Corrected 12/8/15

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE COMMISSION

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| In the Matter of | ) | |
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| SHINE MEDICAL TECHNOLOGIES, INC. | ) | Docket No. M-50-608-CP |
| | ) | |
| (Medical Radioisotope Production Facility) | ) | |
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NRC STAFF RESPONSES TO COMMISSION PRE-HEARING QUESTIONS

Pursuant to the Commission Order (Transmitting Pre-Hearing Questions), dated November 10, 2015, the U.S. Nuclear Regulatory Commission (NRC) staff (Staff) hereby files its responses to the questions posed to the Staff by that Order.

Respectfully submitted,

***/Signed (electronically) by/***

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**Executed in accord with 10 CFR 2.304(d)**

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Dated at Rockville, Maryland
this 24th day of November, 2015

## NRC STAFF RESPONSES TO COMMISSION PRE-HEARING QUESTIONS

**1. Please explain how the Staff determined the aspects of the facility design that were necessary to be analyzed before a construction permit could be granted and those that could be reserved for the Staff's review of the operating license application. Please highlight aspects of the review that were unclear and/or challenging for the Staff in this regard and describe the bases for the Staff's decisions in these instances.**

**Staff Response:** The Staff determined the aspects of the facility design to be evaluated in a construction permit review based on the required content of a 10 CFR Part 50 construction permit application, applicable guidance for non-power production and utilization facilities, and the findings required by 10 CFR 50.34(a). As required by 10 CFR 50.34, a construction permit application must include the following related to the design of the facility:

- The preliminary design of the facility, including principal design criteria, design bases, general arrangement, and approximate dimensions,
- A preliminary analysis of structures, systems, and components, including ability to prevent and mitigate accidents,
- An identification of ongoing research and development.

Title 10 of the Code of Federal Regulations, Paragraph 50.35(a) further provides that if an applicant does not provide all of the technical information to support issuance of a construction permit that approves all proposed design features, the Commission may issue the permit if the applicant "has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design and has identified major features and components incorporated therein for the protection of the health and safety of the public." Thus, 10 CFR sections 50.34 and 50.35 contemplate preliminary information and analysis and identify subjects an applicant must cover in its preliminary safety analysis report (PSAR) (e.g., preliminary design).

The Staff first confirmed that information was provided on each of these areas in SHINE's PSAR. The Staff also reviewed those items that SHINE deferred providing many details on until the submission of its final safety analysis report (FSAR) with its operating license application to ensure the construction permit application met the applicable regulations and guidance. For example, SHINE deferred providing many details on its design. The Staff evaluated the sufficiency of the SHINE preliminary design, as described in the PSAR, based on SHINE's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases and allow adequate margin for safety. Importantly, as indicated by 10 CFR 50.35(b), the Staff's evaluation of SHINE's preliminary design does not constitute approval of any design feature or specification. Such approval would be made following the evaluation of SHINE's final design and analysis submitted in support of SHINE's operating license application.

Given the similarities in the SHINE facility and existing non-power research reactors (e.g., decay heat generation, inherent negative reactivity feedback, etc.) and some fuel cycle facilities (e.g., margin of subcriticality, chemical processes, etc.), the Staff primarily relied on the guidance provided in NUREG-1537, Parts 1 and 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors" and the Interim Staff Guidance (ISG) Augmenting

NUREG-1537, Parts 1 and 2, for its review of the SHINE PSAR to inform its determinations regarding which design aspects should be evaluated before issuance of a construction permit.

An aspect of the review the Staff found challenging was criticality safety in the SHINE radioisotope production facility. The Staff reviewed the acceptance criteria in Chapter 6 of the ISG Augmenting NUREG-1537 to determine which criteria were applicable to design and construction and which criteria were applicable to operation of the facility. In particular, the Staff focused on passive engineered features of the facility and process that could not readily be changed once construction was complete. Design criteria for criticality safety included having a validated criticality code, an acceptable minimum margin of subcriticality, and conservative margin, to ensure the facility and process will be designed to be subcritical under normal and credible abnormal conditions, commitments to ensure compliance with the double contingency principle, and provision for a criticality accident alarm system.

The most challenging aspect of the criticality review was ensuring a properly benchmarked criticality code with sufficient margin to ensure subcriticality, given the relative lack of critical benchmarks for the chemical forms and enrichments expected at the facility, as described in Section 6b.4.5 of the Staff's safety evaluation report (SER). As described in SHINE's response to RAI 6b.3-24, SHINE proposed additional margin and to submit criticality evaluations as they were completed during the construction phase.

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?**

**__Staff Response__:** The Staff reviewed SHINE's application to construct its medical isotope production facility, which includes both utilization facilities and a production facility, under every applicable section of 10 CFR Part 50. In doing its review, the Staff identified provisions of 10 CFR Part 50 that only apply to reactors or power reactors, and therefore do not apply to SHINE's proposed facility, which does not include a reactor.

The Staff did not identify any Part 50 regulations that applied to SHINE's proposed facility that SHINE did not address for purposes of issuing a construction permit. Instead, the Staff found that SHINE's application satisfied applicable regulatory requirements for issuing a construction permit pursuant to 10 CFR Part 50. Therefore, SHINE did not request, and the Staff did not find it necessary to issue, exemptions from the 10 CFR Part 50 regulations that apply to construction permits.

    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?"**

**Staff Response:** As stated on page 1-5 of the Staff's SER, 10 CFR 50.34(a)(3)(i) requires that SHINE describe the principal design criteria for its facility in the PSAR. Because SHINE is not a power reactor, SHINE is not required to follow 10 CFR Part 50, Appendix A, "General Design Criteria [GDCs] for Nuclear Power Plants," which expressly applies only to nuclear power reactors. As stated in the introduction of 10 CFR Part 50, Appendix A, GDCs establish minimum requirements for water-cooled nuclear power plants and are considered to be generally applicable to other types of nuclear power units. Because SHINE has informed the preliminary design of some of its structures, systems, and components (SSCs) based on several of the GDCs, the Staff based its review of SHINE's proposed principal design criteria, in part, on the GDCs SHINE identified.

The Staff considered SHINE's use of all 55 GDCs listed in Appendix A to 10 CFR Part 50. The Staff's evaluation of SHINE's application of GDCs to its facility design was based, in part, on the details provided in Tables 3.5a-1 "Appendix A to 10 CFR 50 General Design Criteria Which Have Been Interpreted As They Apply to the SHINE Irradiation Facility," and 3.5b-1 "Baseline and General Design Criteria for Radioisotope Production Facility," which describe SHINE's application of all 55 GDCs to the design of its facility.

The Staff's listing of considered GDCs on page 1-5 is representative of the list of general design criteria considered in the design of the SHINE instrumentation and control systems, as described in Tables 7a2.2-2, "[Irradiation Facility] Verification Matrix Design Criteria, Bases, Description" and 7b.2-2 "[Radioisotope Production Facility] Verification Matrix Design Criteria, Bases, Description" of the SHINE SER. In this context, while SHINE does not have a containment feature, GDC 16 requires, in part, that the facility "establish an essentially leak-tight barrier against the uncontrolled release of radioactivity to the environment…." As such, SHINE's engineered safety feature actuation system monitors radioactivity in the irradiation units and target solution vessel off gas system shielded cells, initiating process shutdown and isolation in the event that predetermined radiation levels are exceeded.

SHINE and the Staff did consider GDC 1. GDC 1 provides that a quality assurance program be established and implemented to provide assurance that structures, systems and components will satisfactorily perform their safety function. The Staff evaluated SHINE's quality assurance program, as described in Appendix 12C of the SHINE preliminary safety analysis report, in Chapter 12 of its SER. SHINE's description and the Staff's evaluation of SHINE's quality assurance program are comprehensive of the entire facility.

The list of GDCs applied to SHINE's instrumentation and control systems in Chapter 1 of the Staff's SER contains errors. The statement in question on page 1-5 of the Staff's SER should be clarified and revised as follows:

> As required by 10 CFR 50.34(a)(3)(i), SHINE must describe the principal design criteria for its facility in the PSAR; however, SHINE is not required to follow 10 CFR Part 50, Appendix A, "General Design Criteria [GDCs] for Nuclear Power Plants," which applies only to nuclear power reactors. Nonetheless, SHINE has applied the GDCs to the preliminary design of its facility, as appropriate. As such, the Staff based its review of SHINE's principal design criteria, in part, on SHINE's application of GDCs, as described in Tables 3.5a-1 "Appendix A to 10 CFR 50 General Design Criteria Which Have Been Interpreted As They Apply to

the SHINE Irradiation Facility," and 3.5b-1 "Baseline and General Design Criteria for Radioisotope Production Facility," of the SHINE PSAR.

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

**Staff Response:** The Staff reviewed SHINE's proposed design and determined that the proposed irradiation units were similar to existing non-power research reactors while the proposed radioisotope production facility was similar to existing fuel cycle facilities. Therefore, the Staff primarily relied on the guidance in NUREG-1537, Parts 1 and 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors" for its review of the irradiation units described in SHINE's preliminary safety analysis report. The Staff also applied the guidance in its Final Interim Staff Guidance (ISG) Augmenting NUREG-1537 for licensing radioisotope production facilities and aqueous homogeneous reactors. The ISG contains the technical guidance for reviewing SHINE's irradiation units and radioisotope production facility. Additionally, the ISG provides for the usage of additional guidance (e.g., NUREGs, NRC regulatory guides, and American National Standards Institute/American Nuclear Society [ANSI/ANS] standards) in the review of aqueous homogeneous facilities and radioisotope production facilities. The Staff found SHINE's proposed use of guidance to be acceptable if such use met applicable acceptance criteria and demonstrated compliance with regulations.

Because the acceptance criteria in NUREG-1537 and ISG do not distinguish between criteria applicable to a construction permit review versus the review of a final design in support of an operating license application, the Staff used its judgment, informed by regulatory requirements and the detail provided in the application, in deciding which acceptance criteria should be used for the review of a construction permit. For example, per 10 CFR 50.34(a)(5), a construction permit applicant need only identify probable subjects of technical specifications. Thus, acceptance criteria related to establishing technical specifications were not used for review of SHINE's construction permit application. Also, as described in response to Question 1, with respect to the Staff's criticality safety review, Staff reviewed the acceptance criteria in Chapter 6 of the ISG Augmenting NUREG-1537 to determine which criteria were applicable to design and construction and which criteria were applicable to operation of the facility. In particular, the Staff focused on passive engineered features of the facility and process that could not readily be changed once construction was complete.

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?**

**Staff Response:** No, an exemption from the definition of safety-related SSCs in 10 CFR 50.2 is not needed for SHINE because the portions of the definition that SHINE altered expressly apply only to nuclear power reactors. The direct final rule modifying the definition of safety-related SSCs issued on September 8, 1997 (62 Federal Register (FR) 47268), states that the NRC is "amending its regulations to correct an error in the language of several sections in the regulations governing nuclear power plant licensing that define the term, 'safety-related structures, systems, and components.'" In this *Federal Register* notice, the history of this term is explored and connected to several regulations that only apply to nuclear power reactors, such as Appendix B to 10 CFR Part 50, 10 CFR 50.49, and 10 CFR Part 100 Appendix A (62 FR 47268-9).

