Exhibit SHN-002

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE COMMISSION

In the Matter of	)	Docket No. 50-608-CP
	)	
SHINE MEDICAL TECHNOLOGIES, INC.	)	
	)	
(Medical Radioisotope Production Facility)	)	December 8, 2015

SHINE MEDICAL TECHNOLOGIES, INC.'S RESPONSES TO COMMISSION'S PUBLIC PRE-HEARING QUESTIONS

SHINE Medical Technologies, Inc. (SHINE) provides the following responses to the questions in the Commission's November 10, 2015 Order (Transmitting Pre-Hearing Questions) regarding the mandatory hearing for the Construction Permit Application for SHINE's medical radioisotope production facility. SHINE's responses are limited to those questions directed to it.

Responses to Commission Questions

Question 2: On page 11 of the Staff's Statement in Support of the Uncontested Hearing (SECY-15-0130), the Staff discusses why it chose to apply Part 50 in reviewing the SHINE facility, and the paper states that "the NRC staff used its technical judgement in determining the acceptance criteria for SHINE's construction permit application and the applicable regulations."

a. Once the Staff decided to license the facility under Part 50, what was the basis for the Staff using its technical judgement on whether to review the application under every applicable section of Part 50? Why was it not necessary to take exemptions from regulations in Part 50 that apply to construction permits that the applicant did not address?

b. Similarly, the SER states (page 1-5) that SHINE applies several of the General Design Criteria to the preliminary design, and that the Staff based its review, in part, on some of the GDC. Why were these particular GDC chosen for the design and review? Was a systematic process used to identify potentially applicable GDC? For example, why did the Staff and SHINE use GDC 16, "Containment Design," when there is no containment used in this design, but not GDC 1 "Quality Standards and Records?"

c. Further, how did the Staff use its judgement in determining which regulatory guidance and acceptance criteria to apply?

d. Is an exemption from NRC regulations required to alter the definition of safety-related SSCs in 10 C.F.R. 50.2, as discussed in Section 3.4.5 in the SER?

SHINE RESPONSE:

a. SHINE prepared its Construction Permit Application to fully address the requirements in 10 CFR Part 50 that apply to Construction Permits, and that are applicable to the SHINE facility. Any technical judgment was utilized within the confines of the Part 50 regulations. Therefore, SHINE concluded that no exemptions were necessary from the regulations in Part 50. The only exemption identified by SHINE for its Application was the exemption from 10 CFR § 2.101(a)(5) to allow SHINE to submit the Application in two parts. That exemption is discussed on pages 9-10 of SECY-15-0130. The regulations in Part 50 that apply to Construction Permits that SHINE did not address were restricted to those regulations specific to "power reactors" or "nuclear power plants" (*e.g.*, 10 CFR § 50.34(a)(1)(ii), 10 CFR § 50.34(a)(11), 10 CFR § 50.34(a)(12), and 10 CFR § 50.34(a)(13)). Since the SHINE facility is not a power reactor or nuclear power plant, these regulations were judged to not be applicable, and therefore no exemptions were required. This conclusion is consistent with NUREG-1537, Part 1, Appendix A, which addresses the applicability of U.S. Nuclear Regulatory Commission (NRC) regulations to non-power reactors.

b. Section 3.5 of the Preliminary Safety Analysis Report (PSAR) describes SHINE's consideration of the General Design Criteria (GDC) for the SHINE facility. As explained in Section 3.5a of the PSAR and the Introduction to 10 CFR Part 50, Appendix A, the GDC are intended to establish minimum requirements for the design of *nuclear power plants*. Thus, the GDC are not directly applicable to the SHINE facility. That conclusion is consistent with NUREG-1537, Part 1, Appendix A, which addresses the applicability of NRC regulations to non-power reactors. However, the GDC provide a proven basis with which to develop an initial assessment of the safety of the design of the SHINE facility.

Under the provisions of 10 CFR § 50.34 and NUREG-1537, Part 1, an application for a Construction Permit must include the principal design criteria for a proposed facility. The principal design criteria establish the necessary design, fabrication, construction, testing, and performance requirements for structures, systems, and components (SSCs) important to safety; that is, SSCs that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public.

To address this requirement, SHINE undertook a systematic process to identify potentially applicable GDC. This process and the results are described in Section 3.5a of the PSAR for the irradiation facility (IF) and Section 3.5b of the PSAR for the radioisotope production facility (RPF). SHINE compared the design basis of the IF and RPF to all of the GDC, as a means of good design practice. The results of that review are provided in Table 3.5a-1 of the PSAR for the IF and Table 3.5b-1 of the PSAR for the RPF. SHINE's identification of relevant design criteria is much broader than those specified in NUREG-1537, Part 1, Section 3.1.

As discussed in Table 3.5a-1 of the PSAR, SHINE considered GDC 1 (Quality Standards and Records) as applied to the SHINE facility and stated its means of compliance. Specifically, the PSAR states: "The SHINE facility uses a graduated Quality Assurance Program which links quality classification and associated documentation to safety classification and linked to the manufacturing and delivery of highly-reliable products. The quality classification and safety classifications are listed in this chapter. The SHINE [Quality Assurance Program Description (QAPD)] provides details of the procedures to be applied. Refer to Chapter 12 for further discussion." SHINE undertook a similar evaluation of GDC 16 (Containment Design), which is discussed in Table 3.5a-1. The PSAR recognizes that SHINE does not have a containment, but has a confinement per the NUREG-1537 definition.

c. SHINE's consideration of relevant acceptance criteria is discussed above in Part b of this response. Additionally, SHINE reviewed NRC guidance to determine applicability to the SHINE facility, recognizing that the SHINE facility is different than the power reactors typically licensed under 10 CFR Part 50. This review resulted in SHINE preparing the Construction Permit Application to be generally consistent with NRC guidance in NUREG-1537, Parts 1 and 2 (ML042430055 and ML042430048, respectively) and the Interim Staff Guidance (ISG) that augments NUREG-1537, Parts 1 and 2 (ML12156A069 and ML12156A075, respectively).

d. The definition of safety-related SSCs in 10 CFR § 50.2 includes SSCs relied upon to remain functional during and following design basis events to assure: "(1) The integrity of the reactor coolant pressure boundary; (2) The capability to shut down the reactor and maintain it in a safe shutdown condition; or (3) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to the applicable guideline exposures . . . ." As explained in the SHINE Response to request for additional information (RAI) 3.5-1 (ML14296A189), items (1) and (2) of the definition do not apply to any SSCs in the SHINE facility, as SHINE does not have a reactor.

Section 3.5.1.1.1 of the PSAR provides the definition for safety-related SSCs for the SHINE facility. It explains that safety-related SSCs are:

> Those SSCs that are relied upon to remain functional during normal conditions and during and following design basis events to assure:
>
> a. The integrity of the primary system boundary;
> b. The capability to shutdown the target solution vessel (TSV) and maintain the target solution in a safe shutdown (SSD) condition;

c. 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;
d. That all nuclear processes are subcritical, including use of an approved margin of subcriticality;
e. 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
f. 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.

That definition includes item (3) from the 10 CFR § 50.2 definition, modified to include the exposure limits set forth in 10 CFR Part 20, which are more conservative than the limits set forth in 10 CFR § 50.34(a)(1) or 10 CFR § 100.11, which are only applicable to power reactors. Therefore, SHINE's definition of safety-related SSCs is fully consistent with the 10 CFR § 50.2 definition, and no exemption is needed. Furthermore, SHINE developed its definition of safety-related SSCs after considering the definition of safety-related items in ANSI/ANS-15.8-1995 and the performance requirements in 10 CFR § 70.61. SHINE's decision to broaden the PSAR definition of safety-related SSCs to include additional items, including those consistent with items (1) and (2) of the 10 CFR § 50.2 definition as they apply to the SHINE facility, does not require an exemption. The PSAR definition is conservative and fully consistent with the 10 CFR § 50.2 definition.

<u>Question 3</u>: What is the regulatory significance of the commitments in Appendix A of the SER? Are these requirements that an applicant must address in any operating license application, or are they tracked in any design basis document?

<u>SHINE RESPONSE</u>:

SHINE considers the commitments in Appendix A.2 and Appendix A.4 of the Safety Evaluation Report (SER) to be requirements that must be addressed in the Operating License

Application. These Appendix A.2 and Appendix A.4 commitments listed in the SER are tracked in the SHINE Corrective Action Program.

<u>Question 4</u>: Please respond to the concerns raised by the Advisory Committee on Reactor Safeguards (ACRS) in its October 15, 2015, letter. Does the Staff agree with the topics raised by the ACRS (page 4) regarding issues that must be addressed at the operating license stage? Did the Staff include commitments in Appendix A of the SER to address each of these issues?

<u>SHINE RESPONSE</u>:

In its October 15, 2015 letter, the ACRS identified topics to be further addressed in the application for an Operating License, including criticality control and margin, adequacy of confinement, systems that provide support to safety-related systems, partial losses of electrical power, hydrogen generation and control, underwater maintenance issues, and possible "red oil" and acetohydroxamic acid reactions. These topics were addressed to the ACRS's satisfaction for issuance of the Construction Permit. SHINE agrees with the topics raised by the ACRS regarding issues that must be addressed at the Operating License stage and is tracking these topics in the SHINE Corrective Action Program. These topics are not included as commitments in Appendix A of the SER.

<u>Question 5</u>: PSAR Section 13a2.1.1 describes the Maximum Hypothetical Accident (MHA) for the irradiation facility.

a. For SHINE and the Staff: Please describe the reasoning underlying the selection of the MHA for the SHINE facility and how it represents the accident whose dose consequences would not be exceeded by any other accident considered credible.

b. For the Staff: In RAI 13a2.1-1 the Staff asked SHINE to provide the basis for rejecting multiple Target Solution Vessel (TSV) failures. Please provide additional details about why the Staff ultimately agreed with the SHINE response that there were no credible events involving multiple TSV failures.

SHINE RESPONSE:

a. The selection of the MHA and the other accidents considered credible for the SHINE facility was based on the results of the Integrated Safety Analysis (ISA), which included a preliminary design hazards analysis (PHA) and a hazard and operability study (HAZOPS), the list of initiating events and accidents provided in NUREG-1537 and the ISG that augments NUREG-1537, and the experience of the hazards analysis team members.

The MHA for the SHINE facility is the simultaneous rupture of the five noble gas storage tanks in the noble gas removal system (NGRS). The NGRS system collects and accumulates the off-gases from the irradiation units (IUs), where they are held for an appropriate time to allow for radioactive decay. Note that an MHA was postulated for the IF as well, but the RPF-postulated MHA (*i.e.*, the NGRS rupture) was found to be more limiting.

SHINE evaluated potential releases throughout the facility during the accident analysis process. The radiological effects of potential releases are determined, in part, by the quantity of radiological material available for release and the means for dispersal. Throughout most of the facility, target solution batches are kept physically segregated from each other by thick, reinforced concrete walls, such as the IU cell walls, supercell walls, and tank vault walls, and the material is kept at low temperatures and pressures, reducing driving forces and dispersion during a release.

In the NGRS, fission products are transferred from each of the eight IU cells into the NGRS storage tanks after shutdown of the irradiation process. Therefore, the NGRS contains fission product gases from multiple IUs and target solution batches.

Radiological dose calculations were performed and verified that the dose from the rupture of the five NGRS tanks was more limiting than the dose from any other accidents considered credible.

The NGRS storage tanks will be seismically-designed, safety-related tanks with proper isolation between the vessels. Therefore, it is not expected that a release from one tank could result in multiple storage tanks releasing their contents. The rupture of the five tanks simultaneously is considered a non-mechanistic failure, and was assumed for the MHA to ensure that the radiological consequences were not exceeded by any accident considered credible.

b. Not Applicable

Question 6: In Section 13a.4.1, "Maximum Hypothetical Accident," of the SER, the staff states that the ISG augmenting NUREG-1537, Part 2, Section 13a2.1, recommends that external events affecting more than one unit be considered as a maximum hypothetical accident (MHA). In response to an RAI, the applicant stated that external events could not affect multiple irradiation units simultaneously. The NRC staff found the applicant's response acceptable and stated that it satisfied the recommendation of the ISG augmenting NUREG-1537, Part 2, Section 13a2.1. Please explain in more detail why it was not necessary to analyze an MHA that could affect multiple units.

SHINE RESPONSE:

During the preliminary safety analysis process, SHINE considered potential events that could affect multiple irradiation units (IUs), such as earthquakes, aircraft impact, facility fires, and system interaction events. These events were analyzed in the respective sections of Chapter 13 of the PSAR, such as Section 13a2.1.6 for external events, Section 13a2.1.12.2 for irradiation facility (IF) fires, and Section 13a2.1.11 for interaction events. Due to the independence, separation, and design of the facility systems, no scenario was identified during the accident analysis that resulted in a simultaneous release from multiple primary system boundaries (PSBs).

