sprinkler and Alarm Permit	Installation of sprinkler and alarm systems	Q3 2015	Baseline plan is to submit Fire Sprinkler and Alarm Plan with Building Plan Q2 2015	Final sprinkler and alarm design complete.
	City of Janesville Ordinance 15.01.100.A	Building Permit	Construction of buildings	Q3 2015	Baseline plan is to submit Building Plan Q2 2015	All of the above City of Janesville permits.
	City of Janesville Ordinance 15.01.190.A	Occupancy Permit	Occupancy of completed buildings	Q1 2018	Each building will be inspected post-construction to allow occupancy. Baseline plan is to complete Q4 2017	Completion of construction.
Rock County Highway Department	Wisconsin Statutes Chapter 84 Rock County Utility Accommodation Policy 96.00	Permit to Construct, Maintain, and Operate Utilities within Highway Right-of-Way	Construction by the City of Janesville of utility extensions across County Trunk Highway G	Q3 2015	Plans and specifications to be submitted by the City of Janesville once Site Plan is approved, likely Q2 2015	

Section 19.2 – Proposed Action

RAI 19.2-6

The ISG augmenting NUREG-1537, Part 1, Section 19.2, "Proposed Action," states that the applicant should provide a description of the activities that would occur during the major phases of the proposed action, including construction, operational, and decommissioning activities.

SHINE's response to RAI 19.2-2 clarified that the pre-operational phase was included within the construction impacts described in Chapter 4 of the environmental report and SHINE updated some of the data, assumptions, calculations, or analyses in the environmental report.

Section 19.2.5.2 of the environmental report, "Type and Quantity of Radionuclides and Hazardous Materials," provides information on the radioactive materials that would be used during operations at the proposed SHINE facility. Section 19.4.8.2 of the environmental report, "Radiological Impacts," discusses the radiological impacts associated with operations at the proposed SHINE facility. However, the environmental report does not provide information on the types and quantities of radioactive materials and the potential radiological impacts associated with radioactive materials that would be used during the construction and pre-operational testing of the proposed facility.

Describe the types and amounts of radioactive materials and how they would be used during construction and pre-operational testing of the facility. Also, describe the types and amounts of radioactive effluents and waste that may be generated, the potential radiological impacts to workers on the site and to members of the public offsite, as well as any measures that would be used to limit the radiological impacts during construction or pre-operational testing.

SHINE Response

SHINE plans on having radioactive material in the form of [Proprietary Information] and tritium on site during the construction and pre-operational testing of the facility. The estimated maximum [Proprietary Information] inventory on site will be approximately [Security-Related Information] and the estimated maximum tritium inventory on site will be approximately [Security-Related Information].

Prior to bringing radioactive material on site during the construction phase, SHINE will obtain the appropriate NRC approvals.

The [Proprietary Information] will be part of the neutron multipliers for the subcritical assembly systems and will be put in place during construction. The neutron multiplier consists of the [Proprietary Information], which is contained within an aluminum cladding.

SHINE plans to avoid delays in the operational phase by ensuring that an adequate supply of tritium is stored on-site and ready for startup. Any tritium on-site during the construction and pre-operational testing of the facility will be stored in acceptable shipping containers in preparation for operation of the facility. The tritium is expected to be shipped in Type B(U) radioactive material packages.

The neutron multipliers will be installed in the facility during the construction and pre-operational testing of the facility, but are not otherwise planned to be used during this phase. Any tritium will be stored and is not planned on being used during the construction and pre-operational testing of the facility.

The activities during the construction and pre-operational testing of the facility are not expected to generate radioactive effluents or waste. Due to the nature of the [Proprietary Information] and tritium contained within its shipping container, no radiological impacts are expected for workers on the site or members of the public offsite. Therefore, no specific measures are needed to limit the radiological impacts during construction or pre-operational testing.

(Applies to RAIs 19.2-7 through 8)

> *The ISG augmenting NUREG-1537, Part 1, Section 19.2, "Proposed Action," states that the applicant should estimate the amount of materials and equipment requirements including average number of truck deliveries and shipment of waste material offsite per day, week, or month during each of the main phases of the proposed action.*

RAI 19.2-7

SHINE's response to RAI 19.2-5(b) regarding deliveries of materials and off-site shipment of wastes during operation stated there would be 36 truck deliveries and one off-site waste shipment per month during the operations phase.

a) Clarify whether the 36 truck deliveries includes annual deliveries of LEU to the proposed SHINE facility and monthly medical radioisotope shipments. Further, Section 19.4.10.1.3 of the environmental report states that there would be 468 annual shipments of medical isotopes (or approximately 39 shipments per month). Additionally, clarify the total number of truck deliveries per month, as well as the number of medical isotope shipments per month with a clarification as to whether medical isotope shipments are included in the total number of truck deliveries per month. As necessary, provide an update for the relevant portions of the environmental report.

b) SHINE's response to RAI 19.2-5 stated that there would be one off-site waste shipment per month during the operations phase. However, Table 19.2.5-1 in the environmental report states that there would be 24.6 total radioactive waste shipments per year (or approximately 2 shipments per month) and Section 19.4.10.1.3 of the environmental report states that there would be 34 radioactive waste shipments per year (or approximately 3 shipments per month). Clarify the number of waste shipments per year, and, if necessary, provide an update for the relevant portions of the environmental report.