Further, the first definition of "basic component" in 10 CFR 21.3, which explicitly applies only to nuclear power reactors, uses the 10 CFR 50.2 definition of "safety-related structures, systems, and components." The third definition of "basic component" in 10 CFR 21.3 addresses SSCs that are important to safety at Part 50 facilities other than nuclear power plants. This implies that while all 10 CFR Part 50 facilities have SSCs that are important to safety, the formal definition of "safety-related structures systems and components" only applies to nuclear power plants. Although the regulations lack an explicit definition of SSCs important to safety at production facilities or non-power utilization facilities, Staff guidance [e.g., NUREG-1537] indicates that appropriate SSCs should be in place to protect the public health and safety. As such, non-power facility licensees and applicants may propose their own definition of "safety-related structures, systems, and components" without seeking an exemption. Thus, SHINE developed its own facility-specific definition of safety-related SSCs, as discussed in Section 3.5.1.1.1, "Safety-related SSCs," of the SHINE PSAR. And, as documented in Section 3.4.5 of its SER, the Staff finds this definition acceptable.

This aspect of the review is consistent with the Staff's licensing of existing research reactors: In particular, the Staff has not applied the 10 CFR 50.2 definition of "safety-related structures, systems, and components" to research reactors and has not granted exemptions from the 10 CFR 50.2 definition of safety-related SSCs in licensing such facilities. As discussed above, the definition applies to nuclear power plants, and thus does not apply to research reactors.

**3. 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>Staff Response</u>:** The regulatory commitments in Appendix A of the Staff's SER are based on information that SHINE provided in responses to Staff requests for additional information (RAIs) during the review. SHINE committed to provide this information in its final safety analysis report (FSAR) submitted at the operating licensing stage. The Staff reviewed SHINE's responses in accordance with 10 CFR 50.35. The Staff determined that the information was not necessary to meet the requirements of 10 CFR 50.34 and, therefore, may reasonably be left for later consideration as part of SHINE's FSAR. As such, this information is not necessary to support the issuance of the SHINE construction permit. As described in its response to RAIs, SHINE is tracking the status of these items through its Issues Management Report (IMR) System. The Staff is independently tracking these items as regulatory commitments in Appendix A of its SER and will verify their implementation during the review of a future SHINE operating license application.

**4. 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>Staff Response</u>:** In its October 15, 2015 letter, the ACRS raised the following topics as issues that must be addressed at the operating license stage: 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. Each of these topics was discussed with both SHINE and the Staff during the ACRS subcommittee and full committee meetings on June 23, June 24, August 19, September 22, and October 8, 2015.

The Staff agrees that these issues must be addressed at the operating license stage. In responses to requests for additional information, SHINE has committed to provide information on topics related to those raised by the ACRS such as criticality control and margin, confinement isolation, systems that provide support to safety-related systems, electrical isolation requirements, hydrogen concentration measurements, and chemical source terms and concentrations. These commitments appear in Appendix A.2, "Regulatory Commitments Identified in Response to Requests for Additional Information," in the SER. In Chapter 12 of the SHINE PSAR, SHINE stated that it would prepare, review, and approve written procedures related to the "maintenance of major components of systems that may have an effect on nuclear safety."

Importantly, both the ACRS and the Staff determined that SHINE provided sufficient information on each of these topics to support the issuance of a construction permit.

**5. 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.**

**Staff Response:** The underlying reasoning for the selection of the Maximum Hypothetical Accident (MHA) for the irradiation facility is that it represents a complete loss of inventory of a target solution vessel into an irradiation unit. The source term for the MHA results from a non-mechanistic large rupture of the target solution vessel with no credit taken for pool scrubbing.

A realistic failure for the primary system boundary would involve a slower release of the source and a smaller release to the environment before the cell was isolated. For example, the "TSV or Dump Tank Leak Into the Light Water Pool" scenario is an accident that uses more realistic assumptions for the release of the target solution into the pool. The "Dump Tank Leak Into the IU Cell" scenario is an accident that uses more realistic assumptions for releasing the target solution into the irradiation unit gas space. The "Failure of the TOGS" scenario is an accident that uses more realistic assumptions for releasing the radioactive gases inside the primary system boundary into the TOGS shielded cell. These scenarios are bounded by the results from the MHA.

**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.**

**Staff Response:** Based on the information in SHINE's application and responses to RAIs, the Staff determined that the irradiation units, including the target solution vessel, have been designed to withstand any events (e.g., tornado, seismic, or man-made external events) that could cause multiple target solution vessels to fail simultaneously. Additionally, the Staff determined that the robust design of the irradiation units would not allow the failure of a single TSV to cause the failure of another TSV.

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.**

**Staff Response:** SHINE's application shows that the irradiation units, including the target solution vessel, have been designed to withstand any events (e.g., tornado, seismic, or man-made external events) that could cause multiple target solution vessels to fail simultaneously. Additionally, the robust design of the irradiation units would not allow the failure of a single TSV to cause the failure of another TSV. One event that affects all irradiation units is the loss of electrical power to all units. However, the irradiation unit bubble tight dampers will fail closed if there is a loss of electrical power so the release will be largely confined to the irradiation unit. SHINE has identified no dose consequences to either the public or workers from this event. As there are no dose consequences to the event affecting multiple irradiation units simultaneously, it is not necessary to analyze an MHA that could affect multiple units.

7. **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.**

**Staff Response:** Pursuant to 10 CFR 50.34(a)(5), a construction permit applicant need only identify probable subjects of technical specifications. SHINE has identified filters as a probable subject of technical specifications in Table 14a-2-1 of the PSAR, citing its accident analyses as the basis for this decision. However, SHINE's application did not 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. Per 10 CFR 50.34(b)(6), the Staff will review such details (e.g., specific technical specifications, testing requirements, and controls) at the operating license stage when there is actual hardware and the configuration and capabilities of the filtration units are final.

8. **The dispersion coefficients used in the dose consequence accident analyses appear to be based on the 50$^{th}$ 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.**

**Staff Response:** Given the similarities between the SHINE facility and existing non-power research reactors and some fuel cycle facilities, the Staff primarily relied on the guidance provided in NUREG-1537, Parts 1 and 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors" and the Interim Staff Guidance Augmenting NUREG-1537, Parts 1 and 2, for its review of the SHINE PSAR. As such, the Staff reviewed SHINE's dose consequence analysis consistent with the guidance in Chapter 13 of NUREG-1537, which does not specify the use of 95th percentile values. Chapter 13 of NUREG-1537, Part 2 states that the dose calculation methods used for the accident analysis doses are no less conservative than those used for calculating the Chapter 11 doses. Additionally, SHINE has stated that it will use age-dependent dose conversion factors for the operating license dose calculations in place of the ICRP 30 worker dose conversion factors used in the PSAR and operating reactor dose calculations.

The Staff notes that since SHINE is not a nuclear power plant, the accident dose criteria in 10 CFR Part 100 are not applicable to this facility. The SHINE facility must meet the 10 CFR Part 20 occupational and public dose limits, which are more conservative than the limits in 10 CFR Part 100. Based on SHINE's assumptions (e.g., no credit is taken for the light water pool scrubbing or subcritical assembly support structure confinement) for the MHA, the Staff finds that SHINE's maximum hypothetical accident analyses conservatively estimate that dose releases to workers and the public as below 10 CFR Part 20 limits.

**9. 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.**

**Staff Response:** SHINE has not provided the Staff with the basis for the stated conservative assumption that work exposure would not exceed 10 minutes as a result of the MHA. However, during the August 19, 2015 meeting with the ACRS Radiation Protection and Nuclear Materials Subcommittee, SHINE stated that initial calculations have shown a more realistic worker evacuation time to be approximately 3.5 minutes (See page 195 of the meeting transcript, ADAMS Accession No. ML15247A200). As part of its review of the SHINE final safety analysis report, the Staff will review the basis for SHINE's worker evacuation times as a result of the MHA to confirm that dose exposures remain within 10 CFR Part 20 limits.

**10. 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."**

**Staff Response:** The Staff has not asked SHINE to describe its plans for additional radiological dose consequence modeling and analyses to increase the time for evacuation. Therefore, the Staff does not have this information. As described in response to Question 9, as part of its review of the SHINE final safety analysis report, the Staff will review the basis for SHINE's worker evacuation times to confirm that dose exposures remain within 10 CFR Part 20 limits.

**11. 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?**

**Staff Response:** SHINE used an aircraft accident cutoff probability of $10^{-6}$ $yr^{-1}$ for its facility aircraft impact analysis based on the guidance in DOE-STD-3014-96, "Accident Analysis for Aircraft Crash into Hazardous Facilities." This DOE standard is "applicable to all facilities containing significant quantities of radioactive or hazardous chemical materials." Section A.2 of DOE-STD-3014-96 indicates that at least five United States institutions and Federal government agencies, including the Food and Drug Administration, Environmental Protection Agency, DOE, NRC, and American National Standards Institute, utilize a "one in a million" aircraft accident cutoff probability. The Staff finds this approach appropriate and consistent with previous reviews of similar facilities. For example, in the aircraft impact analysis of the research reactor at the University of California at Davis (U.C. Davis), General Atomics provided an evaluation of the probability of an aircraft impact at the facility using DOE-STD-3014-96. This analysis is documented in the U.C. Davis final safety analysis report (ADAMS Accession No. ML053250012). The NRC Staff, in turn, used this DOE standard to perform its own independent verification of U.C. Davis' aircraft impact analysis, as documented in its safety evaluation report (ADAMS Accession No. ML053210295). DOE-STD-3014-96 has also been used for the analysis in the Turkey Point Units 6 & 7 COLA (ADAMS Accession No. ML14311A178), the Public Service Enterprise Group Early Site Permit (ADAMS Accession No. ML15169A283), and Summer Units 2&3 COLA (ADAMS Accession No. ML11187A039).

**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.**

**Staff Response:** No, SHINE's selected cutoff probability for its aircraft accident analysis is not consistent with its explosion, toxic chemical, and fire analyses. The Staff evaluated the applicant's analyses independently to determine whether the results were protective for SHINE.

For its explosion, toxic chemical, and fire analyses, SHINE used cutoff probabilities of less than $10^{-6}$ per year, when based on conservative assumptions, or $10^{-7}$ per year when based on realistic assumptions. The SHINE analyses were done conservatively, thus the $10^{-6}$ $yr^{-1}$ cutoff probability was applied. Since these probabilities are based on NRC nuclear power plant (NPP) guidance (e.g., Regulatory Guide 1.91, NUREG-1805), the Staff believes that using the NPP cutoff probabilities is protective for SHINE. Therefore, the Staff found SHINE's analyses acceptable.

For its aircraft accident analysis, SHINE initially proposed using a cutoff probability from IAEA-TECDOC-1347 of $10^{-5}$ $yr^{-1}$ (PASR, Section 2.2.2.5.3). Based on the information provided by

SHINE in its PSAR, the Staff was not able to determine whether the IAEA probability was protective for SHINE, and in RAI 2.2-4(b) requested that the applicant provide justification for its use. Rather than provide justification for the IAEA probability, SHINE re-did its analysis using a cutoff probability of $10^{-6}$ $yr^{-1}$, as described in the Staff's response to Question 11(a). Because SHINE utilized realistic data from the Southern Wisconsin Regional Airport in its analysis (see SHINE's response to RAI 2.2-4(b)), the Staff considers the SHINE aircraft accident analysis to be a realistic analysis.

Even though both analyses utilized $10^{-6}$ $yr^{-1}$ as the cutoff probability, because the explosion, toxic chemical, and fire analyses were performed conservatively and the aircraft accident analysis was done realistically, the Staff does not consider them to be consistent.