The IF consists of eight IU cells. The neutron driver assembly system (NDAS), subcritical assembly system (SCAS), primary closed loop cooling system (PCLS), TSV off-gas system (TOGS), and light water pool system (LWPS) of each IU cell are independent of each other. Some systems, such as facility cooling water, ventilation systems, the tritium purification system (TPS), and the noble gas removal system (NGRS), do interact with multiple IU cells. The failures of those systems, and the effect on the IUs, were considered in the accident analysis and the resulting scenarios were either included in the accident analysis or bounded by other scenarios.

The IF and the IU cells themselves are Seismic Category I structures. As described in the SHINE Response to RAI 13a2.1-1 (ML14296A189), the safety-related SHINE production facility building is a robust structure that is designed to protect the equipment inside from external events. Because of this protection, it is not credible for an external event such as an aircraft impact, tornado, flood, earthquake, or tornado missile to initiate an accident in one or multiple IUs.

Section 13a2.2 of the ISG that augments NUREG-1537, Part 1, directs the applicant to base scenarios on a single initiating malfunction rather than on multiple causes. Due to the independent nature and robust structure of the IU cells, as discussed above, SHINE determined that there is no single initiating event that could result in the release of radioactive material from multiple PSBs.

<u>Question 7</u>: Please describe the technical specifications or other controls that will be implemented to ensure that the filtration units that are credited in accident dose consequence analyses are tested periodically to maintain the filter efficiencies needed to support the credit taken.

SHINE RESPONSE:

In accordance with 10 CFR § 50.34(a)(5), SHINE has identified the variables and conditions that will likely be the subjects of technical specifications (TS). These variables and conditions are provided in Chapter 14 of the SHINE PSAR. In Table 14a2-1 of the PSAR, Item 3.5, SHINE identifies that limiting conditions for operations (LCOs) will be applied to ventilation systems filters. In accordance with NUREG-1537 and ANSI/ANS-15.1-2007, the TS submitted with the Operating License Application will include surveillance requirements (SRs) corresponding to the LCOs. The SRs for the ventilation systems filters credited in accident dose consequence analyses will prescribe the frequency and scope of the surveillances that demonstrate the filters are able to perform their design basis safety functions. These SRs will include periodically testing the filter efficiencies, as needed to support the credit taken in the accident analysis.

Question 8: The dispersion coefficients used in the dose consequence accident analyses appear to be based on the 50th percentile estimates (as stated in PSAR Tables 13a2.2.1-2 and 13b.2.1-2, both of which are entitled, "Parameters Used in the Dose Consequence Assessment"). NUREG-1537, Part 2, Section 2.3 "Meteorology," states that:

> **The information on meteorology and local weather conditions is sufficient to support dispersion analyses for postulated airborne releases. The analyses should support realistic dispersion estimates of normal releases for Chapter 11 analyses and conservative dispersion estimates of projected releases for Chapter 13 analysis of accidental releases at locations of maximum projected radiological dose and other points of interest within a radius of 8 kilometers.**

Please discuss the use of the 50th percentile values in the dose consequence accident analyses provided for the SHINE facility in lieu of the more conservative 95th percentile values commonly used in power reactor dose consequence accident analyses.

SHINE RESPONSE:

The 50th percentile values for meteorological parameters were used to calculate relative atmospheric concentrations (χ/Q), also known as dispersion values (DV), which were used in the dose consequence assessment for Chapter 13 of the PSAR, as stated in Tables 13a2.2.1-2 and 13b.2.1-2.

The use of these values is consistent with Section 13.2 of NUREG-1537, Part 1, which states, in part, "Prepare realistic analyses to demonstrate a detailed, quantitative evaluation of the accident evolution, including the performance of all barriers and the transport of radioactive materials to the unrestricted area." Section 13.2 of NUREG-1537, Part 1, also states, in part, "Evaluate the potential radiological consequences using realistic methods." Similar guidance is also found in Sections 13a2.2 and 13b.2 of the ISG that augments NUREG-1537, Part 1.

Additionally, the ISG that augments NUREG-1537, Part 2, contains guidance on evaluation findings. Evaluation guidance in Section 13a2.1.1 states, in part, "Realistic but conservative methods are used to compute potential doses and dose commitments to the public in the unrestricted area." Evaluation guidance in Section 13b.1.2 states, in part, "Realistic but conservative methods are used to compute potential doses and dose commitments to the public in uncontrolled areas . . . ."

SHINE has determined that the use of 50th percentile meteorological values contributes to realistic analysis methods. However, the dose consequence analyses in Chapter 13 contain appropriate conservatisms, as described below.

Chapter 13 dispersion values were calculated using the computer code PAVAN, Atmospheric Dispersion Code System for Evaluating Accidental Radioactivity Releases from Nuclear Power Stations, Version 2.0. The dispersion values at the site boundary and for the nearest full-time resident are 3.88E-04 s/m^3 and 5.43E-05 s/m^3, respectively.

The dispersion values used in Chapter 13 are from the period of 0-2 hours following an effluent release, which are conservative with respect to dispersion values calculated for longer time periods. Additionally, the site boundary dispersion value chosen also represents the highest sector dependent χ/Q (based on meteorological observations for wind direction within the sector), and conservatively bounds the overall site dispersion value.

The following assumptions used in the calculation of dispersion values also provide conservatism in the dose consequence assessment in Chapter 13:

- The gaseous effluent in the analysis is modeled as a ground release. This assumption is conservative because the ground release model provides the bounding χ/Q values.
- The cross-sectional area of the building is conservatively assumed to be 0 m^2 to minimize the wake effects on the calculated χ/Q values.
- Distances from the release point to the receptors are calculated from a circle (radius of 70 m) that envelopes the corners of the isotope production facility because the release point could be anywhere on the facility. This is conservative because it minimizes the distance between the release point and any receptor.
- PAVAN assumes no deposition or depletion in the calculation of χ/Q values. This approach is standard in the industry and yields the most conservative χ/Q values.

The use of the 50^{th} percentile values in the dose consequence accident analyses is appropriate for the SHINE facility. The Chapter 13 dose consequence analyses are in agreement with the guidance provided in NUREG-1537, Part 1, and the ISG that augments NUREG-1537, Parts 1 and 2, and include appropriate conservatisms as discussed in this response.

<u>Question 9</u>: Please describe the basis for the stated conservative assumption that the duration of the worker exposure as a result of the MHA would not exceed 10 minutes.

SHINE RESPONSE:

The duration of worker exposure as a result of the Maximum Hypothetical Accident (MHA) will not exceed 10 minutes because SHINE determined that a 10 minute evacuation time is a conservative assumption given the small facility size, open layout, and worker training.

SHINE performed a calculation that determined the egress times from the irradiation facility (IF) and radioisotope production facility (RPF) to the radiologically-controlled area (RCA) exit in the event of a radiological accident. Workers in the SHINE facility will be trained to immediately evacuate the area in response to a high radiation alarm.

In the calculation, workers were assumed to be performing maintenance work in the following locations: 1) at the bottom of a shutdown and empty irradiation unit (IU) cell in the IF; and 2) at the bottom of a shielded storage cell in the RPF. The locations considered are the two farthest locations from the RCA exit. Transit speeds and distances were used to calculate the total time for egress. The egress paths involve climbing and descending ladders in addition to walking. Consideration was given to potential decreased mobility of RCA workers due to factors such as personal protective equipment (PPE) by selecting conservative, slower speeds in the analysis.

The calculated total transit times for the worker evacuations from the IF and the RPF were 3.6 minutes and 2.5 minutes, respectively. Given that the calculated transit times are significantly less than 10 minutes, 10 minutes is considered a conservative estimate for the amount of egress time necessary for a worker to leave the RCA in the event of a radiological accident, including the MHA.

<u>Question 10</u>: Understanding that the results will be presented in the FSAR, please discuss the planned additional radiological dose consequence modeling and analysis that will be performed for certain areas of the facility to increase the time available for evacuation as stated in footnotes in Tables 13a2.2.1-2 and 13b.2.1-2, both of which are entitled, "Parameters Used in the Dose Consequence Assessment."

<u>SHINE RESPONSE</u>:

SHINE plans to perform additional radiological dose consequence modeling and analysis in certain areas of the facility to increase the estimated allowable worker exposure evacuation time. The additional modeling and analysis will include analyzing cells, vaults, trenches, and other areas where radioactive material may be released, the leakage pathways from those areas, and the resulting radionuclide concentrations that workers could be exposed to. The analysis may be performed using computer codes (*e.g.*, GOTHIC) or hand calculations. Given the low driving forces for releases in the SHINE facility, the analyses are expected to result in decreased leak path factors and lower radionuclide concentrations in worker areas, leading to an increase in the estimated allowable evacuation time for workers.

Note that SHINE personnel will be trained to immediately evacuate the area in response to a high radiation or criticality accident alarm system (CAAS) alarm, as this is consistent with the as low as reasonably achievable (ALARA) philosophy.

<u>Question 11</u>: Section 2.4.2, "Nearby Industrial, Transportation, and Military Facilities," of the SER discusses three different sources of potential acceptance criteria for evaluating the aircraft accident probability. NUREG-0800, the Standard Review Plan, states that the probability of aircraft hazards with greater than an order of magnitude of 10^{-7} per year should be considered for nuclear power plants. International Atomic Energy Agency IAEA-TECDOC-1347 has an acceptance criteria for aircraft accident probability of less than 10^{-5} per year. The third source was the NRC precedent of an aircraft accident threshold probability of 10^{-6} per year in the case of *Private Fuel Storage, L.L.C.*

a. **Which aircraft accident probability was used for the SHINE construction permit application and what is the technical basis for this probability?**

b. Please explain if the probability selected for the design basis aircraft accident is consistent with the probability of other internal and external design bases events, such as explosions, flammable vapor clouds (delayed ignition), toxic chemicals, and fires, analyzed for SHINE.

SHINE RESPONSE:

a. An aircraft accident probability of 10^{-6} per year was used for the SHINE Construction Permit Application, as described in Section 2.2.2.5.3 of the PSAR. This value is consistent with the aircraft accident threshold probability provided in U.S. Department of Energy (DOE) Standard DOE-STD-3014-96, "Accident Analysis for Aircraft Crash into Hazardous Facilities," as well as the value approved by the Commission in the case of *Private Fuel Storage, L.L.C.*, CLI-01-22, 54 NRC 255 (2001), *denying reconsideration*, CLI-05-19, 62 NRC 403 (2005) (ML013180536; ML052520232).

A standard of 10^{-6} per year is appropriate for use for the SHINE facility because, similar to the reasoning presented in the case of *Private Fuel Storage, L.L.C.*, and accepted by the Commission, the consequences of a potential accident at the SHINE facility, in terms of how much radiation could be released, would be much less severe than at a nuclear power plant. The standard of 10^{-6} per year is also appropriate because the SHINE facility is similar to the type of facility intended to be evaluated using the DOE standard.

b. The probability of 10^{-6} per year is consistent with the probability that was used for other design bases events analyzed by SHINE, including explosions (Section 2.2.3.1.1.6 of the PSAR), flammable vapor clouds (Section 2.2.3.1.2.6 of the PSAR), and toxic chemicals (Section 2.2.3.1.3.6 of the PSAR). Consequences from off-site fires, as described in Section 2.2.3.1.4 of the PSAR, were evaluated deterministically, not probabilistically; therefore, a probability threshold was not needed to determine acceptability of postulated off-site fires. On-site design basis fires were also evaluated deterministically in Sections 13a2.1.12.2, 13a2.2.12.2, and 13b.2.6 of the PSAR, following the guidance provided in NUREG-1537 and the ISG that augments NUREG-1537.

Question 12: SER Section 13a.4.2 "Insertion of Excess Reactivity/Inadvertent Criticality" states that the Staff expects there to be a potential reactivity insertion in the event of voiding in the Primary Closed-Loop Cooling System (PCLS) because SHINE described the solution in the TSV as over moderated. In RAI 13a2.1-3 the Staff asked SHINE to investigate the impact of PCLS voiding and in response SHINE stated that voiding in the PCLS introduced negative reactivity. Did the Staff perform confirmatory calculations to verify these results since they seem to directly contradict the Staff's expectations? What physical phenomena led to a negative reactivity insertion during the event?

SHINE RESPONSE:

The PCLS cooling water cools the external surfaces of the target solution vessel (TSV). Calculations were performed using the Los Alamos National Laboratory (LANL) Monte Carlo N-Particle code MCNP5 to analyze the effect of uniform voiding in the PCLS, and the results show that the overall reactivity effect is a decrease in reactivity with increased void (*i.e.*, a negative void reactivity coefficient).