SHINE Response

a) During the operations phase, SHINE expects a monthly average of 36 truck deliveries from various vendors to the SHINE site. Monthly truck deliveries will provide the materials necessary to support the operation of the SHINE facility, including low enriched uranium (LEU) metal and tritium, as described in Subsection 19.4.10.1 of the PSAR.

   In addition to the 36 truck deliveries to the SHINE site per month, SHINE expects to make 39 monthly medical isotope shipments (468 shipments per year, as described in Subsection 19.4.10.1.3 of the PSAR). Air and greenhouse gas emissions during the operations phase, estimated in CALC-2013-0007, have been updated to include emissions resulting from medical isotope shipments. Revision 6 of CALC-2013-0007 is provided as Attachment 3.

b) During the operations phase, the number of radioactive waste shipments is expected to average 25.6 per year. SHINE expects radioactive waste shipments to include:

- Neutron Generators, Extraction Columns, and Class A Trash (3 shipments per year);
- Spent Solvent (1 shipment per year);
- Technetium/Iodine Columns (0.3 shipments per year);
- Zeolite Beds (1 shipment per year);
- [Proprietary Information] (0.3 shipments per year);
- [Proprietary Information] (1 shipment per year); and
- Solidified Liquid Waste (19 shipments per year).

Revision 1 of the SHINE Response to RAI 11.2-4 (see Enclosure 3) provides an update to the solidified liquid waste shipment information previously provided in Table 19.2.5-1 of the PSAR (i.e., 19 annual shipments of solidified liquid waste in lieu of 18).

The 34 radioactive waste shipments per year described in Subsection 19.4.10.1.3 of the PSAR are a conservative assumption used for the calculation of dose to the general population due to transportation of the product isotopes. The assumed 34 shipments per year bound the expected average number of shipments.

The one off-site waste shipment per month is described in Revision 6 of CALC-2013-0007, which is provided as Attachment 3. This shipment is non-radiological waste that will be picked up by a local waste disposal company and delivered to a local landfill.

RAI 19.2-8

In Section 19.2 of the environmental report, Table 19.2.5-1, "Estimated Type and Quantity of Radioactive Wastes Associated with the SHINE Facility," describes that estimated types and quantities of radioactive wastes. In this table, SHINE provided an estimate of the volume of waste to be produced each category; however, SHINE did not provide the units for the volume of technetium columns and cesium/cerium media.

Provide the units for the volume of technetium columns and [Proprietary Information], as described in Table 19.2.5-1, "Estimated Type and Quantity of Radioactive Wastes Associated with the SHINE Facility."

SHINE Response

The units for the volume of the technetium columns and [Proprietary Information] in Table 19.2.5-1 of the PSAR are "gallons per year."

Table 19.2.5-1 of the PSAR has been revised to incorporate the units for the volume of the technetium columns and [Proprietary Information]. A mark-up of the change, including additional Section 19.2 revisions related to the change, are provided in Attachment 4. The non-public (proprietary) version of the PSAR, incorporating the changes provided in Attachment 4, is provided in Enclosure 5. The public (non-proprietary) version of the PSAR, incorporating the changes provided in Attachment 4, is provided in Enclosure 6.

Section 19.3 – Description of the Affected Environment

RAI 19.3-2

The ISG augmenting NUREG-1537, Part 1, Section 19.3.2, "Air Quality and Noise" states that the applicant should estimate onsite and offsite vehicle and other emissions resulting from construction, operations and decommissioning.

SHINE's response to RAI 19.2-2 clarified that the length of the construction phase would be 18 months which includes construction of the facility (12 month duration) and pre-operational testing and commissioning (6 month duration). The response to RAI 19.2.-2 provided revised air emissions during the construction phase and Attachment 5 provided the calculations that support the air emissions estimates.

Section 4.0, "Analysis" identifies how SHINE calculated annual emissions for equipment used during the construction phase and introduced the equipment utilization factor (V). SHINE defined the equipment utilization factor (V) as the monthly average of the equipment needed for the construction phase, obtained by dividing the total amount of equipment by 18 months for each piece of equipment. Furthermore, Table 1 and 2 of Attachment 5 identified that this equipment would be used throughout the entire 18 months of construction and pre-operational activities and provided the average equipment use per month. However, Table 19.2.0-2 of the environmental report identifies the equipment that would be used during construction and pre-operation and states that various equipment would not be used during the pre-operation phase (e.g., concrete pump, cranes). Assuming that each piece of equipment would be used for the entire 18 months, as compared to 12 months, and applying that in the utilization factor, results in less conservative annual emissions for the construction phase (Table 1) because the rate of emissions would be spread out over a longer time.