**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?**

**Staff Response:** The Staff's expectations resulted from pre-application discussions with SHINE on its proposed design. Based on these discussions, the Staff was concerned that the PCLS system, a pumped system, had the potential to rapidly introduce a significant amount of void. SHINE's calculations provided in its responses to RAIs 4a2-6.4 and 13a2.1-3 show that introducing voids into the PCLS introduces negative reactivity into the system. Introducing voids into the light water pool system does cause an increase in reactivity as documented in the answer to RAI 4a2-6.4. For the purposes of issuing a construction permit, the Staff did not examine the details of the calculation to determine the specific cause of the negative reactivity coefficient. Void feedback coefficients for a moderator that does not contain dissolved fuel are determined by the balance of changes in parasitic absorption and moderation. The Staff did not perform confirmatory calculations, but will perform confirmatory calculations during the review of the application for an operating license when final design information is available.

**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.**

**Staff Response:** While the Staff has not reviewed the details of the calculations that provide the technical basis for a two-hour hydrogen removal period, the Staff concludes that this time period is sufficient based on its knowledge of hydrogen generation. The generation of hydrogen and oxygen by radiolysis is greatly reduced after shutdown of the accelerator since there is no significant fission power after shutdown. The production rate of radiolytic gases, for example $H_2$, $O_2$, and peroxide, has been shown to be a function of the fission product and gamma energy deposition rate in uranyl solutions. Approximately 98 percent of the hydrogen production in an aqueous fuel system occurs from fission product recoil. Gamma radiation accounts for most of the remaining 2 percent. The rate of energy deposition is a function of the power density. Typical gas generation relationships in the literature (Lane 1958) are of the form: $d(H_2)/dt \approx$

$k_1(G_f \times W_f)$, where the right hand side is amount of $H_2$ (e.g., moles) generated per unit time (e.g., minute), $G_f$ is the $H_2$ yield (molecules/eV) and $W_f$ is the specific power deposited in the solution.

The Staff will further review this system when an operating license or other application with the final design of the TOGS, including descriptions of hardware, is made available for Staff review.

**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.**

**Staff Response:** The Staff concluded that the impact of the loss of the heat removal systems on the integrity of the TOGS pressure boundary will be bounded by the MHA because the irradiation unit bubble tight dampers will fail closed if there is a loss of electrical power so the release will be largely confined to the irradiation unit. SHINE has identified no dose consequences to either the public or workers from this event. As there are no dose consequences from this event, it is bounded by the MHA.

**15. Has SHINE defined how many irradiation units a single operator will be assigned or will this information be provided in the FSAR?**

**Staff Response:** No, SHINE's construction permit application did not define how many irradiation units a single operator will be assigned. The Staff does not consider this information necessary to issue a construction permit.

Chapter 1 of the SHINE application, Section 1.3.3.3, describes the irradiation facility as consisting of 8 irradiation units. Section 1.2 of the SHINE quality assurance program description (QAPD) states that activities included in their quality assurance program shall include those related to irradiation unit safety.

The Staff will review the number of irradiation units assigned to a single operator during the review of SHINE's operating license application.

**16. 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.**

**Staff Response:** PSAR section 4a2.6.2.1 references comparisons to benchmark experiments for validating the acceptable modeling capability of Monte Carlo N-Particle code (MCNP). In its response to RAI 4a2.6-6 (which asked about uncertainty analyses for reactivity worths, coefficients, and $k_{eff}$ values), SHINE references calculations done at Los Alamos National Laboratory (LANL) to predict the behavior of homogeneous solution reactors. Specifically, it cites, "Kimpland, R.H. and Klein, S.K., "A Generic System Model or a Fissile Solution Fueled Assembly – Part II," LA-UR-13-28572."

The Staff did not read SHINE's PSAR to be claiming that SHINE has performed similar benchmarking calculations for SCALE. The PSAR states that further validation work will be performed during final design to determine estimated accuracy of calculated parameters. The Staff concluded that it is acceptable for SHINE to provide these details as part of its operating license application because target solution composition and critical volume are operating parameters and are not necessary for construction of the facility.

**17. 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.**

**Staff Response:** The SHINE PSAR states that the irradiation units have a negative void coefficient (see response to Question 18). So, void production will result in a lower reactivity. In RAI 13a2.1-5, the Staff asked about the maximum reactivity insertion due to the maximum credible deflagration, which would result in a reactivity insertion from the complete collapse of voids in the system. SHINE's analysis determined that the resulting maximum $k_{eff}$ would not be greater than that at cold startup. During normal operation there will be void oscillations due to the inherent variability in natural circulation two-phase flow systems. The SHINE system operates below power densities documented in IAEA-TECDOC-1601 where large power oscillations have been observed to occur. SHINE's response to RAI 4a2.7-1 provided a linear stability analysis, which concluded that accelerator-driven fissile solution systems are unconditionally stable to small perturbations.

**18. The PSAR states (page 4a2-40): "Formation of radiolytic gases during operation increases the void fraction of the target solution. This also causes a decrease in reactivity as a result of the negative void coefficient." 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.**

**Staff Response:** As described in PSAR Section 13a2.1.2.2.7, the target solution is over-moderated. However, the Staff does not consider SHINE's system to be designed as over- or under-moderated. Instead, it is better to think of SHINE's proposed systems as under-concentrated with a negative void coefficient. This is possible because the voids displace the target solution, which comprises both fissionable material and moderator, not just the moderator. Thermal expansion is not expected to be a source of increased reactivity and SHINE has stated that the system has a negative temperature coefficient. The Staff asked SHINE about the effects of water evaporation in RAI 4a2.6-9. SHINE responded that the reactivity increase caused by removing that water from the TSV during irradiation mode has been estimated to be a small reactivity increase in comparison to the expected subcritical reactivity of the SHINE system during irradiation mode. The Staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR. Information on changes related to target solution composition or critical volume are operating parameters and not necessary for construction of the facility.

**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.**

**Staff Response:** The responses to RAIs 13a2.2-4 (ADAMS Accession No. ML14357A345) and 13a2.2-7 (ADAMS Accession No. ML15120A248) describe how the depletion calculations were performed. SHINE used one-group cross sections collapsed from continuous energy MCNP calculations in COUPLE and ORIGEN-S for the depletion analysis used to generate the radionuclide inventory in the target solution following irradiation.

With respect to SHINE's treatment of uncertainty in neutron flux calculations, there are always uncertainties associated with all computational methods for calculating neutron fluxes. It is not a characteristic limited to Monte Carlo calculations. Even the basic cross section data used in the calculations have inherent uncertainty. In an aqueous fuel system, the details of the power profile matter less for calculating quantities like burnup than the total power because the target solution circulates throughout the system on a timescale that is much shorter than the burnup cycle time. The solution will be exposed to the average power during the cycle timescale. Additionally, there are volatile fission products that will not remain in the target solution. The uncertainties associated with these effects are likely to be larger than the statistical uncertainty inherent in the Monte Carlo method.

The PSAR Section 4a2.6.2.1 states that further validation work will be performed during final design to determine estimated accuracy of calculated parameters. Ultimately the calculations need to be compared to startup testing measurements to see how reality compares to the calculations. The Staff concluded that it is acceptable for SHINE to provide these details as part of its operating license application because these calculations will principally affect target solution composition and operating parameters, and are details that are not necessary for construction of the facility.

**20. Please explain the approach SHINE plans to use for determining reactivity coefficients and the $k_{eff}$.**

**<u>Staff Response</u>:** SHINE calculated reactivity worths, coefficients, and $k_{eff}$ values using MCNP5, version 1.60. In response to RAI 4a2.6-6, SHINE stated that its MCNP models can predict reactivity coefficients and reactivity worths with an uncertainty of about 20 percent, allowing for sufficient margin to criticality. SHINE suggests that even with a 30 percent uncertainty, the uncertainty in $k_{eff}$ would still allow sufficient margin to criticality. The Staff determined that even if 30 percent uncertainty is assumed, there is still reasonable margin to criticality.

With respect to $k_{eff}$, as stated in the response to RAI 4a2.6-6, "SHINE does not plan to use the absolute $k_{eff}$ predictions from MCNP as the basis to determine operating $k_{eff}$ of the subcritical assembly. Instead, SHINE plans to use a volume margin-to-critical approach coupled with the calculated reactivity worth of that volume."

Additional details of SHINE's approach to determining reactivity coefficients are described in response to RAI 4a2.6-6 (ADAMS Accession No. ML14357A345).

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

**<u>Staff Response</u>:** In section 4a2.6.3 of the PSAR, SHINE describes how it will use MCNP5 to calculate the axial and radial neutron flux distributions during the final design of the system. Like other nuclear physics parameters, the Staff concluded that this analysis can be left for the operating license application because the information is not needed for construction of the facility.

**22. 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>Staff Response</u>:** The criticality safety monitoring system in SHINE's radioisotope production facility, which is known as the criticality accident and alarm system (CAAS), does not ensure criticality safety in the sense of maintaining subcriticality. Instead, as described in PSAR Section 6b.3, the CAAS provides for the detection and annunciation of criticality accidents.

In SHINE's irradiation units, monitoring criticality during the startup would be accomplished by performing a 1/M startup experiment. The startup uses a fixed source of known strength. The detector response is monitored during startup to ensure that it remains within the acceptable 1/M band. The system temperature is also monitored during startup. If those parameters go outside of the accepted range, the solution will be dumped to the criticality safe dump tank. If the tank was slowly filled past the point of criticality, the power in the system would increase to where the void feedback from gas generation and the temperature feedback from energy deposition in the fluid cancels out the excess reactivity from overfilling the system.

The fundamental licensing basis for the SHINE irradiation units as utilization facilities and not reactors is that they are accelerator-driven subcritical operating assemblies. There is no criticality monitoring system that is active during operation of the irradiation unit. There is only measurement of neutron flux and a high flux trip. Safety is assured by maintaining the operating power below the safety limit and keeping sufficient margin to criticality in the most reactive mode of operation. The neutron flux monitoring instrumentation is sufficiently redundant to assure reliability.

The Staff cannot review the reliability of the on-line reactivity monitoring system without an actual hardware design. Therefore, the Staff will review the safety aspects of the system when the operating license application is docketed.

**23. 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.**

**<u>Staff Response</u>:** The basis for the estimate is information provided by SHINE in response to the RAI 4a2.6-5 (ADAMS Accession No. ML14357A345). In this RAI, the Staff requested that SHINE provide an estimate of reactivity due to xenon and samarium. SHINE calculated that the change in reactivity will reduce operating neutron multiplication by less than 10 percent relative to a system without xenon-135 and samarium-149. The Staff will perform a detailed review of this calculation, among others, during its review of the operating license application, when docketed.

**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."**

**<u>Staff Response</u>:** The SHINE TSV solution is expected to be well mixed due to buoyancy driving forces driven by gas generation proportional to local power density and heat removal along coolant boundaries. The Staff's experience with aqueous homogenous reactors (AHRs) has shown that they are oscillatory systems. However, SHINE's proposed facility is designed to operate below power densities documented in IAEA-TECDOC-1601 where large power oscillations have been observed to occur. Further, SHINE's response to Staff's RAI 4a2.7-1 provided a linear stability analysis performed by LANL (ADAMS Accession No. ML14357A410), which concluded that accelerator-driven fissile solution systems are unconditionally stable in the linear approximation.

**25. 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>Staff Response</u>:** As stated in SHINE PSAR Chapter 4, SHINE will be using a 1/M startup methodology during the target solution vessel fill process. The Staff described this startup procedure as an approach to criticality due to its similarity to approach-to-criticality experiments in reactors. However, as stated in Section 4a2.6.1 of the SHINE PSAR and described in Section 4a.4.12 of the SER, the system would not reach a critical state.