Since the PCLS surrounds the TSV, it effectively increases neutron reflection back to the target solution. Voids in the PCLS result in a reduction of the reflection of neutrons back into the TSV, as well as altering the interactions with the neutron multiplier, affecting the number and energy spectrum of neutrons entering the TSV. With fewer reflected neutrons, the reactivity of the assembly decreases.

Question 13: Section 13.a.4.5, "Loss of Electrical Power," states that the uninterruptable power supply system (UPSS) is available to supply battery power for essential loads for at least two hours, including the target solution vessel off-gas system (TOGS) to remove hydrogen. Please explain the technical basis for why two hours is sufficient for the UPSS to provide power to the TOGS for hydrogen removal.

SHINE RESPONSE:

The preliminary design assumes each of the redundant Class 1E battery subsystems is capable of delivering required emergency power for the required duration during facility normal and abnormal operations. Design studies are on-going to establish design features that could be used for maintaining stable long term post-accident conditions assuming that off-site power or the standby generator is not available. These potential design features include:

- Passive hydrogen recombiners;
- On-site safety-related emergency diesel generators;
- Robust piping systems;
- Deflagration flame arrestors; and
- Other potential design features identified during the detailed design.

The emergency power system will operate for the required mission time as delineated in the final detailed design, which will be provided in the Final Safety Analysis Report (FSAR). These requirements to describe the emergency power system mission time and describe any newly identified hydrogen mitigation design features are described in Sections 3.5a.12.6.1, 4a2.8.5, and 9b.6.1.1.5 of the PSAR.

Question 14: Section 13.a.4.5, "Loss of Electrical Power," states that the applicant has not provided an analysis of the impact of the loss of the heat removal systems on the integrity of the TOGS pressure boundary, but the event will still be bounded by the MHA. Please explain this conclusion.

SHINE RESPONSE:

SHINE will perform an analysis during detailed design that will determine the effects of the loss of heat removal systems on the TSV off-gas system (TOGS) operation, and will ensure that the TOGS pressure boundary integrity is maintained.

Without active heat removal systems, temperature in the TOGS would increase due to effects such as hydrogen recombination, blower heat, and heat transfer from the target solution. However, the TOGS system is also in contact with the light water pool, which will serve as a heat sink for excess heat in TOGS during loss of heat removal system events. The analysis will determine the temperatures in TOGS and in the TOGS shielded cell during such events, and ensure the design accommodates sufficient heat transfer capabilities to maintain acceptable temperatures so that the TOGS safety functions can be maintained.

The TOGS design will ensure sufficient heat rejection capabilities so that the loss of the active cooling systems will not result in a release of radiological material. Therefore, the radiological consequences associated with the Maximum Hypothetical Accident (MHA) still bound this scenario.

<u>Question 15</u>: Has SHINE defined how many irradiation units a single operator will be assigned or will this information be provided in the FSAR?

<u>SHINE RESPONSE</u>:

SHINE has not defined how many irradiation units a single operator will be assigned. This information will be provided with the Operating License Application, and will be informed by operator duties, human factors engineering, and the human-machine interface.

<u>Question 16</u>: The PSAR describes various codes that will be used to model the SHINE facility. For the MCNP computer code, the PSAR states (page 4a2-44) that preliminary validation has been completed using historic solution reactor data for uranyl nitrate solution systems (because "[h]istorical data for uranyl sulfate solution systems is limited") and that "[f]urther validation work will be performed during final design to determine estimated accuracy of calculated parameters." Please discuss the work done up to this point to benchmark MCNP and SCALE and describe SHINE's plans for further validation at the final design stage.

SHINE RESPONSE:

Work performed to benchmark the Monte Carlo N-Particle (MCNP) transport code during preliminary design has shown it has acceptable accuracy for modeling the SHINE system. The complete validation effort will determine the ability of MCNP to predict both absolute k_{eff} values and reactivity coefficients.

MCNP has been benchmarked using various solution reactor experiments from the International Handbook of Evaluated Criticality Safety Benchmark Experiments. MCNP5 calculations of historic uranyl nitrate solution systems provided validation of the ability of the Monte Carlo code to model uranyl nitrate systems. Validation on uranyl sulfate systems in the criticality safety benchmark process was also performed. This work has validated MCNP (and related cross section data) for homogeneous fuel systems at various enrichments, interacting materials, geometries, and average neutron energies causing fission relevant to the SHINE process.

Additional validation work is in-progress and planned for the target solution vessel (TSV). This includes analyzing additional cases from the International Handbook of Evaluated Reactor Physics Benchmark Experiments and the International Handbook of Evaluated Criticality Safety Benchmark Experiments, and determining the accuracy of MCNP to predict nuclear physics parameter variations, such as temperature reactivity coefficients. Subsequent startup testing during facility commissioning will then be used to compare actual system performance with MCNP predictions and ensure that acceptable nuclear physics parameter accuracy is obtained.

SCALE is a broad modeling and simulation suite for nuclear safety analysis and design. SHINE uses only a small portion of the available codes, namely COUPLE and ORIGEN-S, for design calculations. SHINE does not use SCALE packages for criticality or radiation transport modeling. Oak Ridge National Laboratory has documented testing and validation for various modules and data libraries to qualify the SCALE system. Verification and validation of the ORIGEN-S and COUPLE codes and associated nuclear data libraries have been performed previously (References 1-4). SCALE is installed in accordance with SHINE's Software Quality Assurance Program requirements, which also includes verification through SCALE's built in sample problems.

This validation process will be completed prior to the codes being used for final design calculations and will ensure that the codes are qualified for their intended application.

<u>References</u>:

1. Gauld, I.C., and Litwin, K.A., "Verification and Validation of the ORIGEN-S Code and Nuclear Data Libraries," RC-1429, Aug. 1995.

2. Hermann, O.W., Bowman, S.M., Brady, M.C., and Parks, C.V., "Validation of the SCALE System for PWR Spent Fuel Isotopic Composition Analyses," ORNL/TM-12667, Mar. 1995.

3. Hermann, O.W., "Benchmark of SCALE (SAS2H) Isotopic Predictions of Depletion Analyses for San Onofre PWR MOX Fuel," ORNL/TM-1999/326, Feb. 2000.

4. Gauld, Ian, "Validation of ORIGEN-S Decay Heat Predictions for LOCA Analysis," PHYSOR-2006 ANS Topical Meeting on Reactor Physics, Sep. 2006.

<u>Question 17</u>: The PSAR states that the system is always in a subcritical state. The SER (page 4-9) states: "Reactivity is determined by seven variables: uranium concentration in the target solution, uranium enrichment, TSV fill-volume, target solution temperature, target solution pressure, temperature of the light water pool, and temperature of the PCLS. During operation, the last four can be manipulated to control reactivity, while the others are generally not altered." The last four parameters seem to be all slow response parameters.

Please explain how the reactivity increase caused by changes in the solution volume due to bubble formation and collapse is controlled. Relatedly, please address instability inherited with natural circulation.

SHINE RESPONSE:

During the filling operation of the target solution vessel (TSV), there is no appreciable void fraction in the solution due to the insignificant generation of radiolysis products. After transition to irradiation mode, the accelerator is energized and fission power is generated in the target solution, resulting in the generation of radiolysis gases and voiding of the solution (expected bulk void fraction of less than five percent). As the target solution is maintained below boiling temperatures, the void fraction in the solution is due principally to non-condensable gases. Changes in the solution volume due to this radiolytic bubble generation results in an overall decrease in the reactivity of the system.

The startup process for SHINE fills the TSV using an inverse multiplication factor (1/M) process, and solution addition is terminated at approximately five percent by volume below critical. During the subsequent irradiation process, the temperature increase and solution voiding drives the system further from critical.

While the radiolysis gases are non-condensable, certain events could decrease the void fraction by altering the pressure in the TSV. These events include normal pressure variations in the TSV off-gas system (TOGS) and a potential deflagration in the system. The reactivity effects of pressure variations in the TOGS are small relative to the margin to subcriticality during operation. The reactivity effects of a potential deflagration were also evaluated, and it was shown that the system will remain subcritical following this event. The reactivity decrease from the bubble generation is considered in the neutronics models and active control is not required, nor provided, to compensate.

The TSV is internally cooled during operation via natural circulation of the target solution, augmented by the formation and movement of radiolysis gas bubbles. The TSV itself is a relatively simple, single vessel that contains the target solution. No natural circulation loop must be set up or maintained through other vessels or piping to provide cooling. The TSV external surfaces are simply directly cooled by cooling water. Heat is convected from the target solution to the vessel surfaces, conducted through the metal, and then transferred to the cooling water via forced convection. The internal natural convection in the solution is similar to natural convection demonstrated and measured by the experiments listed in References 1-4, below.

As described above, the bubble formation results in a negative reactivity addition to the TSV and analyzed scenarios have shown that the system will remain subcritical, even with large void fraction fluctuations in the TSV, and active control is not required. In addition, the natural convection in the TSV is a simple, well-demonstrated process with known heat transfer coefficients.

<u>References</u>:

1. Kulacki, F.A and A.A. Emara, "Steady and transient thermal convection in a fluid layer with uniform volumetric energy sources," J. of Fluid Mechanics, Vol. 83, pp. 375-395, 1977.

2. Felde D.K., H.S. Kim, and S.I. Abdel-Khalik, "Convective heat transfer correlations for molten core debris pools growing in concrete," Nuc., Eng. Design, Vol. 58, pp. 65-74, 1980.

3. Bull, G.R., "Effects of Gas Bubble Production on Heat Transfer from a Volumetrically Heated Liquid Pool," Dissertation, University of Wisconsin – Madison, 2014.

4. Chemerisov, S., et al., "Experimental Results for Direct Electron Irradiation of a Uranyl Sulfate Solution: Bubble Formation and Thermal Hydraulics Studies," ANL/NE-15/19, Argonne National Laboratory, January 30, 2015.

<u>Question 18</u>: The PSAR states (page 4a2-40): "Formation of radiolytic gases during operation increases the void fraction of the target solution. <u>This also causes a decrease in reactivity as a result of the negative void coefficient.</u>" However, PSAR section 13a2.1.2.2.3, "Moderator Addition Due to Cooling System Malfunction," states: "A dilution event such as this is expected to lower the overall reactivity of the target solution due to the high

hydrogen to uranium ratio in the target solution (target solution is over-moderated.") Also, section 13a2.1.2.2.7, "Inadvertent Introduction of Other Materials into the Target Solution," states: "Therefore, water is the only significant material that could be potentially introduced into the TSV either through a leak from the PCLS or the return of water from the recombiner in the [TSV off-gas system] TOGS. A dilution event such as this lowers the reactivity of the TSV since the target solution is over-moderated and is expected to be well mixed.") Is the system designed to be over-moderated or under-moderated?

a. If the system is designed to be over-moderated, please explain how it is controlled to ensure it remains subcritical under all operating conditions, such as evaporation of water in the solution, bubble formation, or thermal expansion of the solution.

b. If the system is designed to be under-moderated, please explain how it is controlled to ensure it remains subcritical as the fissile materials deplete and fission products build up over the period of operation.

SHINE RESPONSE:

a. The target solution is over-moderated, as a decrease in hydrogen content in the solution (with constant fissile material content) will result in increased reactivity in the system. However, being over-moderated has different effects in the TSV than traditional solid-fueled reactor designs. Because the fissile material and water are intimately mixed in the TSV, voids in the target solution displace both fissile material and moderator. The reactivity effect of displacing the fissile material is more significant, resulting in a negative void coefficient.

The TSV is filled to an initial subcritical state, approximately five percent by volume below critical, and reactivity effects during operation drive it further subcritical due to large negative void and temperature coefficients.

The evaporation of water does lead to a positive reactivity effect, but the magnitude of the effect is small due to the closed loop nature of the TOGS and the design criterion to minimize water hold-up in the system (*i.e.*, holdup less than one percent of the TSV volume). The reactivity effect of water evaporation will be included in final design calculations, and preliminary analyses have shown it to be acceptable.

As described above, bubble formation in the target solution displaces uranium and hydrogen, and the net effect is strong negative void feedback coefficients.

The thermal expansion of the solution has an effect similar to the voiding of the solution, where the expansion results in a decrease in the atomic density of uranium and hydrogen atoms and the net result is a strong negative temperature coefficient.