Provide annual emissions for equipment used for the construction phase that are consistent with the proposed construction and pre-operation equipment used and duration identified in Table 19.2.0-2 of the environmental report.

SHINE Response

SHINE has revised CALC-2013-0007, "Annual Emissions During Construction, Operation, and Decommissioning Activities," to be consistent Table 19.2.0-2 of the PSAR. For construction equipment identified in Table 19.2.0-2 as only being in use during the construction activities portion of the construction phase, equipment utilization factors were calculated based on the equipment only being on site for a duration of 12 months.

Revision 6 of CALC-2013-0007 is provided as Attachment 3. Annual emissions for equipment used during the construction phase are provided in Table 1 of CALC-2013-0007.

Section 19.4 – Impacts of Proposed Construction, Operations, and Decommissioning

RAI 19.4-2

The ISG augmenting NUREG-1537, Part 1, Section 19.4.11, "Postulated Accidents," states that the applicant should describe the radiological impacts from potential accidents.

In Section 13.b.1.1 of the preliminary safety analysis report (PSAR), SHINE describes the total effective dose equivalent (TEDE) from the accidental release of the inventory stored in the noble gas removal system storage tanks to be 0.0820 rem at the site boundary and 0.0115 rem for the nearest resident. Section 19.4 of the environmental report, however, describes the TEDE to be 0.0798 rem at the site boundary and 0.012 rem for the nearest resident.

Clarify the TEDE from the accidental release of the inventory stored in the storage tanks for the noble gas removal system.

SHINE Response

Subsection 19.4.11.2.1 of the PSAR contains an administrative error, stating that the release of the inventory stored in the Noble Gas Removal System (NGRS) storage tanks scenario results in a total effective dose equivalent (TEDE) of 7.98E-02 rem at the site boundary and 1.12E-02 rem for the nearest resident.

Subsection 13b.2.1.7 of the PSAR correctly describes the radiological consequences due to a release of inventory stored in the NGRS storage tanks. As described in Subsection 13b.2.1.7, the TEDE to a member of the public for the maximum hypothetical accident (MHA) in the radioisotope production facility (RPF) is 8.20E-02 rem (site boundary) and 1.15E-02 rem (nearest resident).

An IMR has been initiated to address the error.

References

(1) NRC letter to SHINE Medical Technologies, Inc., dated September 19, 2014, SHINE Medical Technologies, Inc. – Request for Additional Information Regarding Application for Construction Permit (TAC Nos. MF2305, MF2307, and MF2308) (ML14195A159)

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

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

(4) SHINE Medical Technologies, Inc. letter to NRC, dated October 15, 2014, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information (ML14296A190)

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

(6) NRC letter to SHINE Medical Technologies, Inc., dated January 6, 2015, SHINE Medical Technologies, Inc. – Request for Additional Information Regarding Application for Construction Permit (TAC Nos. MF2305, MF2307, and MF2308) (ML15005A407)

(7) U.S. Nuclear Regulatory Commission, "Evaluating the Habitability of a Nuclear Power Plant Control Room During a Postulated Hazardous Chemical Release,“ Regulatory Guide 1.78, Revision 1, December 2001 (ML013100014)

(8) U.S. Department of Transportation, Federal Aviaiton Administration, "Airspace Designations and Reporting Points," Order JO 7400.9Y, August 6, 2014

(9) U.S. Department of Transportation, Federal Aviaiton Administration, "Facility Operation and Administration," Order JO 7210.3Y, April 3, 2014

(10) U.S. Department of Transportation, Federal Aviaiton Administration, "Flight Standards Information Management System (FSIMS)," Order 8900.1, September 13, 2007

(11) U.S. Department of Energy, "Accident Analysis for Aircraft Crash into Hazardous Facilities," DOE-STD-3014-2006, October 1996 (Reaffirmation May 2006)

(12) 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)

(13) U.S. Nuclear Regulatory Commission, "Aircraft Hazards," NUREG-0800, Section 3.5.1.6, Revision 4, March 2010 (ML100331298)

(14) Boyle, J.W., et al., "Radiation Chemistry of Aqueous Reactor Solutions," Oak Ridge National Laboratory, Oak Ridge, TN, 1952

(15) Saunders, K.W. and H.A. Taylor, “The Photolysis of Acetone in Presence of Mercury,” *The Journal of Chemical Physics*, Volume 9:616-625

(16) SHINE Administrative Procedure (AP) 2000-10-01, “Glossary of Terms,” Revision 7

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

(18) SHINE Medical Technologies, Inc. letter to NRC, dated October 4, 2013, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Environmental Requests for Additional Information (ML13303A887)