**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?**

**<u>Staff Response</u>:** As described in PSAR Chapter 7, the target solution vessel reactivity protection system will shut down the accelerator and dump the target solution to the criticality safe dump tank in the event of the neutron flux signal or any other measured parameter that goes outside operational limits. There is no shutdown margin in the classical reactor sense since there are no adjustable control elements in the system. However, the $k_{eff}$ of the criticality safe dump tank is less than 0.95. The margin to criticality during cold startup is approximately 5 percent of the target solution vessel volume. During operation, the margin is increased due to the negative solution void and temperature feedback.

**27. 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.**

**<u>Staff Response</u>:** As described in SHINE PSAR Section 4a2.6.3.6, "Redundancy and Diversity of Shutdown Methods," there are independent and diverse means of shutting down each irradiation unit. The TSV solution will be dumped through redundant dump valves and the accelerator will be shut down by safety-related trip circuitry for the high voltage power supply (HVPS). Thus, the Staff concluded that sufficient independence and diversity will be provided.

**28. Please reconcile the repeated statements in Chapter 12 of the SER that "RAIs were necessary to confirm the adequacy of the scope of the information provided in the preliminary emergency plan" (pages 12-18, 12-19, 12-21, 12-24, 12-28, 12-30, 12-32) with the similarly repeated conclusion that "information provided in the SHINE Preliminary Emergency Plan [Sections 4-10] is not necessary to meet regulatory requirements and acceptance criteria for the issuance of a construction permit" (pages 12-18, 12-20, 12-21, 12-25,12-29,12-30,12-33).**

**<u>Staff Response</u>:** Under 10 CFR 50.34(a)(10), the PSAR must include a discussion of SHINE's preliminary plans for coping with emergencies. The regulation points to 10 CFR Part 50, Appendix E, for the specific items that should be addressed.

Appendix E of 10 CFR Part 50, Section II, "The Preliminary Safety Analysis Report," identifies eight areas that should be described in the proposed emergency plan at the time of the construction permit application.

Notably, the eight areas that should be described in the PSAR are the same eight areas that must be described in the FSAR submitted at the operating license stage pursuant to 10 CFR 50.34(b)(6)(v). (See Appendix E of 10 CFR Part 50, Section III, "The Final Safety Analysis Report.") Thus, the emergency planning information required at the construction permit stage versus the operating license stage is in some instances a matter of detail and not a matter of subject area. Further, the review guidance the Staff used to determine the sufficiency of SHINE's preliminary emergency plan (NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors.") listed ten planning standards that encompass the eight areas identified in Appendix E, Section II. This guidance is also used to determine the sufficiency of emergency plans submitted at the operating license stage.

The preliminary emergency plan in SHINE's PSAR follows the format of NUREG-0849 and addresses each of the ten planning standards. Therefore, the Staff's review used the detailed evaluation criteria in NUREG-0849 to assess the adequacy of SHINE's preliminary emergency plan. This resulted in Staff requests for additional information related to meeting the acceptance criteria in NUREG-0849. Many of SHINE's responses to the RAIs indicted that the detailed information that was requested would be included in the emergency plans to be submitted along with the operating license application. Upon reviewing the acceptance criteria and SHINE's responses, the Staff determined that in many instances, the information or level of detail that was sought by the RAIs was in fact beyond that which was needed to support the construction permit. In the Staff's view, many aspects of emergency planning are programmatic in nature and pertain more to the operation of a facility than the construction of the facility.

Therefore, the SER reflected the Staff's conclusions that SHINE provided sufficient preliminary information to meet the requirements for a construction permit and that the other information could reasonably be left to the emergency plan submitted as part of the operating license application.

**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?**

**Staff Response:** As described in SHINE PSAR Chapter 4, after irradiation, the target solution is transferred (using gravity) from the target solution vessel (TSV) to the dump tank connected to the TSV. The irradiated solution is held in the dump tank for a period of time to allow for decay heat removal and the decay of short lived fission and activation product. Following the decay period in the dump tank, the irradiated solution is then pumped to the Molybdenum extraction and purification system (MEPS) located within radioisotope production facility. The radioisotope production facility is located adjacent to the irradiation facility (IF).

SHINE's primary engineered safety feature for the facility is the confinement. As described in Table 6a2.1-1, "Summary of IF Design Basis Accidents and ESF Provided for Mitigation," the confinement system mitigates the potential mishandling or malfunction of the target solution. This is accomplished by reliance on the following structures, systems, and components:

- Irradiation unit cells including penetration seals
- RCA ventilation system Zone 1 (RVZ1) ductwork up to bubble-tight isolation dampers
- Bubble-tight isolation dampers

- Isolation valves on piping systems penetrating the irradiation unit cells
- TOGS shielded cells including penetration seals
- Engineered safety features actuation system (ESFAS)
- Double-walled pipe used for tritium purification system (TPS)
- TPS gloveboxes
- TPS confinement system

The radiological consequence analysis for the mishandling or malfunction of the target solution design basis accident is described in SHINE PSAR Section 13a2.2.4. This analysis considers the release or leak of the entire contents of the dump tank into the irradiation cell after a number of cycles.

**30. 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.**

**Staff Response:** Section 4a2.8.5 of the PSAR states that there is a pressure safety valve connected to the TOGS piping to passively prevent an over-pressurization within the primary system boundary. In section 13a2.1.2.2.1, SHINE states that a target solution pressurization event is mitigated by the TRPS high neutron flux trip, which de-energizes the neutron driver and opens the TSV dump valves.

According to Section 4a2.2.5 of the SHINE PSAR, the SASS would be operated near atmospheric pressure. While the SHINE PSAR does not describe overprotection features for the SASS, the SASS is designed for an internal pressure of 100 pounds per square inch to accommodate forces resulting from a hydrogen deflagration event followed by a failure of the TSV integrity.

**31. 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.**

**Staff Response:** Target solution vessel integrity is maintained and solution boiling is prevented through the management of several parameters including target solution pressure and temperature limits. In general, pressure in the primary closed loop cooling system will correlate with temperature. In response to RAI 4a2.8-3, SHINE provided a list of parameters, including system pressure, that could be used as trip inputs to shutdown the irradiation unit to ensure the integrity of the primary system boundary and, ultimately, safe operation of the facility. SHINE has committed to providing a final list of automatic trips in its FSAR. The staff is tracking this commitment in Appendix A of its SER. The Staff will evaluate the need for a pressure trip in the final design, if SHINE identifies a scenario wherein a pressure increase may challenge the operational safety of the irradiation unit without a corresponding temperature increase.

**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?**

**Staff Response**: None. This question was for the applicant only.

**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.**

**Staff Response:** PSAR, Section 2.3.1.2.4 describes how the wind loading applicable to the SHINE design was determined. The 50 year recurrence interval wind speed was determined for the SHINE site from Minimum Design Loads for Buildings and Other Structures (ASCE Standard ASCE/SEI 7-05 Including Supplement No. 1, American Society of Civil Engineers, Reston, Virginia, 2006), and was obtained for two nearby sites from the Engineering Weather Data (2000 Interactive Edition, Air Force Combat Climatology Center, National Climatic Data Center, Asheville, North Carolina, 1999). All three sites had a 50 year recurrence wind speed of 90 mph (40.2 m/s). Next, the 100 year recurrence interval wind speed of 96.3 mph (43.0 m/s) was determined using the methodology from ASCE (2006), Section C6.5.5. PSAR, Section 3.2.1 describes that the design wind velocity was converted to velocity pressure in accordance with ASCE (2006), Equation 6-15.

Likewise, PSAR, Section 2.3.1.2.5, provides information on the historical record of tornados in the SHINE climate region. The NCDC Storm Events Database provided information on historic storm events for the 27 counties that are at least partially included within the SHINE climate region over a 62 year period from May, 1950 through July, 2011. As shown in PSAR Tables 2.3-8 and 2.3-9, most SHINE area tornados were of either F2 (113–157 mph) or F3 (158–206 mph) intensity, with a single F4 (207–260 mph) tornado recorded in Rock County on April 21, 1967.

PSAR, Section 2.3.1.2.5 and 3.2.2 describe how tornado loading was incorporated into the SHINE design. SHINE utilized Region I design-basis tornado characteristics provided in Regulatory Guide (RG) 1.76, Table 1, and the design-basis tornado missile spectrum and maximum horizontal speeds given in RG 1.76, Table 2. The RG 1.76, Table 1, Region I design-basis tornado has a maximum wind speed of 230 mph, which is consistent with the historical record of the SHINE region provided in PSAR, Section 2.3.1.2.5.

**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?**

**Staff Response:** Yes, extreme winds, tornadoes, and tornado missiles have been considered as external events. For the design of Seismic Category I (SCI) structures, systems, and components, SHINE stated in PSAR Table 3.1-3, that it will use the guidance provided in Regulatory Guide 1.76, R1 (March 2007), "Design Basis Tornado and Tornado Missiles for Nuclear Power Plants."

**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?**

**Staff Response:** Yes, safety-related structures, systems, and components will be protected from extreme high winds, tornadoes, and tornado missiles. Non-safety-related structures, systems, and components will also be designed to resist these external hazards, if their damage could threaten safety-related structures, systems, and components.

**35. 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?**

**Staff Response:** The Staff evaluated the facility for a loss of offsite power (i.e., the impact from an external electric utility). The facility has a non-safety-related diesel generator and safety-related battery power in the case of a loss of offsite power. Thus, the facility can be brought to and maintained in a safe condition for this postulated design basis event. In addition, the facility has a safety related battery UPS for those safety-related systems needed to maintain the facility in a safe condition upon loss of offsite power and loss of onsite non-safety-related power.

As discussed in response to Question 4, in its October 15, 2015 letter, the ACRS raised the issue of partial losses of electrical power as something that must be addressed at the operating license stage. The Staff agrees that this issue must be addressed at the operating license stage. Related to this topic, SHINE has committed to providing additional information on electrical isolation requirements in its operating license application. This commitment appears in Appendix A.2, "Regulatory Commitments Identified in Response to Requests for Additional Information," in the SER.

The Staff also considered the impact of a natural gas pipeline supplying the Boiler Room (FA-17), which is adjacent (i.e., shares a common wall) to the Fire Brigade/Hazmat Room (FA-16) that contains the Fire Zone Panels. In RAI 9a2.3-6, the Staff requested additional information on the potential for a fire in the Boiler Room and asked the applicant to provide, in its response, the effects of the pipeline gas combustible load (until the pipeline can be shut off outside the Boiler Room) on room FA-17 and on the rest of the building.

In response to RAI 9a2.3-6, SHINE stated that the walls, floors, and ceilings of the FA-17 room boundary have a 3-hour fire resistive rating as required by a high combustible loading in the room and where an adjacent room contains equipment or systems from a different safety train.

The 3-hour fire barrier provides adequate time for operators to manually isolate the natural gas supply, if required.

The applicant further stated that the potential release of natural gas into room FA-17 will be limited by the installation of safety controls, as required by Wisconsin Administrative Code Chapter SPS 341. The Staff will further evaluate the effects of the pipeline gas combustible load on the boiler room and adjacent fire areas needs in the SHINE FSAR.