The overall result of these design considerations and inherent nuclear feedback effects is that the system is filled to a subcritical state and is moved farther away from critical during irradiation by bubble formation and heating of the solution.

b. Not Applicable

Question 19: In section 4a2.6.2.1, "Analysis Methods and Code Validation," the PSAR states: "MCNP5-1.60, the LANL MCNP radiation transport code is used with ENDF/B-VII cross sections libraries to calculate various nuclear physics parameters for the TSV and IU." The PSAR further states: "COUPLE, a module of the larger SCALE (Standardized Computer Analyses for Licensing Evaluations)-6.1.2 computational system from ORNL, is used to generate flux-dependent cross sections and fission yields for the SHINE subcritical assembly using the flux profiles calculated by MCNP5." Because MCNP calculates neutron flux distribution with Monte Carlo method, there are always uncertainties associated with the answer. These uncertainties associated with the calculated flux need to be treated diligently if the calculated flux using MCNP is to be used as an input value to the COUPLE code.

Please explain how flux-dependent cross sections are used in the depletion analyses and how the uncertainty part of the neutron flux calculated by MCNP was fed into the ORIGEN code.

SHINE RESPONSE:

SHINE performed isotope generation and depletion analysis using the ORIGEN-S module of the SCALE code package. COUPLE, another module within the SCALE code, was used to compute the binary format nuclear data libraries that are used by ORIGEN-S.

COUPLE collapses the energy-dependent cross section data into flux-dependent one-group cross section data for use in the time-dependent differential equation set solved by

ORIGEN-S. COUPLE can collapse the cross sections itself using a known flux spectrum, and it can also add/replace specific user-defined one-group cross sections determined from another source. SHINE calculated neutron flux spectrums and individual one-group cross sections for the target solution in the target solution vessel (TSV) using the Monte Carlo N-Particle code MCNP5, and then input this data into COUPLE. SHINE then used the COUPLE results to perform isotope generation and depletion analyses with ORIGEN-S. ORIGEN-S results were then used to generate source terms for accident evaluations and to provide inputs to other nuclear calculations (*e.g.*, xenon and samarium worth calculations, Mo-99 yields).

As MCNP is a statistical code, the calculated neutron flux spectrums and individual one-group cross sections input into COUPLE contain statistical uncertainty. For preliminary design, enough particles were simulated in MCNP to achieve relative errors of approximately one percent or less for the tallied flux. In addition, sensitivity studies were performed to analyze the convergence of the calculated cross sections with the number of particle histories run. Cases were run using 1000, 5000, and 10000 particles per calculation cycle, and the results showed sufficient convergence of the cross section results. The activities of the primary dose contributors were found to vary by less than 0.1 percent when doubling the number of particles per cycle. The small statistical errors were deemed a sufficient level of precision for preliminary calculations and the errors were not propagated through to the ORIGEN-S calculations.

During final design, SHINE will evaluate the effects of the statistical errors of the MCNP-calculated neutron fluxes and cross sections used in ORIGEN-S calculations and ensure that final results of calculations appropriately account for the uncertainty.

<u>Question 20</u>: Please explain the approach SHINE plans to use for determining reactivity coefficients and the k_{eff}.

SHINE RESPONSE:

The approach to calculating reactivity coefficients and k_{eff} values in the subcritical assembly involves initial design calculations, measurements during startup testing of the facility, and the startup fill process used for each irradiation cycle.

As described in the SHINE Response to RAI 4a2.6-6 (ML14356A527), the actual operating k_{eff} of the target solution vessel (TSV) will be determined with a volume margin-to-critical approach coupled with a calculated reactivity worth of that volume. The planned stepwise approach is provided below:

During Facility Design:

- MCNP5 models will be used to predict the desired uranium concentration to give an acceptable fill height of the TSV. MCNP5 models will be used to predict the critical solution height of the TSV at this uranium concentration.
- MCNP5 models will be used to predict reactivity coefficients by altering relevant parameters (*e.g.*, target solution temperature) in the models and observing the reactivity change. These calculations will include the reactivity worth per liter of target solution for the range of allowable uranium concentrations.
- The allowable margin to criticality will be estimated based on the instrument uncertainty and calculated reactivity parameters. The allowable margin to criticality will ensure the TSV remains subcritical during normal conditions and postulated accidents.

During Facility Commissioning:

- Startup physics tests will determine the critical solution height of the TSV by subcritical approaches and using the inverse multiplication factor (1/M) technique. The TSV will remain subcritical for these facility startup physics tests.
- The bias of the MCNP5 models will be determined by computing the difference in uranium concentration between tests and the models that yield the same predicted critical height. Sufficient tests will be performed to ensure statistical significance.
- Startup physics tests will also measure the effects of other parameter variations (*e.g.*, uranium concentration, target solution temperature), as determined necessary during detailed design, and the corresponding variations of critical volume as a function of these parameters. These results will be compared to MCNP predictions of the effects of the parameter variations and the differences will be used to estimate the uncertainty of the relevant reactivity coefficients.

During Normal Startups After Commissioning:

- Normal startups will be performed by using the 1/M methodology. The TSV fill process is planned to be terminated at approximately five percent by volume from critical.
- The actual margin to criticality at Mode 1 startup conditions will be determined by multiplying the measured volume margin to criticality (*e.g.*, 10 liters) by the computed reactivity worth per liter (*e.g.*, 30 pcm/liter of target solution). The k_{eff} value of the TSV will be estimated by subtracting the actual margin to criticality from 1.0.

Using the above approach, the reactivity coefficients and k_{eff} will first be calculated with validated neutronics models. Subsequent startup testing will be used to determine the accuracy of those predictions. Once the acceptable testing results have been obtained, the normal TSV startup process is then used to fill the TSV prior to each irradiation. The normal TSV startup process does not determine k_{eff} directly, but ensures that k_{eff} is less than a known, acceptable value (1.0 - acceptable margin).

Question 21: Please explain how the neutron flux distribution in the vessel/solution is determined.

SHINE RESPONSE:

SHINE uses the LANL Monte Carlo N-Particle transport code (MCNP) to determine the spatial and energy distribution of the neutron flux in the target solution vessel (TSV). The MCNP model defines the geometries of components in the irradiation unit (IU) cell (including the TSV, neutron multiplier, and the target solution), the materials of the components in the IU cell, the temperature distribution in the TSV, the void fraction of the target solution, the neutron source distribution, and other neutronically-important parameters.

Calculations assuming a critical source distribution (such as calculations of k_{eff}) use the kcode criticality source model in MCNP. Calculations for externally-driven source multiplication use the appropriate external neutron source (*e.g.*, a fusion neutron source from the accelerator for irradiation operations or an installed fixed neutron source for startup and filling the TSV).

Tallies (such as mesh tallies or volume flux tallies) are then used during the MCNP simulations to calculate the flux distribution in the system.

<u>Question 22</u>: Please describe the criticality safety monitoring system to be installed and how it works to ensure criticality safety.

Please explain the reliability of the on-line reactivity monitoring system and why the Staff considers it acceptable.

<u>SHINE RESPONSE</u>:

In the irradiation facility (IF), target solution is contained within the target solution vessel (TSV) and the TSV dump tank.

The TSV is maintained subcritical at all times, including during startup, irradiation, and shutdown. During startup, the inverse multiplication factor (1/M) is calculated by monitoring the neutron flux level and solution fill volume. The solution volume as a function of 1/M is compared to a predicted graph with an acceptance band for the 1/M value. The TSV is filled to a level five percent by volume below the predicted critical volume. Protective trips as part of the TSV reactivity protection system (TRPS) ensure that the system remains subcritical by initiating protective action when a trip setpoint (*e.g.*, high neutron flux) is reached.

During irradiation, the power level in the TSV is monitored using neutron flux detectors located around the TSV. Reactivity in the system is not directly measured during operation; however, the power level in the TSV is correlated to the reactivity. The neutron flux detection system (NFDS) calculates a percent power and displays it to operators in the control room. Due to the subcritical multiplication of the assembly, an increase in reactivity will increase neutron population and fission power, and this increase will be detected by the neutron flux detectors. The design of the TSV, TSV off-gas system (TOGS), supporting systems, and protective trips actuated by the TRPS ensure that the TSV reactivity remains subcritical during irradiation. Protective trips from TRPS currently include high hydrogen concentration, high neutron flux, high and low temperature in the primary closed loop cooling system (PCLS), and loss of PCLS flow.

The NFDS consists of three neutron flux detectors placed around the subcritical assembly and a monitoring system in the control room that displays level and period information. The neutron flux detectors and the monitoring system are safety-related components.

After irradiation, the solution is transferred from the TSV to the TSV dump tank. The dump tank maintains the k_{eff} below 0.95 for the most reactive uranium concentration. The system remains subcritical post-irradiation due to the geometry and design of the TSV dump tank.

The radioisotope production facility (RPF) handles uranium solutions in various vessels, piping, and process equipment, as well as uranium in solid metal and oxide forms. The RPF has a criticality accident and alarm system (CAAS), which will detect actual occurrence of criticality through neutron and gamma radiation detectors. When the radiation level at the CAAS detectors exceeds a predetermined threshold, a clearly audible alarm is sounded. The CAAS does not monitor the approach to criticality. Although the CAAS does not provide any on-line reactivity monitoring, it will alert personnel in the RPF in the event an unintended criticality event occurs to ensure a prompt evacuation. The Nuclear Criticality Safety Program and the established criticality safety controls, as described in Sections 6b.3 and 13b.2.5 of the PSAR, ensure that a criticality event in the RPF is highly unlikely.

The combination of the processes above ensures that the TSV and other locations where fissile material may be located remain subcritical with acceptable margin.

<u>Question 23</u>: Please explain the basis for the estimate on page 4-17 of the SER that the reactivity of Xe-135 and Sm-149 will be less than 10% of clear core reactivity.

SHINE RESPONSE:

The two fission products that will have the largest reactivity effects on the subcritical assembly are xenon-135 (Xe-135) and samarium-149 (Sm-149).

The reactivity worths for Xe-135 and Sm-149 were calculated using Monte Carlo N-Particle (MCNP) models of the subcritical assembly. ORIGEN-S was used to generate the Xe-135 and Sm-149 concentrations for various times spanning multiple SHINE irradiation cycles, and the resulting concentrations were input into the MCNP model.

Multiple irradiation cycles were studied in order to capture transient behavior of the fission products between cycles and during the startup of subsequent cycles. Note that fission products will be removed from the uranium during the planned periodic cleanup of the target solution using the uranium extraction (UREX) process.

Xenon gas was assumed to not escape the target solution, resulting in a bounding xenon reactivity worth. As shown in the SHINE Response to RAI 4a2.6-5 (ML14356A527), xenon reactivity worth reaches equilibrium during the course of the irradiation cycle. The reactivity worth of Sm-149 increases during the analyzed cycles, and the overall reactivity effect is small.

The total reactivity change per cycle was estimated by adding together the potential reactivity change from xenon and samarium. This reactivity change was estimated to result in less than a 10 percent change in fission power in the assembly during operation, as stated on page 4-17 of the staff's SER. Due to the subcritical multiplication process in the assembly, this is equivalent to approximately a 10 percent change in clear core reactivity during irradiation conditions.

Question 24: Please explain the bases for the conclusion made on page 4-6 of the SER that "Non-uniformities, such as non-uniform void distribution, non-uniform temperature, and non-uniform power distribution, are not expected to impact operational limits."

SHINE RESPONSE:

Non-uniformities in void fraction, temperature, and power distribution exist in the system. Preliminary computational fluid dynamics (CFD) calculations show adequate mixing due to natural convection flow (with flow rates on the order of a few cm/second). Due to the homogenous nature of the target solution and the natural convection flow, non-uniformities and their effects are generally small, as described below.

Increased void fractions occur in the upper region of the target solution vessel (TSV) as bubbles move upwards after being formed throughout the solution (due to volumetric power deposition). Based on void fractions in preliminary CFD simulations, this non-uniformity in void is expected to lead to a change of less than a few percent in the power density throughout the TSV versus uniform void distribution.

Temperatures within the TSV will vary, generally increasing from bottom to top (since power is continually added to the rising liquid). This temperature gradient has been estimated based on preliminary CFD calculations, and the gradient leads to a decrease in total power of approximately one percent and a slight downward shift in the location of the peak power generation.

The power distribution in the TSV is inherently non-uniform primarily due to geometry and resulting neutron leakage. The power distribution is also affected slightly by the non-uniformities in void and temperature, described above. The power profile has a skewed cosine shape in both the vertical and radial directions. The power density peaking and its effects on target solution temperature distribution and fluid flow have been analyzed in preliminary thermal-hydraulic calculations, and the results have shown the power peaking results in small, acceptable changes in the temperature distribution.

Current operating limits for the target solution include temperature, uranium concentrations, and pH limits, as described in Table 4a2.2-3 of the PSAR. The non-uniformities discussed above are not expected to affect these operating limits.

Operating limits of importance for the TSV and subcritical assembly will be provided with the Operating License Application. These limits are expected to include available reactivity insertion limits, stability criteria (such as neutron flux and power density), and limiting core configuration criteria. The final design of the TSV will ensure that it operates within the target solution and subcritical assembly operating limits, including consideration of potential non-uniformities in void, temperature, and power.

<u>Question 25</u>: The SER states (at page 4-7) that in its response to the Staff's RAI 4a2.2-6, SHINE stated that during startup and approach to criticality, the TSV is expected to be at approximately the same temperature. This statement seems to indicate that the system will be brought to critical at some point during startup. This appears to contradict the design criterion that the system will never approach criticality, i.e., the system will always be subcritical. Please clarify if the system would ever reach a critical state.

<u>SHINE RESPONSE</u>:

The system is designed to not reach a critical state during either normal operations or accident conditions. The target solution vessel (TSV) startup process is similar to traditional critical system startup processes, where reactivity is added incrementally and the 1/M startup curve is plotted at each step to ensure that the critical configuration is well predicted. However, with the SHINE device, the startup process is terminated early, before reaching criticality. The startup process for SHINE will terminate solution addition at approximately five percent by volume below critical.

The subsequent irradiation process will add heat and void to the target solution, which both act to drive the system farther from critical. In addition, there are no accidents described in Chapter 13 of the PSAR that would result in the TSV reaching a critical condition.

Given that the system is filled to a subcritical state, reactivity is decreased from that state during normal operations, and there are no accidents described in Chapter 13 of the PSAR that would result in reaching a critical state, the system will remain subcritical during normal operations and accident conditions.

Question 26: Please explain how the criticality safety control system works and how it is assured that the Irradiation Unit (IU) will be shut down safely and promptly from any operating condition (e.g., how the control system will shut down the assembly when the IU is found to be critical or supercritical given that there is no control rod). What is the shutdown margin?

SHINE RESPONSE:

The control system that ensures subcriticality in the target solution vessel (TSV) is the TSV reactivity protection system (TRPS), which trips the IU in the event that a safety parameter is determined to be outside the allowable range. The TRPS can shut down the IU safely and promptly from normal and accident conditions by transferring the solution to a safe-by-geometry subcritical tank (*i.e.*, the dump tank) and terminating the neutron source from the accelerator. Although the TRPS is designed to ensure the TSV remains in a subcritical state, the transferring of solution to the dump tank will shut down the TSV even if it was in a critical or supercritical state.

As described in Section 7a2.4.1 of the PSAR, when the TRPS actuates a trip of an IU, it performs the following functions: opens the TSV dump valves to drain the target solution to the TSV dump tank, closes the TSV fill valves (if not already closed), closes the TSV dump tank outlet valves (if not already closed), and de-energizes the neutron driver by opening the safety-related circuit breakers supplying power to the high voltage power supply (HVPS).

The TRPS initiates an IU trip on the following parameters being outside of allowable ranges: neutron flux (source and high range), primary closed loop cooling system (PCLS) temperature, PCLS flow, and hydrogen concentration in the primary system. The high neutron flux trip set points will include consideration for transient neutron behavior, detector uncertainties, maximum solution fill rate, and delay for opening the dump valves. Section 7a2.4.1 of the PSAR describes the TRPS in more detail. As described in the SHINE Response to RAI 4a2.8-3 (ML14296A189), SHINE will finalize the required trip variables during detailed design, and expects TRPS trips will include primary system pressure and sweep gas flow.

The dump subsystem consists of two completely independent flow paths between the TSV and TSV dump tank. The solution drains from the TSV, through the dump valves and lines, to the dump tank via gravity. The delay time between the conditions that would trigger a dump signal and the start of the dump valves opening will be a maximum of one second, and the duration of time it takes for the dump valves to open will be less than five seconds.

The TSV dump tank is criticality-safe by geometry and maintains a k_{eff} less than 0.95 at cold conditions for the most reactive uranium concentration for normal operation and accident conditions. Therefore, the shutdown margin in the IU is 0.05 delta-k. As the dump paths are redundant, a single dump path can safely shut down the TSV to a k_{eff} less than 0.95.

<u>Question 27</u>: Section 4a.4.4, "Reactivity Control Mechanisms," of the SER, states that when an abnormal condition arises in the Irradiation Unit, the control system of the neutron driver assembly will shut down the accelerator and terminate the reaction.

Please explain if the shutdown will include independent and diverse means of terminating the reaction.

SHINE RESPONSE:

The shutdown of the irradiation unit (IU) is accomplished through independent and diverse means. As described in Section 7a2.1.1 of the PSAR, the TSV reactivity protection system (TRPS) is a safety-related control system that protects the target solution vessel (TSV) and other components of the primary system boundary (PSB). The TRPS is responsible for monitoring various essential inputs and has the ability to mitigate abnormal or accident conditions through automated protective actions. The protective actions include opening the TSV dump valves, de-energizing the neutron driver, closing the TSV fill valves, and closing the TSV dump tank outlet valves.

The TRPS de-energizes the neutron driver with two independent, redundant trip breakers. The trip breakers remove power to the high voltage power supply (HVPS) of the accelerator, preventing it from being able to accelerate ions, and terminating the fusion neutron source.

In addition to de-energizing the neutron driver, the TRPS dumps the target solution to the subcritical-by-geometry TSV dump tank, which maintains the target solution in a subcritical, passively-cooled state. The dump subsystem consists of two independent paths and independent dump valves. Even if the neutron driver remained energized, the TSV would still be shut down by the opening of the TSV dump valves.

The TRPS is designed to the single failure criterion, such that it contains sufficient redundancy and independence that a single failure of any active component does not result in a loss of capability of it to perform its safety functions.

The neutron driver has its own separate, internal control system. This control system controls the operation of the various components of the neutron driver (*e.g.*, ion source, pumping stages), but it is not relied on to de-energize the neutron driver for safety-related purposes. The control system of the neutron driver does not perform any safety-related functions; therefore, it is classified as a nonsafety-related system.

As described above, the shutdown of the fission process in the subcritical assembly is accomplished through independent means (*i.e.*, two independent trip breakers and two independent dump valves), as well as through diverse means (*i.e.*, by terminating the neutron source and by moving the solution to a subcritical holding tank).

Question 29: Chapter 6 describes engineered safety features for the irradiation facility and the radioisotope production features.

What safety features exist for the facility mode when the target solution has been irradiated and is being transferred back to the radioisotope production facility?

SHINE RESPONSE:

During the transfer of target solution to the radioisotope production facility (RPF) following irradiation, target solution is contained in piping, tanks, and other supporting components designed to safely contain the target solution. Those solution-containing components are surrounded by a continuous boundary of reinforced concrete cells, trenches, and vaults, isolable ventilation systems, seals, isolation valves, and single-failure-proof safety actuation systems.

As the SHINE irradiation facility (IF) is contiguous with the RPF, the target solution is maintained within these continuous confinement boundaries during the entire transfer from the IF to the RPF. A transfer of target solution from the IF to the RPF consists of moving the target solution from a confinement area in the IF (an irradiation unit (IU) cell), through confinement areas in the RPF (piping trenches), and into a confinement area in the RPF (an extraction hot cell).

The engineered safety features (ESFs) performing confinement functions for transferring target solution between the IF and RPF include:

- IU cells and hot cells and their penetration seals;
- radiologically controlled area (RCA) ventilation ductwork;
- tank vaults and piping trenches;
- bubble-tight ventilation isolation dampers;
- isolation valves on piping systems penetrating the cells; and
- the engineered safety features actuation system (ESFAS) and the radiologically integrated controls system (RICS).

These ESFs continuously provide confinement for irradiated target solution during transfers of the solution between the IF and RPF.

<u>Question 30</u>: Sections 4a.4.7, "Subcritical Assembly Support Structures [SASS]," of the SER, and 4a.4.10, "Target Solution Vessel [TSV] and Light Water Pool," describe the physical characteristics of those components and their design and fabrication parameters.

Please explain if the SASS and TSV will have overpressure protection features.

<u>SHINE RESPONSE</u>:

The TSV is provided with overpressure protection via the TSV off-gas system (TOGS). A pressure safety valve is connected to the TOGS piping to prevent an over-pressurization within the primary system boundary (PSB).

The setpoint of the pressure safety valve will not exceed the design pressure of the PSB components, and the setpoint value will be provided with the Operating License Application. The TSV, TOGS, and TSV dump tank share the same gas space, and the design does not include valves that could isolate the TOGS pressure safety valve from the TSV or TSV dump tank.

As described in the SHINE Response to RAI 4a2.8-5 (ML14356A527), SHINE plans on connecting the pressure safety valve in TOGS to the noble gas removal system (NGRS). Final design of the NGRS will ensure the system contains a relief volume capable of receiving gas from TOGS in the event of an over-pressurization. Relief gases in the NGRS will be sampled and held for decay. Upon completion of an appropriate decay period, the gases in the NGRS will again be analyzed for radioactivity, and released to the process vessel vent system (PVVS). This process will ensure that the radioactive release and dose requirements of 10 CFR Part 20 are met.

The subcritical assembly support structure (SASS) will also be provided with overpressure relief capability. The SASS and the primary closed loop cooling system (PCLS) form a continuous pressure boundary for the primary cooling water. The primary cooling water is continuously treated using filters and an ion exchange bed to maintain acceptable purity. SHINE plans to evaluate the appropriate location of the overpressure relief capability for the PCLS and SASS during detailed design and will provide the information with the Operating License Application.

<u>Question 31</u>: Section 4a.4.12, "Nuclear Design," of the SER, states that the Irradiation Unit can be shut down by the control systems (TRPS and TPCS), which will trip on high PCLS temperature or flux.

Please explain why system pressure is not another parameter necessary to shut down the Irradiation Unit to ensure safe operation of the facility.

<u>SHINE RESPONSE</u>:

As described in the SHINE Response to RAI 4a2.8-3 (ML14296A189), transient system modeling will be performed during the detailed design process. The input to these analyses requires the final primary system boundary (PSB) (target solution vessel (TSV), TSV off-gas system (TOGS), and TSV dump tank) layout and positions of relevant sensors. The results of this final analysis will be used to determine the necessary trip inputs from the TOGS to the TSV reactivity protection system (TRPS) to ensure that the integrity of the PSB is maintained under normal and accident conditions.

As stated in the SHINE Response to RAI 4a2.8-3 (ML14296A189), SHINE expects that these trip inputs will include primary system pressure, sweep gas flow, and hydrogen concentration measurements. SHINE will provide a final list of automatic trips with the Operating License Application.

Question 32: PSAR Section 13a2 describes the postulated accidents that can occur in the SHINE facility. Opening the TSV dump valves is one of the primary mitigating actions required to ensure a safe system configuration. Please describe the design considerations that will be used for the valves. Will the dump system be designed to prevent significant solution hold up in the TSV during an accident?

SHINE RESPONSE:

As described in the SHINE Response to RAI 4a2.6-7 (ML14296A189), the dump valves will be designed to be highly reliable, corrosion-resistant, fail-open valves. They will be qualified for service in the environmental conditions of the target solution vessel (TSV) dump lines and light water pool, including applicable pressure, temperature, radiation, corrosion, and immersion specifications. The dump valves will be designed to allow a flow rate sufficient to drain the TSV in an adequate period of time even if only one valve opens.

SHINE plans to use solenoid valves, and the valve opening times are expected to be less than 5 seconds. Each valve will be equipped with a valve position indicator. As described in the SHINE Response to RAI 7a2.2-1 (ML14356A527), the draining of the TSV is monitored by valve position indication and level instrumentation in the TSV. Periodic surveillance testing will verify proper functioning of the valves. A failure of a valve to respond or abnormal change in drain rate will be thoroughly investigated and corrected, as part of the SHINE Corrective Action Program, to ensure the valves can be relied upon when required.

The dump subsystem is designed to prevent significant solution holdup during an accident. The design includes two completely independent flow paths between the TSV and the TSV dump tank. Each path consists of a dump line connecting from an opening on the bottom surface of the TSV to the TSV dump tank, with a dump valve to allow or prevent flow. Two completely independent overflow lines are also present, which serve as vent lines from the dump tank to the TSV to equalize gas pressures during solution dumps. The dump subsystem is designed to perform its safety functions with the failure of a single active component. Each dump line is independently capable of fully draining the TSV.

Question 33: Section 2.4.3, "Meteorology," of the SER, discusses the different meteorological events applicable to SHINE.

Please discuss the parameters for maximum extreme winds and tornadoes that the staff determined were applicable to SHINE.