**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?**

**Staff Response:** SHINE has not stated where the seismic instrumentation will be located. If this instrumentation is located in a non-safety, non-Seismic Category I (SCI) structure, then SHINE will need to provide justification in the FSAR as to how the instrumentation will be able to record information unimpeded during a seismic event. The seismic instrumentation will be non-safety-related. However, the purpose for these instruments is to record the quantitative seismic acceleration time-histories experienced by Seismic Category I SSCs. This information will help confirm whether the felt earthquake accelerations and responses were within the design values of the SCI SSCs.

**37. 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?**

**Staff Response:** As shown in PSAR Figure 1.3-2, the exhaust stack is located on a non-Seismic Category I (SCI) structure approximately 10 feet south of the SCI structure that contains safety-related SSCs. In addition, in response to RAI 9a2.1-3, SHINE stated that the 56-inch diameter stack has its discharge point approximately 10 feet above the roof line of the SCI structure. Finally, as stated in PSAR Section 3.4.5, the SCI structure is designed to withstand the impact of a small aircraft.

While this is sufficient for the purposes of issuing a construction permit, the design specifics for the exhaust stack need to be provided in the FSAR to ensure that the exhaust stack is protected from external hazards of seismic damage and does not affect safety-related SSCs.

**38. 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.**

**Staff Response**: None. This question was only for the applicant.

**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?**

**Staff Response**: None. This question was only for the applicant.

**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?**

**Staff Response**: None. This question was only for the applicant.

**For the Staff: Does the Staff have any comments about the proposed methodology?**

**Staff Response:** The Staff does not have any comments as it has not reviewed any validation of the SHINE thermal hydraulic design methods. The review of the thermal hydraulic model validation will occur during the operating license review.

**41. 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 °F (42 °C) 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?**

**Staff Response**: None. This question was only for the applicant.

**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.**

**Staff Response:** As indicated by its title, the requirements for Appendix B to 10 CFR Part 50 only apply to nuclear power plants and fuel reprocessing plants. The introduction of 10 CFR Part 50, Appendix B, also provides that the appendix establishes quality assurance (QA) requirements for nuclear power plants and fuel reprocessing plants. Since SHINE is not an applicant to construct or operate either of these types of facilities, Appendix B of 10 CFR Part 50 does not apply to the proposed SHINE facility. However, 10 CFR 50.34(a)(7), requires that all preliminary safety analysis reports for utilization and production facilities include a description of the quality assurance (QA) program to be applied to the design, fabrication, construction, and testing of structures, systems, and components of the facility. Section 50.34(a)(7) also states that Appendix B to 10 CFR Part 50 sets forth the requirements for QA programs for nuclear power plants (NPPs) and fuel reprocessing plants and such permit applications must include a discussion of how the applicable requirements of Appendix B will be satisfied.

Rather than prepare its quality assurance program description using Appendix B to 10 CFR Part 50, SHINE used Regulatory Guide 2.5, "Quality Assurance Requirements for Research and Test Reactors," which endorses the use of American National Standards Institute/American Nuclear Society (ANSI/ANS)-15.8-1995 for addressing the requirements needed in the QA program for all phases of a facility's life (ANSI/ANS-15.8-1995 was reaffirmed in 2005). Similar to Appendix B to 10 CFR Part 50, it allows a graded approach to the application of the QA program to a facility's activities. Based on (1) the information provided in SHINE's quality assurance program description, (2) SHINE's responses to requests for additional information, and (3) the guidance in NUREG-1537 and the Interim Staff Guidance augmenting NUREG-1537, the Staff finds SHINE's use of Regulatory Guide 2.5 and ANSI/ANS-15.8 acceptable for implementing the applicable quality assurance requirements in 10 CFR 50.34.

**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.**

**Staff Response:** PSAR Section 3.3.1.1.2 states that safety-related SSCs are protected from flooding by fire suppression discharge. In addition, SHINE's response to RAI 3.3-1 stated the following:

> "The safety-related function(s) of structures, systems, and components (SSCs) that are subject to the effects of a discharge of the fire suppression system will be appropriately protected by redundancy, separation, and a fail-safe design of each SSC. If deemed necessary by SHINE for the purposes of asset protection, electrical equipment may be protected from unacceptable damage if wetted by fire sprinkler system discharge by sprinkler water shields or hoods, in accordance with National Fire Protection Association (NFPA) 13."
>
> "The SHINE facility design will ensure that fire suppression system discharge in one fire area does not impact safety-related SSCs in adjacent fire areas.'

The Staff finds that this response establishes a design basis for ensuring that the fire suppression system discharge in one fire area will not impact safety-related SSCs in adjacent fire areas, and is acceptable for the issuance of a construction permit. The Staff will review the details for how this will be accomplished during its review of the FSAR submitted as part of the operating license.

**44. Please provide an overview of the Staff's proposed process for conducting the required NEPA analyses for SHINE and how the Staff decided what aspects of the project to include in the analysis for the construction permit and what aspects to**

**address later for the additional licensing actions required prior to the commencement of operations.**

**Please provide a general description of the NEPA analyses that remain to be conducted by the Staff for SHINE, their scope, and the type of NEPA document that will be prepared (e.g. Supplemental EIS, EA).**

**Staff Response**: Below provides an overview of the environmental review process for the SHINE construction permit application, a description of the scope of the analysis in the EIS for the SHINE construction permit, and an overview of additional analyses to be performed by the Staff as required by the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 et seq.; herein referred to as NEPA).

*Environmental Process for the SHINE Construction Permit Application:*

The Staff fulfilled its NEPA obligation for the SHINE construction permit application by following the environmental process described in 10 CFR Part 51 and in the Interim Staff Guidance augmenting NUREG-1537, "*Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors*." This guidance was used given the similarities of SHINE's design with research reactors and some fuel cycle facilities. After looking at SHINE's application for a construction permit, the Staff used its discretion to determine that an Environmental Impact Statement (EIS) should be prepared in light of SHINE's unique technology, the possibility of significant impacts on the environment, and the opportunity to increase public participation. The Staff published a notice of intent to prepare an EIS in the *Federal Register* in accordance with 10 CFR 51.27, "Notice of Intent." In addition, the Staff sent copies of the notice to appropriate Federal, State, and local agencies; affected American Indian tribes; and any interested members of the public. The notice explained the scoping process, stated that the environmental report was available for public inspection on the NRC website and at the local Janesville library, and invited public participation in the scoping process. In accordance with 10 CFR 51.28, "Scoping—Participants," and 10 CFR 51.29, "Scoping—Environmental Impact Statement and Supplement to Environmental Impact Statement," the Staff invited appropriate agencies, organizations, and members of the public to participate in the process. In addition, the Staff visited the proposed site and met with local, regional, and State officials.

In accordance with 10 CFR 51.70, "Draft Environmental Impact Statement— General," and 10 CFR 51.71, "Draft Environmental Impact Statement—Contents," the Staff developed a Draft EIS by independently evaluating the information provided in SHINE's environmental report and information from independent sources. In accordance with 10 CFR 51.73, "Request for Comments on Draft Environmental Impact Statement," and 10 CFR 51.74, "Distribution of Draft Environmental Impact Statement and Supplement to Draft Environmental Impact Statement; News Releases," the NRC published a notice of the availability of the EIS in the *Federal Register* and distributed copies of the Draft EIS to the U.S Environmental Protection Agency (EPA); other appropriate Federal agencies; affected American Indian tribes; appropriate State, regional, and local agencies; and organizations and individuals who requested a copy.

In accordance with 10 CFR 51.91, "Final Environmental Impact Statement—Contents," the Staff considered comments received on the draft EIS, responded to all comments in Appendix A of the Final EIS, and modified the EIS based on in scope comments and newly available information. The Staff published a notice of the availability of the Final EIS in the *Federal Register* and distributed copies of the Final EIS to those who participated in the environmental review and as described in CFR 51.93, "Distribution of Final Environmental Impact Statement and Supplement to Final Environmental Impact Statement; News Releases."

A discussion of the environmental process to be followed if SHINE were to submit an operating license is described in the last section below.

*Scope of the EIS for SHINE's Construction Permit:*

The EIS for SHINE's construction permit evaluated potential impacts from the proposed action as well as related or connected actions. As described in Section 1.2 of the EIS, the proposed Federal action is for the NRC to decide whether to issue a construction permit under 10 CFR Part 50 that would allow construction of the SHINE facility, which would include up to eight utilization facilities and a production facility. If the NRC were to issue a construction permit, SHINE could build the proposed facility on a 91-acre (37-hectare) site in Rock County, which is located about 4 mi (6 km) south of the city center of Janesville, Wisconsin.

In addition to the potential impacts from the proposed action, the Council on Environmental Quality's regulations implementing NEPA state that the NEPA analysis should also include connected actions (40 CFR 1508.25). Connected actions are defined in 10 CFR 1508.25, as follows,

> "a) Actions (other than unconnected single actions) which may be:
>
> Connected actions, which means that they are closely related and therefore should be discussed in the same impact statement. Actions are connected if they:
>
> (i) Automatically trigger other actions which may require environmental impact statements.
>
> (ii) Cannot or will not proceed unless other actions are taken previously or simultaneously.
>
> (iii) Are interdependent parts of a larger action and depend on the larger action for their justification."

Therefore, the Staff determined that it was appropriate to evaluate the potential impacts from operations and decommissioning given that such activities are connected to construction because such activities cannot proceed unless other actions (e.g., issuance of a construction permit) are taken previously. Further, a discussion of potential impacts from operations is consistent with previous environmental reviews conducted by the Staff for construction permit applications (e.g., Final Environmental Statement related to the Arkansas Nuclear One Unit 2; Final Environmental Statement related to the construction of Washington Public Power Supply System Nuclear Projects 1 and 4, NUREG-75/012).

*Environmental Review Process for Remaining NEPA Analyses*:

The issuance of a construction permit is a separate licensing action from the issuance of an operating license. If the NRC issues a construction permit, 10 CFR Part 50 requires that SHINE must submit a separate application for an operating license.

If SHINE were to submit an application for an operating license for a production or utilization facility, the Staff would prepare a supplement to the EIS for the construction permit in accordance with 10 CFR 51.95(b). Section 10 CFR 51.95(b) directs the Staff to prepare a

supplement to the final EIS that updates the environmental review conducted for the issuance of the construction permit. The supplement would only cover matters that differ from the final EIS or that reflect significant new information concerning matters discussed in the final EIS.
As described in 10 CFR 51.53(b), an operating license applicant must submit with its application a separate document entitled "Supplement to Applicant's Environmental Report – Operating License Stage." In this supplement, the applicant shall discuss the same matters described in 10 CFR 51.45, 51.51, and 51.52, but only to extent that they differ from those discussed or reflect new information in addition to that discussed in the final EIS in connection with the construction permit.

As required by 51.95(b), the Staff would independently evaluate the information provided in the supplemental environmental report to prepare a supplement to the final EIS. In addition, the Staff would conduct its own independent evaluation of any new and significant information that has become available since publication of the final EIS to be included in the supplement. The Staff would follow the environmental review process described in 10 CFR Part 51 in preparing the supplement to the EIS, including scoping, requesting comments on the EIS, and updating the supplemental EIS based on public comments received.

**45. Although only applicable to reactors, would performing a Severe Accident Mitigation Design Alternative (SAMDA) analysis, or something similar, be useful for a production facility such as SHINE? Why or why not?**

**Staff Response:** The Staff does not believe that performing a Severe Accident Mitigation Design Alternative (SAMDA) analysis would be useful for SHINE's proposed production facility (i.e., the Radioisotope Production Facility). Likewise, the Staff does not believe that performing a SAMDA analysis would be useful for SHINE's proposed utilization facilities (i.e., each Irradiation Unit (IU)).