SHINE RESPONSE:

The parameter for extreme wind applicable to the SHINE preliminary design is found in Section 3.4.2.6.3.7 of the PSAR. The maximum extreme wind speed is 96.3 miles per hour. This parameter represents a 100-year recurrence interval wind speed for the SHINE site, and was calculated by multiplying the basic (50-year recurrence interval) wind speed for the SHINE site by a factor of 1.07. This parameter was selected based on guidance found in American Society of Civil Engineers (ASCE) 7-05, "Minimum Design Loads for Buildings and Other Structures," as described in Section 3.2.1.1 of the PSAR, for the area in which the SHINE site is located.

The parameters for tornadoes applicable to the SHINE preliminary design are found in Section 3.4.2.6.3.8 of the PSAR. These parameters correspond to the characteristics of a

Region I design basis tornado as described in Regulatory Guide 1.76, "Design Basis Tornado and Tornado Missiles for Nuclear Power Plants," which is the region in which the SHINE site is located. Parameters applicable to a nuclear power plant design basis tornado were selected because an F5 intensity tornado was found to be the maximum historical intensity tornado within a radius of about 100 km, as described in Section 2.3.1.2.5 of the PSAR.

Question 34: Section 3.4.2, "Meteorological Damage," of the SER discusses the sufficiency of facility design features. This section states that the design criteria are compatible with local architectural and building codes for similar structures and that design specifications for SSCs are compatible with the functional requirements and capability to retain function throughout the predicted meteorological conditions.

a. Will extreme high winds, tornadoes and tornado missiles be considered as an external event? If so what will the design parameters be for structures, systems and components (SSCs) designated safety-related Seismic Category 1, non-safety-related Seismic Category II, or non-safety-related Seismic Category III to protect against these hazards?

b. Will safety-related and non-safety-related systems and components located outside of safety-related and non-safety-related structures also be protected from extreme high winds, tornadoes and tornado missiles?

SHINE RESPONSE:

a. Extreme high winds, tornadoes, and tornado missiles are considered external events, as described in Sections 13a2.1.6 and 13b.2.3 of the PSAR.

The design parameters for SSCs designated as safety-related Seismic Category I are found in Sections 3.4.2.6.3.7 and 3.4.2.6.3.8 of the PSAR, and further described in the SHINE Response to Question 33. The design parameters were established based on the guidance contained in:

- Regulatory Guide 1.76, "Design Basis Tornado and Tornado Missiles for Nuclear Power Plants," Revision 1, for tornado characteristics (Region I)

- ASCE 7-05, “Minimum Design Loads for Buildings and Other Structures,” for other meteorological parameters (*e.g.*, extreme high winds)

Based on the accident analysis described in Chapter 13 of the PSAR, nonsafety-related SSCs are not required to perform safety functions. Therefore, there are no identified design parameters for nonsafety-related SSCs that are required for protection against extreme high winds, tornadoes, or tornado missiles. However, nonsafety-related SSCs will be designed in accordance with applicable codes. For example, structures designated nonsafety-related Seismic Category II and nonsafety-related Seismic Category III will be designed for a basic wind speed of 90 mph, as described in ASCE 7-05, and as required by the 2009 International Building Code. In Wisconsin, the Uniform Building Code has been superseded by the 2009 International Building Code.

b. Safety-related systems and components will be protected from extreme high winds, tornadoes, and tornado missiles. The SHINE preliminary design does not locate any safety related systems or components outside of safety-related structures.

Based on the accident analysis described in Chapter 13 of the PSAR, nonsafety-related systems and components are not required to perform safety functions. Therefore, there are no identified design parameters for nonsafety-related systems or components that are required for protection against extreme high winds, tornadoes, or tornado missiles. However, as described in Section 3.5.2 of the PSAR, SSCs co-located with Seismic Category I systems are reviewed and supported in accordance with II over I criteria. This avoids any unacceptable interactions between SSCs.

<u>Question 35</u>: Section 3.4.4, “Seismic Damage,” of the SER states that SHINE was assessed for accidental explosions inside the facility, accidental explosions due to storage of

hazardous material outside the facility, and accidental explosions due to external transportation including aircraft impact.

Did the Staff or SHINE assess whether SHINE was impacted due to any external utilities that could affect the SHINE facility?

SHINE RESPONSE:

SHINE assessed the potential impact on the facility due to external natural gas pipelines. Information on these pipelines is provided in Section 2.2.1.1.2 and Table 2.2-3 of the PSAR. The pipeline hazard analysis is provided in Sections 2.2.3.1.2.1 and 2.2.3.1.4 of the PSAR. SHINE has determined that external natural gas pipelines are not a hazard to the SHINE facility. There are no other utilities (*e.g.*, oil pipelines, electrical or water) in the vicinity that are expected to adversely affect the safety-related portions of the SHINE facility or the ability of safety-related SSCs to perform their safety function.

Question 36: Section 3.4.4, "Seismic Damage," of the SER, discusses the applicant's response to NRC staff RAI 3.4-6 and 3.4-9, which discussed the installation of non-safety-related seismic instrumentation.

Will the placement of the non-safety-related seismic instrumentation be within a safety-related Seismic Category I structure? If not, what is the justification for placement in an alternate structure?

SHINE RESPONSE:

SHINE has not selected the specific seismic monitoring instrumentation to be installed for the SHINE facility. Detailed information about the seismic monitoring system will be provided with the Operating License Application. The components of the seismic instrumentation that are expected to be used to characterize the actual motion that may occur in the SHINE facility will be placed within a safety-related Seismic Category I structure. In addition, a seismic monitoring system may also include "free field stations" which are, by design, placed away from large buildings or buildings with significant basements or foundations.

Any free-field stations used by SHINE would not be located within Seismic Category I structures.

<u>Question 37</u>: Will the exhaust stack (66 feet above the site grade per Section 13a.4.1) be protected from external hazards or seismic damage such that it does not affect safety-related SSCs?

<u>SHINE RESPONSE</u>:

The exhaust stack, like other nonsafety-related structures, is designed according to the 2009 International Building Code. It is not designed to the standards involving external hazards or seismic damage requirements that apply to safety-related SSCs. During final design, the effect of the failure of the exhaust stack on safety-related SSCs due to external hazards will be shown to be bounded by the tornado missile or aircraft impact evaluations, as described in Section 3.2.2.3 of the PSAR. As described in Section 3.5.2 of the PSAR, SSCs co-located with Seismic Category I systems are reviewed and supported in accordance with II over I criteria. This avoids any unacceptable interactions between SSCs. These final evaluations will be provided with the Operating License Application.

<u>Question 38</u>: PSAR Section 4a2.7.4.1, "Code Validation," states that validated and verified models will be used to model the thermal-hydraulics using Computational Fluid Dynamics (CFD) software. Section 4a2.6.2.1 states that historical data for uranyl sulfate solution systems is limited and that further validation work will be performed during the final design. Please describe the planned efforts to validate the thermal-hydraulic models.

<u>SHINE RESPONSE</u>:

For the thermal-hydraulic analysis of the target solution vessel (TSV), SHINE plans to use correlation-based methodology for safety calculations and CFD predictions for best-estimate normal operating conditions.

Computer codes used to perform the safety-basis and best-estimate thermal-hydraulic analysis will be validated. As described below, the validation process involves comparison to previous solution reactor behavior, purpose-built experimental results, and historic experimental data.

As described in the SHINE Response to RAI G-2 (ML15043A404), 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 uses a neutronics model, a thermal-hydraulic model, gas production and release effects, and a gas recombiner system model. The code can calculate solution temperature distributions and fission power for steady state and transient scenarios in aqueous nuclear systems.

LANL is validating the 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). The solution reactor comparisons include data from SUPO, SILENE, and KEWB reactors. SHINE plans to use the code to perform a portion of the transient modeling for accident and operational transients to be provided with the Operating License Application.

Transients not analyzed with the LANL code may be bounded by considering the worst case steady state conditions (*i.e.*, using hand calculations) or by using other codes, such as RELAP. Other thermal-hydraulic codes are expected to be validated using a combination of comparison to the University of Wisconsin – Madison and the Argonne National Laboratory (ANL) experiments (described below), and previous experimental studies of natural convection behavior in a similar thermal-hydraulic regime as the TSV, such as the studies by Kulacki and Emara (Reference 1) and Felde, et al. (Reference 2).

For the CFD best-estimate modeling, LANL is also supporting SHINE by performing FLUENT simulations of the natural convection behavior of the TSV and performing validation of these calculations. The CFD simulations are being compared against the thermal-hydraulic experimental data from the University of Wisconsin – Madison and the ANL experimental data. Additional comparisons are planned against data from the SUPO reactor.

Additionally, as described in the SHINE Response to RAI G-2 (ML15043A404), thermal-hydraulic experiments at the University of Wisconsin – Madison have been performed using a thermal-hydraulics test assembly designed to study the thermal-hydraulic regime applicable to SHINE (Reference 3). 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.

Another thermal-hydraulic experiment was performed by ANL, where a scanned electron beam was used to irradiate a uranyl sulfate solution in a rectangular solution vessel with cooled walls (Reference 4). The volumetric heating of the beam and the cooled walls supported similar natural convection flow to the TSV, and temperature distributions were recorded throughout the solution to support validation efforts. The recorded temperatures, solution properties, and electron beam power distribution will be used to assist with computer code validation.

The above validation efforts using solution reactor data, historic natural convection experimental data, and purpose-built experiments will ensure that the thermal-hydraulic models of the TSV adequately predict its behavior.

References:

1. Kulacki, F.A and A.A. Emara, "Steady and transient thermal convection in a fluid layer with uniform volumetric energy sources," J. of Fluid Mechanics, Vol. 83, pp. 375-395, 1977.

2. Felde D.K., H.S. Kim, and S.I. Abdel-Khalik, "Convective heat transfer correlations for molten core debris pools growing in concrete," Nuc., Eng. Design, Vol. 58, pp. 65-74, 1980.

3. Bull, G.R., "Effects of Gas Bubble Production on Heat Transfer from a Volumetrically Heated Liquid Pool," Dissertation, University of Wisconsin – Madison, 2014.

4. Chemerisov, S., et al., "Experimental Results for Direct Electron Irradiation of a Uranyl Sulfate Solution: Bubble Formation and Thermal Hydraulics Studies," ANL/NE-15/19, Argonne National Laboratory, January 30, 2015.

Question 39: PSAR Section 4a2.7.4, "Thermal-Hydraulic Methodology," states that it is thought that mixing will take place due to natural convection. In RAI 4a2.2-4, the Staff asked if there were any effects on operation if mechanical mixing is not included in the design of the TSV. In the response, SHINE stated that preliminary calculations show adequate mixing due to natural circulation flow. However, it is unclear how this flow is established. Are there, or will there be any *transient* thermal-hydraulic analyses of the TSV from startup to steady-state operation to confirm the design promotes natural convection and adequate mixing?

SHINE RESPONSE:

The target solution vessel (TSV) is internally cooled during operation via natural circulation of the target solution, augmented by the formation and movement of radiolysis gas bubbles. The TSV itself is a relatively simple, single vessel that contains the target solution. No natural circulation loop must be set up or maintained through other vessels or piping to provide cooling. The TSV external surfaces are simply directly cooled by cooling water. Heat is convected from the target solution to the vessel surfaces, conducted through the metal, and then transferred to the cooling water via forced convection. Due to the simple nature of the design, natural convection in the TSV does not require any specific system states or conditions to be established.

Transient thermal-hydraulic modeling will be performed as part of the planned coupled neutronic and thermal-hydraulic transient modeling of the TSV. The transient modeling will look at anticipated system transients, which would include normal startup of the assembly from energizing the neutron driver to steady-state operation, and ensure that the design promotes natural convection and adequate mixing. The results of the analysis will be provided with the Operating License Application.

Question 40: PSAR Section 4a2.7.4, "Thermal-Hydraulic Methodology," states that CFD software will be used for detailed thermal hydraulic design and optimization. However, the only validation presented by the applicant used University of Wisconsin-Madison experiments. These are separate effects experiments that may not capture many important aspects of the actual solution.

> **For SHINE: Does SHINE plan to perform any additional experiments to validate the codes used in the current methodology?**
>
> **For the Staff: Does the Staff have any comments about the proposed methodology?**

SHINE RESPONSE:

SHINE does not plan to perform any new, additional experiments to validate the thermal-hydraulic codes used for the analysis of the subcritical assembly. The current validation process involves comparison to previous solution reactor behavior, purpose-built experimental results, and historic experimental data. This validation process is described in detail in the SHINE Response to Question 38.

As described in that response, validation data includes data from aqueous reactors and an experiment at ANL that irradiated a representative test section of uranyl sulfate directly. This range of data ensures that enough breadth is included in the validation process to capture the important thermal-hydraulic characteristics of the solution.