SAMDAs, by definition, pertain to severe accidents.[1] Severe accidents are reactor accidents more severe than design basis accidents and may involve substantial damage to the reactor core.[2] SHINE's proposed production facility and proposed utilization facilities are not power reactors. Instead, the radioisotope production facility contains hot cells that resemble fuel cycle facilities. The irradiation units closely resemble non-power reactors in their proposed operational power level and potential radiological consequences. Therefore, the severe accidents contemplated by a SAMDA analysis are not expected to occur at SHINE's proposed facility.

Further, the purpose of a SAMDA analysis is to identify potential changes to a nuclear power plant or procedures that could reduce the risk of a severe accident (including offsite risk). Because there are no severe accidents expected at SHINE's proposed medical isotope production facility, there is no need to identify potentially cost-beneficial mitigative measures for such accidents. Moreover, it is unlikely that any cost-beneficial measures would be identified

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[1] A SAMDA analysis is a NEPA analysis that examines whether implementing a SAMDA would decrease the probability-weighted consequences of severe accidents. *See Entergy Nuclear Generation Co.* (Pilgrim Nuclear Power Station), CLI-10-11, 71 NRC 287, 291 (2010).

[2] Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants, 50 Fed. Reg. 32,138, 32,138 (Aug. 8, 1985). *See* NUREG-2122 (defining severe accidents as beyond design basis accidents that could lead to core damage). *See also* ASME/ANS PRA Standard (including "with fission product release to the reactor vessel and containment with potential release to the environment," in its definition of severe accident).

given the limited magnitude of the potential radiological consequences postulated for SHINE's proposed facility. Therefore, in the Staff's view, a SAMDA would not provide useful information for NEPA purposes, because it would be presuming unforeseeable impacts and remote and speculative accidents.

Instead, SHINE's application and the Staff's review focused on reasonably foreseeable impacts and the expected accidents, risks, and consequences of SHINE's proposed facility. In particular, SHINE's construction permit application applied accident review methodologies used for non-power reactors and for fuel cycle facilities which include the maximum hypothetical accident (MHA) and the integrated safety analysis (ISA). Similar to a SAMDA, the MHA assumes a failure that results in radiological release and radiological consequences that exceed those of any postulated credible accidents. Typical events for research reactor MHAs are events that involve significant fuel failure or experiment failure. The radiological consequences resulting from the MHA are compared to the 10 CFR Part 20 occupational and public exposure (dose) limits. If the accident dose to workers and the public are less than the Part 20 exposure limits, then licensing of the facility is supported.

The Staff's independent analysis of the MHAs for the irradiation facility and the radioisotope production facility are in Chapter 4.11.1 of the EIS and Chapter 13 of the SER. The calculated radiological doses from the irradiation facility MHA are 16.5 mrem (0.16 mSv) at the site boundary and 2.30 mrem (0.023 mSv) at the nearest residence, which is 788 m (0.49 mi) away. The calculated radiological doses from the radioisotope production facility MHA are 82.0 mrem (0.82 mSv) at the site boundary and 11.5 mrem (0.11 mSv) at the nearest residence. The calculated doses for the both the irradiation facility and radioisotope production facility MHAs would be within the annual dose limits of 100 mrem (1.0 mSv) in 10 CFR 20.1301 to a member of the public. The Staff's independent analysis of the MHA consequences in Chapter 13 of the SER came to the same conclusion on dose to the public.

Based on these analyses and the nature of SHINE's proposed facility, as well as NEPA's rule of reason, the Staff does not believe a SAMDA would provide the Commission or the public useful information regarding the mitigation of accidents at SHINE's proposed facility.

**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)?**

__Staff Response__: The Staff's reliance on the discussion in SER Chapter 13 to consider the environmental impacts of postulated accidents is consistent with the Third Circuit's holding in *Limerick Ecology Action Inc. v. NRC*, 869 F.2d 719 (3d Cir. 1989).

In *Limerick Ecology*, the court invalidated a Commission policy statement that would have precluded the consideration of SAMDAs at the operating license stage. The court found that the policy statement was not a sufficient vehicle to preclude the consideration of SAMDAs, and held that the Commission must take the requisite "hard look" at SAMDAs, giving them the careful consideration and disclosure required by the NEPA.

In so holding, the Third Circuit rejected the NRC's argument that its Atomic Energy Act (AEA) safety findings precluded the need for consideration of environmental implications under

NEPA.[3] The court noted that NEPA's language "to the fullest extent possible" indicated that Congress did not intend that it be precluded by the AEA.[4] Further, the court noted that NEPA may require consideration of issues not considered under the AEA.[5] The court also recognized that the NRC had already accepted that accident consequences varied given site-specific features of plants (e.g., location/population nearby).[6]

The Staff recognizes its obligation to conduct an AEA and a NEPA review related to the postulated accidents discussed in SHINE's construction permit application. Further, the Staff recognizes that these reviews may overlap. This overlap is seen in the Staff's discussion of accidents in Chapter 4 of the EIS, which references SER Chapter 13. As the *Limerick Ecology* court noted, the Commission considered "NEPA and Atomic Energy Act reviews [as] both directed at cost-effective measures to reduce the risk from accidental discharges of radioactive materials."[7] Thus, while NEPA requires further consideration of matters that fall outside the purview of the AEA, both NEPA and the AEA require review of similar issues with respect to accidents. The *Limerick Ecology* court was familiar with the idea that agencies review similar issues for the purpose of meeting multiple statutes.[8]

Therefore, the Staff's reference to and reliance on portions of its safety review in the EIS is not contrary to *Limerick Ecology*. Further, the Staff is not simply relying on its safety analyses to meet its NEPA obligations. For example, SHINE's environmental report and the Staff's EIS did consider "the alternatives available for reducing or avoiding environmental and other effects" as required by 10 CFR 51.71(d).[9] The Staff considered the site specific features of the Janesville and alternative sites, the proposed design of SHINE's irradiation facility and radioisotope production facility, and the MHAs for the irradiation facility and radioisotope production facility (discussed in the Staff's answer to Question 45). The Staff determined that SHINE's administrative controls as well as proposed structures, systems, and components to control the likelihood of accidents would adequately provide for the prevention and the mitigation of the consequences of those accidents, and therefore that the likelihood of accidents would be reliably controlled, and that doses to members of the public from the MHAs would be within the dose limits in 10 CFR 20.1301. The Staff's findings of a SMALL impact in the EIS presumed the SER finding that doses to members of the public from the MHAs would be within the dose limits in 10 CFR 20.1301.

The Staff's discussion of accidents in Chapter 13 of the SER and Chapter 4 of the EIS contains a sufficient discussion of mitigation measures to satisfy *Robertson v. Methow Valley Citizens*

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[3] 869 F.2d 719 at 729.

[4] *Id*.

[5] *Id*. at 730 (explaining that NEPA may require consideration of additional alternatives even if there is overlap in the considerations required by other statutes).

[6] *Id*. at 738 ("As the NRC itself has noted, 'the population distribution in the vicinity of the site affects the magnitude and location of potential consequences from radiation releases.'" 48 Fed. Reg. at 16,020.").

[7] *Id*. at 733 (citing Philadelphia Elec. Co. (Limerick Generating Station, Units 1 & 2), CLI-86-5, 23 NRC 125, 127 (1986)).

[8] *See Limerick Ecology*, 869 F.2d 719 at 729 n. 7 (discussing the "functional equivalent" principal).

[9] *See id*. at 730 (noting requirement for NRC to consider this).

*Council*, 490 U.S. 332 (1989). In *Methow Valley*, the Supreme Court held that NEPA § 102(2)(C) implicitly requires agencies to consider measures to mitigate environmental impacts. As the Commission has explained:

> The purpose of addressing possible mitigation measures in an FEIS is to ensure that the agency has taken a "hard look" at the potential environmental impacts of a proposed action. An EIS therefore must address mitigation measures "in sufficient detail to ensure that environmental consequences have been fairly evaluated." An EIS need not, however, contain "a complete mitigation plan," or "a detailed explanation of specific measures which will be employed." Indeed, a mitigation plan "'need not be legally enforceable, funded or even in final form to comply with NEPA's procedural requirements."' As long as the potential adverse impacts from a proposed action have been adequately disclosed, it is not improper for an EIS to describe "mitigating measures in general terms and rel[y] on general processes …."

*Hydro Resources, Inc*. (P.O. Box 777, Crownpoint, NM 87313), CLI-06-29, 64 NRC 417, 427 (2006).

The Staff's EIS, including its references to the SER analysis, contains such a discussion of mitigation measures. For example, in Section 6.3.1, "Unavoidable adverse environmental impacts," the Staff presents the unavoidable adverse impacts from construction, operations, and decommissioning of the proposed SHINE facility and presents mitigations and controls intended to lessen the adverse impact. And for accidents, the Staff determined that SHINE's administrative controls as well as proposed structures, systems, and components to control the likelihood of accidents would adequately provide for the prevention and the mitigation of accident consequences, such that the likelihood of accidents would be reliably controlled, and that doses to members of the public from the MHAs would be within the dose limits in 10 CFR 20.1301.

Thus, the EIS discusses mitigation in sufficient detail so that both the decisionmaker and the public are informed of the environmental consequences of SHINE's proposal to construct a medical radioisotope production facility. Further, the Staff's mitigation discussion demonstrates that the Staff took a hard look at the potential environmental consequences of the proposed action and that these impacts have been fairly evaluated.

**47. 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.**

**Staff Response**: To begin the alternative technology evaluation, the Staff initially considered the range of possible alternatives, or various methods to produce molybdenum-99. For example, several international commercial entities are currently producing molybdenum-99 and several commercial entities have proposed new methods to produce molybdenum-99. The Council on Environmental Quality's regulations implementing NEPA provides guidance when a large number of potential alternatives exist. In such situations, NEPA only requires that an agency analyze a reasonable number of examples, covering the full spectrum of alternatives, in the EIS (46 FR 18026).

For the purposes of the SHINE EIS, the Staff initially limited the alternative technologies analysis to the three technologies that the Department of Energy's (DOE's) National Nuclear Security Administration (NNSA), through the Office of Nuclear Nonproliferation's Global Threat Reduction Initiative, awarded cooperative agreements (as of February 2015) for several reasons. One, these three technologies were chosen for the alternatives analysis, because they appear to be reasonable. For example, in awarding the cooperative agreements, NNSA based its decision, in part, on an evaluation of the technical feasibility. In addition, no entity has proposed constructing a new facility in the United States using technology currently being used in other countries. Therefore, based on the technology that has been proposed to create a domestic source of molybdenum-99, the alternative technologies examined in the EIS include the type of technologies most likely to be constructed and operated within the United States. Lastly, the Staff concluded that three entities awarded cooperative agreements covered the spectrum of potential alternatives based on the general land use requirements, power levels, and other factors.

As described in Section 5.3.1 of the EIS, "Identification of Reasonable Alternatives," the Staff considered three technologies for the purposes of this alternatives analysis.
These three alternative technologies are the following:

(1) neutron capture technology,
(2) aqueous homogenous reactor technology, and
(3) linear-accelerator-based technology.