<u>Question 41</u>: PSAR Section 13a2.1.2.2.3 states, "A dilution event such as this [a breach between the TSV and PCLS] is expected to lower the overall reactivity of the target solution due to the high hydrogen to uranium ratio in the target solution (target solution is over-moderated)." It is not clear if the expected malfunction is a large breach or a small leak or even if there is a limiting leak rate. The PCLS operates at a much lower temperature, and based on the limiting design conditions, water up to 108 ºF (42 ºC) cooler could be injected into the TSV during operation. Was temperature reactivity considered in the system response to a leak from the PCLS into the TSV or just the dilution effect? Is there a limiting leak rate?

<u>SHINE RESPONSE</u>:

The primary closed loop cooling system (PCLS) operates at temperatures below the temperature of the target solution in the target solution vessel (TSV). A breach between the TSV and the PCLS would result in both a dilution of the target solution and a decrease in temperature of the TSV. The dilution of the target solution has a negative feedback effect. The decrease in TSV temperature has a positive feedback effect.

While there are competing effects involved, the temperature reactivity effect has been considered in the system response to a leak from the PCLS into the TSV and the overall effect is strongly negative feedback.

First, water entering the TSV due to a breach would have a small overall effect on the bulk temperature in the TSV (*i.e.*, a liter of water would result in less than a 0.5°C change) given the temperature differential between the TSV and the PCLS and the volume of the target solution in the TSV during normal operations. The preliminary water inventory and temperature reactivity coefficients are provided in Section 4a2.6.2.4 of the PSAR. Given these reactivity coefficients, the magnitude of the reactivity effect from dilution (*i.e.*, from the water inventory coefficient multiplied by the volume of dilution) is more than an order of magnitude greater than the temperature reactivity effect (*i.e.*, from the temperature coefficient multiplied by the temperature change).

There is no limiting leak rate currently determined. PCLS water leaking into the TSV would cause a reactivity decrease as described above, regardless of leak rate.

Question 42: Please explain the determination not to apply 10 C.F.R. Part 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants to the SHINE facility.

SHINE RESPONSE:

The SHINE determination not to apply Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to the SHINE facility was based on SHINE's conclusion that applying Appendix B to 10 CFR Part 50 is not necessary to protect the public, the environment, or the workers.

10 CFR § 50.34(a)(7) requires the PSAR to include 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. Section 50.34(a)(7) only requires application of the Appendix B requirements, or a discussion of how the applicable requirements of Appendix B will be satisfied, for nuclear power plants and fuel reprocessing plants. The SHINE facility is a radioisotope production facility, and is not a nuclear power plant, nor does the SHINE facility reprocess spent nuclear fuel.

Instead, Part 1 of the ISG that augments NUREG-1537 provides guidance on the format and content of a Construction Permit Application or Operating License Application for a radioisotope production facility. Section 12.9 of NUREG-1537 and Part 1 of the ISG that augments NUREG-1537 describes the guidance contained in Regulatory Guide 2.5, "Quality Assurance Program Requirements for Research and Test Reactors," and ANSI/ANS-15.8, "Quality Assurance Program Requirements for Research Reactors," as providing an acceptable method of complying with the program requirements of 10 CFR § 50.34. SHINE has determined that ANSI/ANS-15.8 is sufficient for use in the development of the SHINE QAPD, which is applied to the design, fabrication, construction, and operation of the SHINE facility.

Question 43: Section 3.4.3, "Water Damage," of the SER states that the applicant indicated that fire suppression system discharge in one fire area will not impact safety-related SSCs in adjacent fire areas.

Please describe in detail how this would be accomplished in the design.

SHINE RESPONSE:

As described in Sections 3.3 and 3.3.1.1.2 of the PSAR, water sensitive safety-related equipment is either raised from the floor or located in flood-protective compartments to prevent the equipment from being impacted by water accumulation. These design features will prevent fire suppression system discharge in one fire area from impacting safety-related SSCs in adjacent fire areas.

Water sensitive safety-related equipment in the radioisotope production facility (RPF) and in safety-related areas outside the radiologically controlled area (RCA) is installed a minimum of 8 inches above the floor slab at grade. The minimum elevation for water sensitive safety-related equipment in the irradiation facility (IF) is 12 inches above the floor. The depth of water accumulation is based on a credible volume of discharge of the fire protection system in accordance with Section 5.10 of National Fire Protection Association (NFPA) 801, "Standard for Fire Protection for Facilities Handling Radioactive Material." The credible volume of water from fire suppression discharges and the corresponding minimum required elevations of water sensitive safety-related equipment will be validated during detailed design.

Question 46: Please discuss whether relying on the discussion in SER Chapter 13 to consider the environmental impacts of postulated accidents is consistent with the holding in *Limerick Ecology Action Inc. v. NRC*, 869 F.2d 719 (3d Cir. 1989). Does the discussion of accidents in Chapter 13 also contain a sufficient discussion of mitigation measures to satisfy *Robertson v. Methow Valley Citizens Council*, 490 US 332 (1989)?

SHINE RESPONSE:

Section 19.4.11 of the PSAR provides SHINE's evaluation of the environmental impacts of postulated accidents. That section includes consideration of the Maximum Hypothetical Accident (MHA), which is defined as an event that results in radiological consequences that exceed those of any accident considered to be credible. The MHA is used to demonstrate that the maximum consequences of an accident at the SHINE facility are within the acceptable regulatory limits of 10 CFR § 20.1301. Thus, because the consequences are within the regulatory dose limits, the impacts are SMALL (See definition of SMALL in Final Environmental Impact Statement (FEIS) Section 1.4).

FEIS Section 4.11 provides the staff's review of the environmental impacts of potential radiological accidents at the SHINE facility. Section 4.11 relies upon information provided by SHINE from its environmental review. The FEIS repeats SHINE's conclusion that the calculated doses for the MHA would be within the annual dose limits in 10 CFR § 20.1301 to a member of the public, and concludes that this would result in impacts from potential radiological accidents that are SMALL. However, the FEIS states that the NRC staff was conducting an independent review of the MHA as part of the SER.

The above evaluation of the environmental impacts of postulated accidents is consistent with the holding in *Limerick Ecology Action Inc. v. NRC*, 869 F.2d 719 (3d Cir. 1989). In

Limerick Ecology, the Third Circuit held that a finding of adequate protection under the Atomic Energy Act of 1954, as amended (AEA), does not preclude consideration of the same issue under the National Environmental Policy Act (NEPA). The FEIS is consistent with that holding. The FEIS does not preclude an evaluation of the environmental impacts of postulated accidents under NEPA based on the consideration of those accidents in SER Chapter 13. Rather, the FEIS fully considers the environmental impacts of postulated accidents, and concludes that the calculated doses of the MHA would be within the regulatory limits, which results in SMALL impacts from potential radiological accidents. Nonetheless, the FEIS accurately states that the staff was still considering the MHA as part of the safety review. That review is now complete. The staff has issued SER Chapter 13, which concludes that SHINE's preliminary analysis of the MHA is sufficient and meets applicable regulatory requirements.

Additionally, the FEIS's consideration of mitigation measures satisfies *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332 (1989). In *Methow Valley*, 490 U.S. at 351-52, the U.S. Supreme Court held that NEPA requires a "reasonably complete discussion of possible mitigation measures" for "adverse environmental consequences," but that there is no "substantive requirement that a complete mitigation plan be actually formulated and adopted." As discussed above, the FEIS concluded that the potential impacts from postulated accidents are SMALL, because the doses from the MHA would be within regulatory limits. In other words, the potential impacts are not "adverse," and therefore do not require mitigation.

Nonetheless, although SER Chapter 13 considers the design of the SHINE facility to mitigate against the consequences of accidents, Section 19.4.11 of the PSAR and FEIS Section 4.11 also discuss mitigation of postulated accidents. For example, the FEIS explains that "the radiation effects of this MHA would be mitigated by several controlling mechanisms, including confinement provided by the irradiation unit cell's exterior walls; confinement by the RCA ventilation system; radiation monitoring; shielding of the pipe penetrations; and the collection of gas, vapor, or particulates by the TSV off-gas system." Therefore, even if required, the FEIS provides a reasonably complete discussion of possible mitigation measures, as discussed in *Methow Valley*.

<u>Question 47</u>: Section 5.3 of the EIS analyzes the environmental impacts from alternative technologies. After identifying three technologies as reasonable alternatives, the EIS states that there is only sufficient information available to analyze the environmental impacts from one of those technologies in depth.

a. Describe in more detail how the Staff and SHINE identified which technologies were reasonable alternatives and how they determined whether there was sufficient information available to do a more in-depth environmental review.

b. Why did the Staff not include any of the technologies currently being used in other countries to produce molybdenum-99 as a reasonable alternative?

<u>SHINE RESPONSE</u>:

a. As described in Section 19.5.2.2 of the PSAR, in early 2013 when the analysis was performed, the DOE had provided support to SHINE and three additional technologies for the domestic production of medical isotopes. The DOE conducted a rigorous technical review of proposed technologies for producing molybdenum-99 (Mo-99) domestically before selecting its four cooperative agreement partners. The DOE intentionally chose four distinct technologies to support. Rather than repeat this selection process for the purpose of this section, the three other DOE cooperative agreement partner technologies were selected as the alternative technologies to be considered in this section.

The three technologies considered were:

- Linear accelerator-based technology (for production of Mo-99 only).
- Neutron capture using existing power reactors (for production of Mo-99 only).

- Low enriched uranium (LEU) aqueous homogenous reactors.

Each of these technologies was evaluated to determine if they could be reasonably implemented at the Janesville site. While both an aqueous homogeneous reactor and linear accelerator facility could conceivably be built at the SHINE site, there is no power reactor at the site. As a result, neutron capture in an existing power reactor was considered unreasonable for the purpose of this section and eliminated from the list.

The two remaining technologies were considered reasonable alternatives to the SHINE technology for the Janesville site and were evaluated in the PSAR.

Based on publically available information on the alternative technologies, SHINE determined that there was sufficient information available to evaluate the major environmental impacts associated with construction and operation of the alternative technologies at the SHINE site.

b. The vast majority of Mo-99 is produced today using solid targets irradiated in multipurpose research reactors. SHINE did not include this technology as a reasonable alternative because it was not selected for support by the DOE.

Question 48: Did the non-finalized nature of the design impact the preparation of the environmental documents for this proceeding? If so, how? Will the final environmental documents for the Operating License consider whether the finalized design creates any new environmental impacts or modifies any of the significance determinations reached in the EIS?

SHINE RESPONSE:

The design of the facility was sufficiently advanced to allow the determination of the impact of the proposed action on the environment, any adverse environmental effects which cannot be avoided should the proposal be implemented, alternatives to the proposed action, the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented. The design of the facility was sufficient to support an analysis that considered and balanced the environmental effects of the proposed action, the environmental impacts of alternatives to the proposed action, and alternatives available for reducing or avoiding adverse environmental effects. In instances where the non-finalized state of the design did not provide specific inputs for the analysis of the proposed action, conservative and/or bounding estimates were made to allow the determination of the impact of the proposed action on the environment. The state of the design also supported the identification of all Federal permits, licenses, approvals and other entitlements which must be obtained in connection with the proposed action.

Consistent with the requirements of 10 CFR § 51.95(b), a Supplemental Environmental Impact Statement at the initial Operating License stage is anticipated, which will update the environmental review conducted during the review of the SHINE Construction Permit Application. The supplement will only cover matters that differ from the FEIS or that reflect significant new information concerning matters discussed in the FEIS.

Consistent with the requirements of 10 CFR § 51.53(b), SHINE will provide a supplement to the Environmental Report with the Operating License Application, which will discuss only different and/or new information that has become available since the publication of the FEIS. The NRC staff will use the information provided in the supplement to the Environmental Report to prepare the Supplemental Environmental Impact Statement.

Question 54: Did SHINE propose any novel review approaches in the environmental portion of its application? How did the Staff address these approaches?

SHINE RESPONSE:

The SHINE Environmental Report follows the content and organization of the Final ISG that augments NUREG-1537, Part 1, Chapter 19, and did not propose any novel review approaches.

Question 60: EIS Table B-4 states that Federal Aviation Administration (FAA) Form 7460-1 will be resubmitted in 2015. What is the status of the FAA's review of Form 7460-1? What is the status of the other environmental permits that must still be applied for?

SHINE RESPONSE:

Federal Aviation Administration (FAA) Form 7460-1 was submitted on October 26, 2011, and a determination that the structure does not exceed obstruction standards and would not be a hazard to air navigation was received from the FAA on November 9, 2011. This determination expired on November 7, 2014. As shown in the table below, SHINE currently plans to resubmit FAA Form 7460-1 in 2016.

The table below also provides an update to EIS Table B-4 with the status of the other environmental permits for which SHINE must still apply. This update reflects SHINE's current plans for the project.

Permits and Approvals Required for Construction and Operation

Agency	Regulatory Authority	Permit or Approval	Summary of Activities	Expected Timeframe Of Receipt	Status
Permits and Approvals from Federal Agencies					
NRC	Atomic Energy Act 10 CFR 50.50 and 10 CFR 50.35	Construction Permit	Construction of the SHINE facility	2015–2016	Preliminary Safety Analysis Report for the construction permit was submitted in 2013.
	Atomic Energy Act 10 CFR 50.57	Operating License	Operation of the SHINE facility	2018	
	Atomic Energy Act 10 CFR Part 40	Source Material License	Possession, use, and transfer of radioactive source material	2018	

Agency	Regulatory Authority	Permit or Approval	Summary of Activities	Expected Timeframe Of Receipt	Status
	Atomic Energy Act 10 CFR Part 30	By-Product Material License	Possession, use, and transfer of radioactive by-product material	2018	
	Atomic Energy Act 10 CFR Part 70	Special Nuclear Material License	Receipt, possession, use, and transfer of special nuclear material	2018	
FAA	Federal Aviation Act	Construction Notice FAA Form 7460-1	Construction of structures that could affect air navigation	2016	FAA Form 7460-1 was submitted in 2011; Determination of No Hazard was received 11/2011; Determination of No Hazard extension was received 04/2012; Determination of No Hazard expired 11/2014; SHINE plans to resubmit FAA Form 7460-1 in 2016.
		Construction Notice FAA Form 7460-2	Construction of structures that could affect air navigation	2018	SHINE intends to submit FAA Form 7460-2 within 5 days of when construction reaches its greatest height.
EPA	CWA, 40 CFR Part 112, Appendix F	Spill Prevention, Control and Countermeasure (SPCC) Plan for Construction and Operation	Storage of oil during construction and operation	2016	SHINE intends to develop the SPCC plan in 2016.
DOT	Hazardous Material Transportation Act, 49 CFR Part 107	Certificate of Registration	Transportation of hazardous materials	2019	SHINE intends to submit DOT Form F-5800.2 Q1 in 2019.
Permits and Approvals from State Agencies					

Agency	Regulatory Authority	Permit or Approval	Summary of Activities	Expected Timeframe Of Receipt	Status
WDNR	Federal CAA; Wisconsin Statutes, Chapter 285; Wisconsin Administrative Code, Chapter NR 406	Air Pollution Control Construction Permit; Air Pollution Control Operation Permit	Construction of an air pollution emissions source that is not specifically exempted	2017	SHINE intends to submit an application for a Type A Registration Construction Permit and Operation Permit in 2017.
	Federal CWA; Wisconsin Statutes, Chapter 283; Wisconsin Administrative Code, Chapter NR 216	Construction Storm Water Discharge Permit	Discharge of stormwater runoff from the construction site	2017	SHINE intends to submit a Water Resource Application for Project Permits to request coverage under a General Permit in 2017, at least 14 working days before construction begins.
	Federal CWA; Wisconsin Statutes, Chapter 283; Wisconsin Administrative Code, Chapter NR 216	Industrial Storm Water Discharge Permit	Discharge of stormwater runoff from the site during facility operation	2019	SHINE intends to submit a No Exposure Certification at least 14 working days before initiation of operations in 2019.
	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	2016	A permit is 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	2018	SHINE intends to notify WDNR of Storage and Treatment Conditional Exemption (NR 666, Subchapter N) in 2018 or within 90 days of low-level mixed waste generation.

Agency	Regulatory Authority	Permit or Approval	Summary of Activities	Expected Timeframe Of Receipt	Status
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	2017	SHINE intends to submit the Building Plan in 2017.
Wisconsin DOT	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	2017	SHINE intends to request the permit simultaneously or before the submission of the Site Plan in 2017.
	Wisconsin Statutes, Chapter 85; Wisconsin Administrative Code, Chapter Trans 231	Right-of-Entry Permit	Construction by the City of Janesville of utility extensions across U.S. Route 51	2016	The permit is 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	2017	SHINE does not anticipate that this variance will be needed based on the refined building and stack heights developed during the Preliminary Design.
Permits and Approvals from Local Agencies					
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, and similar local issues	2017	SHINE intends to submit Site Plan and building elevations in 2017.
	City of Janesville Ordinance 15.06.070	Stormwater Plan Approval (may be included in Site Plan Approval)	Administrative approval of grading and drainage plans	2017	SHINE intends to submit Stormwater Management Plan with Site Plan in 2017.
	City of Janesville Ordinance 15.05.080	Erosion Control Permit (may be included in Site Plan Approval)	Administrative approval of erosion control plans	2017	SHINE intends to submit the Erosion Control Plan with the Site Plan in 2017.

Agency	Regulatory Authority	Permit or Approval	Summary of Activities	Expected Timeframe Of Receipt	Status
	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	2018	Construction and installation will be approved in the Plumbing Plan. For operation, SHINE intends to provide baseline monitoring report to wastewater treatment plant at least 90 days before discharge in 2018.
	City of Janesville Ordinance 15.01.100.A	Plumbing Plan Approval	Installation of plumbing systems	2017	SHINE intends to submit the Plumbing Plan with the Building Plan in 2017.
	City of Janesville Ordinance 15.04.010.A	HVAC Plan Approval	Installation of HVAC systems	2017	SHINE intends to submit the HVAC Plan with the Building Plan in 2017.
	City of Janesville Ordinance 8.32.010	Fire Sprinkler and Alarm Permit	Installation of sprinkler and alarm systems	2017	SHINE intends to submit the Fire Sprinkler and Alarm Plan with the Building Plan in 2017.
	City of Janesville Ordinance 15.01.100.A	Building Permit	Construction of buildings	2017	SHINE intends to submit the Building Plan in 2017.
	City of Janesville Ordinance 15.01.190.A	Occupancy Permit	Occupancy of completed buildings	2018	Each building would be inspected after construction to allow occupancy.
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	2017	Plans and specifications will be submitted by the City of Janesville once the Site Plan is approved, likely in 2017.

<u>Question 61</u>: Does SHINE and/or the Staff have a general estimate of the volume of solid radioactive waste expected to be generated over a year? Does SHINE expect that it will have adequate space to store the waste? Is it reasonably foreseeable that any of the

proposed waste disposal pathways will not be available and, if so, how has the Staff addressed this in its impacts analysis?

SHINE RESPONSE:

A general estimate of the volume of solid radioactive waste expected to be generated over a year is provided in Table 9b.7-7 of the PSAR. The total "volume as shipped" included in this table is approximately 12,000 cubic feet, which includes solidified liquid waste.

SHINE expects to have adequate space to temporarily store the waste prior to shipment in shielded storage areas in the SHINE facility and in the Waste Staging and Shipping Building. The Waste Staging and Shipping Building has the approximate dimensions of 50 ft. by 100 ft. The exact dimensions of the Waste Staging and Shipping Building will be provided with the Operating License Application.

SHINE anticipates the ultimate disposal sites for radioactive waste will be the EnergySolutions facility in Clive, Utah, and the Waste Control Specialists facility in Andrews, Texas. Small amounts of organic waste will also be sent to the Diversified Scientific Services, Inc. facility in Kingston, Tennessee. SHINE has had discussions with representatives from these facilities and anticipates that these waste disposal pathways or a future alternative commercial disposal pathway will be available. Additionally, a provision of the American Medical Isotopes Production Act of 2012 (42 U.S.C. 2065(c)(3)(A)(ii)) states that the DOE shall take title to, and be responsible for, the final disposition of radioactive waste created by the irradiation, processing, or purification of uranium leased from DOE if it determines that the producer (*e.g.*, SHINE) does not have access to a disposal path.

Question 62: Section 2.7.1.2 of the EIS states that there will be a GTCC waste stream. In the absence of a disposal pathway for GTCC, would the GTCC waste created by SHINE remain on site?

SHINE RESPONSE:

In the absence of a disposal pathway, greater than Class C (GTCC) waste is not expected to remain on site at the SHINE facility. SHINE is pursuing the option of contracting with Waste Control Specialists to store GTCC waste if it is generated at the SHINE facility. Waste Control Specialists is currently licensed to store GTCC waste.

Additionally, a provision of the American Medical Isotopes Production Act of 2012 (42 U.S.C. 2065(c)(3)(A)(ii)) states that the DOE shall take title to, and be responsible for, the final disposition of radioactive waste created by the irradiation, processing, or purification of uranium leased from DOE if it determines that the producer (*e.g.*, SHINE) does not have access to a disposal path.

Question 66: Please discuss in more detail why the "preliminary license amendment request process" included as Appendix B to the draft Construction Permit is necessary for a construction permit. The process was developed for combined licenses, in part, because of the specificity of information in a combined construction permit and operating license.

a. When only a construction permit is issued, is this process necessary?

b. Further, the preliminary license amendment request process includes a 50.59-like change process (B-3). Why was this standard chosen as the appropriate change process?

c. In implementing this process, does the Staff intend to use COL-ISG-025, or will it create new guidance?

SHINE RESPONSE:

a. The draft Construction Permit (ML15272A009) for the SHINE facility included three proposed conditions (3.D(2), 3.D(3), and 3.D(4)) and an Appendix B that addressed a preliminary amendment request (PAR) process and a screening and evaluation process for changes during construction. The PAR process is not necessary for a Construction Permit. Construction under a Construction Permit should result in the need for very few, if any, amendments. SHINE understands that Construction Permits for earlier power reactors resulted in relatively few amendments during construction, and those amendments typically addressed non-design issues, such as ownership or expiration dates.

Based on this past NRC precedent involving Construction Permit amendments, SHINE recommends the proposed conditions 3.D(2) and 3.D(3) and the entirety of Appendix B be removed from the Construction Permit for the SHINE facility (and proposed condition 3.D(4) be modified accordingly).

b. SHINE concludes that the 50.59-like change process in Appendix B of the draft Construction Permit does not provide the appropriate threshold for determining whether a Construction Permit amendment is needed. In this regard, the change control process under 10 CFR § 50.59 does not apply to Construction Permits. Previous holders of Construction Permits have not been subject to a 50.59-like change process. In fact, the NRC regulations themselves do not specifically require amendments to Construction Permits unless, pursuant to 10 CFR § 50.90, the Construction Permit holder "desires to amend the license or permit." SHINE believes the NRC's decision to apply 10 CFR § 50.59 to holders of an Operating License and not holders of a Construction Permit was deliberate and reflects the differences in the level of design development between a Construction Permit and an Operating License, and the nature of the two-step licensing process. In that regard, it is anticipated that a holder of a Construction Permit will develop its design during construction, and that the final design will be subject to review and approval by the NRC during the Operating License proceeding, thus obviating any need for NRC review and approval of individual design changes during construction. In contrast, an Operating License holder has a final, as-built design, and it is appropriate to apply a process such as 10 CFR § 50.59 to changes in such designs.

SHINE also notes that there is no requirement to maintain the PSAR in the same manner as an FSAR for operating plants. The absence of any requirement for a Construction Permit holder to maintain or update its PSAR during construction provides another reason not to apply a 50.59-like change process to Construction Permit holders.

Finally, application of a 50.59-like change process likely would result in a significant burden to both SHINE and the NRC. Given the numerous design changes that typically occur during construction of a Part 50 facility, SHINE likely would need to evaluate numerous design changes under a 50.59-like process, which would be very resource intensive. Additionally, such a process could require SHINE to seek numerous amendments to a Construction Permit, resulting in potential delay in construction and expenditure of substantial NRC resources to process the amendment applications. All of these expenditures are unnecessary, because the FSAR will identify the final design and will be subject to NRC review and approval at the Operating License stage.

For these reasons, SHINE respectfully requests that a 50.59-like change process not be included in the Construction Permit for the SHINE facility. This would result in SHINE proceeding through construction in the same manner as earlier power reactor projects constructed under Construction Permits. SHINE still would be subject to inspection by the NRC. SHINE will carefully evaluate and manage design changes through its configuration management process. The NRC also will be able to evaluate the final design once SHINE submits the Operating License Application and the FSAR.

c. As stated in response to part "a" above, SHINE recommends that the PAR process be removed from the Construction Permit for the SHINE facility.

Respectfully submitted,

<u>Executed in Accord with 10 CFR § 2.304(d)</u>

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Counsel for SHINE Medical Technologies, Inc.

Dated in Washington, D.C.
this 8th day of December 2015

CERTIFICATION AND DECLARATION OF WITNESS

I certify that SHINE's responses to the Commission's questions were prepared by me or under my direction; that the responses are true and correct to the best of my information, knowledge and belief; and that I adopt these responses as part of my sworn testimony in this proceeding.

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

Executed on December 8, 2015.

Executed in Accord with 10 CFR § 2.304(d)

/s/ James Costedio

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