The Staff then determined whether sufficient environmental data existed to conduct a meaningful analysis for each of the three alternative technologies awarded a cooperative agreement by NNSA. For example, the Staff looked for publically available documents that described the air emissions, estimated dose exposures, water use, building heights and footprints, and other environmental parameters to assess the environmental impacts of each alternative technology. The Staff determined that the DOE's *Environmental Assessment for NorthStar Medical Technologies LLC Commercial Domestic Production of the Medical Isotope Molybdenum-99* provided sufficient environmental data to conduct a meaningful alternatives analysis. The Staff did not identify any documents with sufficient data to assess the environmental impacts for a reactor using neutron capture or aqueous homogenous reactor. Therefore, the Staff eliminated these two technologies from further detailed analysis because the Staff determined there was insufficient data to meaningfully inform the NEPA analysis.

**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?**

**Staff Response**: As described above, numerous alternative technologies currently exist or have been proposed to produce molybdenum-99. The Council on Environmental Quality's regulations implementing NEPA provides guidance when a large number of potential alternatives exist. In such situations, NEPA only requires that an agency analyze a reasonable number of examples, covering the full spectrum of alternatives, in the EIS (46 FR 18026).

For the SHINE EIS, the Staff initially limited the alternative technologies analysis to the three technologies DOE-NNSA awarded cooperative agreements (as of February 2015) because the

Staff concluded that this covered the spectrum of potential alternatives. Further, no entity has proposed constructing a new facility in the United States using technology currently being used in other countries. Therefore, based on the technology that has been proposed to create a domestic source of molybdenum-99, the alternative technologies examined in the EIS include the type of technologies most likely to be constructed and operated within the United States.

**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?**

**Staff Response:** The Staff's environmental review was not impacted due to the non-finalized nature of SHINE's design. SHINE submitted an environmental report as part of its application for a construction permit. The environmental report included an analysis of the potential impacts of construction, operations, and decommissioning. In instances where SHINE had not yet finalized some aspects of the facility, SHINE's environmental report used a bounding or conservative estimate in order assess the environmental impacts. For example, SHINE's environmental report stated the bounding dimensions of the production facility building for the visual impact assessment. Similarly, SHINE used conservative, bounding assumptions to estimate chemical inventories and waste generation.

The Staff independently verified all information included in SHINE's environmental report. In addition, the Staff used the bounding estimates provided by SHINE to assess the environmental impacts from construction, operations, and decommissioning of the SHINE facility. For example, the Staff used SHINE's bounding estimate of the production facility building height to assess potential impacts to birds due to collisions with the building.

If SHINE were to submit an application for an operating license, the Staff would prepare a supplement to the EIS for the construction permit in accordance with 10 CFR 51.95(b). The supplement to the final EIS would update the environmental review conducted for consideration of the issuance of the construction permit by describing matters that differ from the final EIS or that reflect significant new information.

As stated in 10 CFR 51.53(b), an operating license applicant must submit with its application a separate document entitled "Supplement to Applicant's Environmental Report – Operating License Stage." In this supplement, the applicant shall discuss the same matters described in 10 CFR 51.45, 51.51, and 51.52, but only to extent that they differ from those discussed or reflect new information in addition to that discussed in the final EIS in connection with the construction permit.

Therefore, if SHINE were to update its design in an OL application, the Staff would independently evaluate the information provided in the supplemental environmental report to prepare a supplement to the final EIS, as required by 10 CFR 51.95(b). In such cases, the Staff would assess whether the updated design affects the analyses and conclusions reached in the final EIS for the construction permit application. In addition, the Staff would conduct its own independent evaluation of any new and significant information that has become available since publication of the final EIS to be included in the supplement.

**49. Discuss the NRC's National Historic Preservation Act (NHPA) Section 106 consultation efforts for this project. Summarize any issues raised by the Tribes or**

**other interested parties. Please update the status of the Staff's efforts to contact the Forest County Potawatomi Community (FEIS at 4-29, A-9). Has the Staff concluded the Section 106 consultation? If not, explain what remains to be done.**

**Staff Response:** In July 2013, the Staff initiated National Historic Preservation Act (NHPA) Section 106 consultations regarding the proposed licensing action by letter to the Advisory Council on Historic Preservation (ACHP), the State Historic Preservation Office (SHPO) (Wisconsin Historical Society), and 13 Federally-recognized tribes with historic ties to southern Wisconsin (ADAMS Accession Nos. ML13136A011, ML13135A635, and ML13136A014). In its letters, the Staff provided information about the proposed action, defined the area of potential effect, and indicated that the NHPA review would be integrated with the NEPA process, in accordance with 36 CFR 800.8.

The Staff invited participation in the identification and possible decisions concerning any historic properties and also invited participation in the scoping process. As stated in Section 4.6.3 of the final EIS, the Staff received scoping comments from one tribe, the Forest County Potawatomi, in July 2013. The tribe indicated that the proposed SHINE project occurs within Potawatomi ancestral land and expressed concern for any impacts to historic and cultural properties within the area of potential effect. The tribe also requested to receive results of associated archival reviews, cultural resource investigations, and archaeological reports (ML13224A164). In response, the Staff made three attempts to contact representatives of the Forest County Potawatomi via telephone to discuss the undertaking. The last attempt to contact the Forest County Potawatomi in this manner was in March 2015, wherein the Staff shared with them, by voicemail message, the process and contact information for obtaining the Phase I archaeological survey report that had been prepared by the applicant.

In May 2015, the Staff distributed the Draft EIS to the ACHP, SHPO, and affected Tribes (including the Forest County Potawatomi), and notified these parties by letter of the Staff's preliminary determination that no historic properties would be affected by this undertaking (ADAMS Accession Nos. ML15107A403, ML15107A183, and ML15118A820). In addition, these letters identified the basis for the Staff's preliminary determination, and requested comments on the draft EIS and preliminary determination. As discussed in Section A.2.5 of the final EIS, the Staff received comments on the draft EIS from one tribe, the Peoria Tribe of Indians of Oklahoma, in June 2015 (ML15175A169). The Peoria Tribe indicated that the proposed SHINE project location does not appear to be directly linked to Indian religious sites, associated with objects of cultural significance or artifacts linked to their Tribe, or associated with items covered under the Native American Graves Protection and Repatriation Act (NAGPRA). While stating they have no objection to the proposed undertaking at this time, the Tribe requested immediate notification and consultation if, at any time, items are discovered that fall under the protection of NAGPRA.

In July 2015, the NRC received notification that the Wisconsin Historical Society concurred with the Staff's preliminary determination that no historic properties would be affected (ADAMS Accession No. ML15191A323). No additional comments were received on the Draft EIS concerning historic and cultural resources.

In October 2015, the Staff distributed the final EIS to the ACHP, SHPO, and affected tribes (including the Forest County Potawatomi and the Peoria Tribe of Indians of Oklahoma), and notified these parties by letter that the Staff did not identify any new information that would change the earlier determination that no historic properties would be affected by this undertaking (ADAMS Accession Nos. ML15281A177, ML15281A216, and M15281A230). Accordingly, the Staff considers this Section 106 consultation process to be closed.

**50. Is it typical Staff practice to have the EIS serve as the Biological Assessment (BA)? Why did the Staff elect to use the EIS as the BA? Did the Fish and Wildlife Service have any comments on this approach?**

**Staff Response:** Yes, it is the Staff's practice in the Office of Nuclear Reactor Regulation to have the EIS serve as the Biological Assessment (BA) for purposes of satisfying the Endangered Species Act (ESA). This practice is consistent with the ESA.
As described in Appendix D.1.3, "Chronology of ESA Section 7 Consultation," the ESA and the regulations that implement ESA section 7, 50 CFR Part 402, "Interagency cooperation—Endangered Species Act of 1973, as amended," describe the consultation process that Federal agencies must follow in support of agency actions. These regulations state that biological assessments are required for any agency action that is a "major construction activity" (50 CFR 402.12(b)), which the ESA regulations define to include major Federal actions significantly affecting the quality of the human environment under NEPA (50 CFR 402.02). Federal agencies may fulfill their obligations to consult with the Services under ESA section 7 and to prepare a biological assessment in conjunction with the interagency cooperation procedures required by other statutes, including NEPA (50 CFR 402.06(a)). In such cases, the Federal agency should include the results of the ESA section 7 consultation in the NEPA document (50 CFR 402.06(b)). Accordingly, Sections 3.5 and 4.5 and Appendix D of the EIS describes the biological assessment prepared for the proposed agency action.

The Staff used this practice in the review of SHINE's construction permit application. Likewise, the Staff recently issued several EISs related to the license renewal of power plants that had the EIS serve as the Biological Assessment (e.g., Final Supplemental Environmental Impact Statement Regarding Byron Station, NUREG–1437, Supplement 54; Final Supplemental Environmental Impact Statement Regarding Braidwood Station, NUREG–1437, Supplement 55; Draft Supplemental Environmental Impact Statement Regarding Fermi 3 Station, NUREG–1437, Supplement 56). The Fish and Wildlife Service (FWS) did not have any comments on this approach for these reviews.

Likewise, the FWS did not have any comments on this approach for the SHINE review. For the SHINE review, the Staff initially requested information from FWS on Federally listed, proposed, and candidate species and critical habitat that may be in the vicinity of the SHINE site and the two alternative sites, in accordance with the ESA section 7 regulations at 50 CFR 402.12(c) in a letter dated July 1, 2013 (ADAMS Accession No. ML13134A385). The FWS responded to the Staff's request in a letter dated August 15, 2013, and stated that "no Federally-listed, proposed, or candidate species would be expected within the project area. No critical habitat is present. If any construction is to take place within these sites [Chippewa Falls or Janesville], there is no need for further action as required by the 1973 Endangered Species Act, as amended" (ADAMS Accession No. ML13234A020). In Section 3.5 of the EIS, the Staff concludes that no ESA-protected species or critical habitats occur in the action area, and Section 4.5 concludes that the proposed action would have no effect on any ESA-protected species or critical habitats. The FWS does not typically provide its concurrence with "no effect" determinations by Federal agencies. Thus, the ESA did not require further informal consultation or the initiation of formal consultation with the FWS for the proposed SHINE construction permit. Nonetheless, because the EIS constitutes the NRC's biological assessment, the Staff submitted a copy of the Draft EIS to the FWS for its review in accordance with 50 CFR 402.12(j) in a letter dated May 13, 2015.
In response, the U.S. Department of the Interior (DOI) Office of Environmental Policy and

Compliance stated in a letter dated July 6, 2015, that the DOI, which includes the FWS, had no comments on the Draft EIS (ADAMS Accession No. ML15191A322).

**51. How did the Staff define the action area with respect to its review under the Endangered Species Act? (FEIS at 3-35)**

**Staff Response**: As described in Section 3.4.1 of the EIS, the implementing regulations for section 7(a)(2) of the ESA define "action area" as all areas affected directly or indirectly by the Federal action and not merely the immediate area involved in the action (50 CFR 402.02). The action area effectively bounds the analysis of ESA-protected species and habitats because only species that occur within the action area may be affected by the Federal action.

The Staff recognizes that while the action area is stationary, Federally listed species can move in and out of the action area. For instance, a flowering plant known to occur near, but outside, of the action area could appear within the action area over time if its seeds are carried into the action area by wind, water, or animals. Thus, in its analysis, the Staff considers not only those species known to occur directly within the action area, but those species that may passively or actively move into the action area. The Staff then considers whether the life history of each species makes the species likely to move into the action area where it could be affected by the construction, operations, and decommissioning of the SHINE facility.

For the purposes of the ESA analysis in the EIS, the Staff considered the action area to include the lands within the 91-ac (37-ha) proposed site and the adjacent offsite area in which construction of the sewer line would occur. The Staff defined the action area based on the fact that all direct and indirect effects of the proposed action are expected be contained within these areas. The Staff reviewed the occurrence of threatened, endangered, proposed, and candidate species that could occur within a 6-mi (10-km) radius given that Federally listed species can move in and out of the action area.

In response to a request for a list of threatened, endangered, proposed, or candidate species that could occur within or near the proposed site, FWS stated that "no Federally-listed, proposed, or candidate species would be expected within the project area. No critical habitat is present. If any construction is to take place within these two sites [Chippewa Falls or Janesville], there is no need for further action as required by the 1973 Endangered Species Act, as amended" (ML13234A020). During the comment period for the draft EIS, the U.S. Department of the Interior (DOI) Office of Environmental Policy and Compliance stated that the DOI, which includes the FWS, had no comments on the draft EIS (ML15191A322).

**52. Discuss the Staff's determination not to perform a cumulative impacts analysis for accidents since there is another medical isotope facility proposed to be located within 5 miles of SHINE.**

**Staff Response:** In its evaluation of cumulative impacts, as described in Section 4.13 of the final EIS, the Staff considered the incremental impacts of the proposed action in combination with other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person was undertaking the action. To be considered in the cumulative impacts analysis, the Staff determined, in accordance with Interim Staff Guidance Augmenting NUREG 1537, Part 2, whether the project would occur within the noted geographic areas of interest and within the noted timeframes, whether it was reasonably foreseeable, and whether there would be potential overlapping effects with the proposed project. The geographic area over which past, present, and reasonably foreseeable actions would occur was considered specific to each resource area. In addition, the potential for overlapping impacts was also specific to each resource area. For example, construction of two facilities several miles apart could have overlapping impacts to air quality because the emissions may be dispersed over several miles, and therefore overlap. However, noise during construction may not overlap if the audible range of construction-related noise is limited to the immediate area surrounding each facility.

For accidents, the only activities considered are operating nuclear facilities. This approach is consistent with the approach taken in the EISs associated with combined license applications for new power reactors, such as Fermi 3 and South Texas, Units 3 and 4. As listed in Table 4-16 of the Final EIS, the only nuclear facility within 10 mi (16.1 km) of the proposed SHINE facility is NorthStar Medical Radioisotopes. This facility is currently under construction and is located approximately 7.7 miles (12.4km) south of the proposed SHINE site. The Staff did not consider NorthStar's facility in its cumulative impacts accident analysis because the Staff determined that the probability of simultaneous accidents involving the dispersal of radioactive material was extremely low, the risk and consequences of the simultaneous accidents would be extremely low, and that the impact finding for the simultaneous accidents would be as low as the single accident analysis impact finding in the EIS, which the Staff determined to be SMALL. Therefore, the Staff determined that assessing the extremely unlikely event of simultaneous accidents would not meaningfully inform the NEPA analysis. Further, the cumulative impacts assessment focuses on resource areas and potential activities that could have detectable, overlapping impacts with the SHINE facility. The focus on detectable, overlapping impacts is in accordance with 10 CFR Part 51, Appendix A, and 40 CFR 1502.15, which states that the level of detail provided within the EIS should be commensurate with the potential for adverse or significant environmental impacts. This is consistent with one of the goals of NEPA, which is to concentrate on issues significant to the proposed action and their potential environmental impacts. Below provides additional details describing why the impacts would be SMALL for simultaneous accidents at the SHINE facility and the NorthStar facility.

In determining the impacts from radiological accidents at the proposed SHINE facility, the Staff reviewed SHINE's analysis of the MHAs at the proposed facility. An MHA is an event that could result in radiological consequences exceeding those of any credible accident. The MHA is based on events unique to the design of the proposed SHINE facility that hypothetically could release radioactive materials into the environment. The proposed SHINE facility would have two major operation facilities involving radioactive materials: the irradiation facility and the radioisotope production facility. The irradiation facility and the radioisotope production facility are designed to function as two physically separated, independent areas within the facility. Although the irradiation facility and the radioisotope production facility have interconnected processes and systems, they are physically separated by concrete walls.

The Staff analyzed separate MHAs for both the irradiation facility and the radioisotope production facility in the EIS and the SER. Those analyses are found in Chapter 4.11.1 of the EIS and Chapter 13 of the SER. The calculated radiological doses from the irradiation facility MHA are 16.5 mrem (0.16 mSv) at the site boundary and 2.30 mrem (0.023 mSv) at the nearest residence, which is 788m (0.49mi) away. The calculated radiological doses from the radioisotope production facility MHA are 82.0 mrem (0.82 mSv) at the site boundary and 11.5 mrem (0.11 mSv) at the nearest residence. The calculated doses for the both the irradiation facility and radioisotope production facility MHAs would be within the annual dose limits of 100 mrem (1.0 mSv) in 10 CFR 20.1301 to a member of the public. The Staff's independent analysis of the MHA consequences in Chapter 13 of the SER came to the same conclusion on dose to the public.

In the preparation of an Environmental Assessment for the NorthStar Facility, DOE did not analyze the MHA for the facility. Instead, DOE analyzed different accident scenarios involving dispersal of radioactive material. The largest calculated dose to the maximally exposed individual (MEI) was estimated to be 11 mrem (0.11 mSv) at 66 ft (20 m), which is the assumed distance of the closest member of the public to the NorthStar facility. The estimated dose is within the annual dose limit of 100 mrem (1.0 mSv) in 10 CFR 20.1301. DOE concluded that construction and operations of the NorthStar facility would not result in any significant impacts, including potential radiological exposures from accidents at the NorthStar facility. Given that the radiological dose decreases with distance from a site, that the dose to members of the public from SHINE or NorthStar would not exceed regulatory limits, and that the consequence and risk of an accident at the SHINE facility and NorthStar facility is so low within a small distance from each site, the Staff determined that overlapping impacts from the two facilities would not be any different than the impacts assessed in the analysis of accident impacts in the SHINE EIS itself. Therefore, no assessment was provided in the EIS.

As mentioned above, the EISs associated with combined license applications for new power reactors, such as Fermi 3 and South Texas, Units 3 and 4, assess the cumulative impacts from simultaneous accidents at multiple power reactors. The accident analysis performed in those EISs assess the risk and consequence of design basis accidents and severe accidents at power plants. As explained in the response to Question 45, severe accidents are reactor accidents more severe than design basis accidents and may involve substantial damage to the reactor core. SHINE's proposed production facility and proposed utilization facilities are not power reactors, and therefore, severe accidents are not expected to occur at SHINE's proposed facility. Further, the potential radiological consequences for SHINE's proposed facility and the NorthStar facility would be much more limited in magnitude compared to simultaneous accidents at multiple power reactors. Thus, the potential risk and consequences from simultaneous accidents at the proposed SHINE facility and the NorthStar facility would be significantly less than the potential risk and consequences at multiple power reactors. Based on the extremely low risk and consequences of the simultaneous accidents and that the impact finding for the simultaneous accidents would be as low as the single accident analysis impact finding in the EIS, which the Staff determined to be SMALL, the Staff determined that assessing the extremely unlikely event of simultaneous accidents at the SHINE and NorthStar facilities would not meaningfully inform the NEPA analysis for the SHINE construction permit.

**53. Describe the process the Staff used to identify projects or activities to be considered in the cumulative impacts analysis? How did the Staff look out 30 years (i.e., the license term) to determine potential projects to be considered?**

**Staff Response**: The NRC Staff reviewed the information provided in the applicant's environmental report; responses to requests for additional information; information from other Federal, State, and local agencies; scoping comments; and information gathered during the visits to the potential SHINE facility site to identify potential projects and activities to be considered in the cumulative impacts analysis. The NRC Staff then determined whether the project would occur within the noted geographic areas of interest and within the SHINE facility's proposed 30-year operating period, whether it was reasonably foreseeable, and whether there would be potential overlapping effects with the proposed project, in accordance with ISG Augmenting NUREG 1537, Part 2. Although the effects of past actions were generally included in the description of the affected environment, past actions that would continue to have an overlapping effect on a resource potentially affected by the proposed action were also carried forward in the cumulative analysis.

The Staff searched for reasonably foreseeable projects during the proposed 30-year operating period following the process described above, which included reviewing SHINE's environmental report, meeting with other governmental officials with expertise in city planning, searching databases of local permits and proposed projects, and searching for other reasonably foreseeable activities. For example, the Staff reviewed the Rock County, Wisconsin Comprehensive Plan, which addresses a planning horizon through 2035. In addition, Staff met with representatives from the Janesville Community Development Department to discuss reasonably foreseeable future construction and urbanization near the proposed SHINE facility and in the general vicinity of Janesville (ML15062A234). Between the draft and final EIS, Staff also followed up with this office to update the status of the potential projects that were discussed, and updated the analysis accordingly.

The Staff also considered the cumulative effects of global climate change on the affected resources. For example, the Staff reviewed reports that described changes to the climate that are likely occur through the 30 year operating period. In the Midwestern U.S., such changes are likely to include an increase in the annual mean temperature combined with an increase in the frequency, duration, and intensity of droughts.

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

**Staff Response**: No. SHINE did not propose any novel review approaches in its Environmental Report (ER). However, SHINE's ER followed the content and organization of the Final ISG that augments NUREG-1537, Part 1, Chapter 19 in order to address any unique site-specific or project-specific conditions. For example, SHINE determined environmental parameters for aspects of the facility that have not yet been finalized. In such cases, SHINE used a bounding or conservative estimate in order to assess the potential environmental impacts. For example, in its environmental report, SHINE stated the bounding dimensions of the production facility building for the visual impact assessment. Similarly, SHINE used conservative, bounding assumptions to estimate chemical inventories and waste generation.

The Staff addressed this approach by independently verifying all information included in SHINE's environmental report during the site audit and through independent research and analysis. The Staff also used the bounding estimates provided by SHINE in order to assess the environmental impacts from construction, operations, and decommissioning of the SHINE facility. For example, the Staff used SHINE's bounding estimate of building height to assess potential impacts to birds due to collisions with the production facility building.

Another way in which SHINE's environmental report followed the ISG given the unique site-specific conditions is related to SHINE's approach to address post-construction stormwater management. This approach is driven by the conceptual design of the facility and proposed site layout. As discussed in the environmental report, SHINE proposes to enclose its facility with an earthen berm and flanked by an interior and exterior drainage ditch. The exterior ditch would function to intercept stormwater that would otherwise run on to the facility site and redirect it to flow spreaders away from the facility and associated structures. The interior ditch would collect and convey all stormwater runoff within the facility site and direct it to a downgradient vegetated swale. This concept goes beyond the norm of providing for a stormwater detention or retention pond in order to meet soil erosion and sediment control and post-construction stormwater runoff requirements established by the governing municipality (the City of Janesville in this case). The

Staff considered this approach in its analysis of potential environmental impacts on water resources, as contained in Section 4.4 of the Final EIS.

In addition, the Staff identified and discussed in the Final EIS the relevant environmental permits and authorizations that the applicant will be required to obtain from the State of Wisconsin with respect to construction-related and post-construction stormwater runoff, which include a Wisconsin General Permit to Discharge Construction Site Storm Water Runoff (Wisconsin Pollutant Discharge Elimination System (WPDES) Permit No. WI-S067831-4) and approval of an associated stormwater management plan.

**55. In preparing the EIS, did the Staff consider the impacts of "preconstruction" activities together with "construction" activities? See 10 C.F.R. §§ 50.10, 51.4.**

**Staff Response:** Yes, the Staff considered the impacts of "preconstruction" and "construction" activities in its review of SHINE's construction permit application. The definition of "construction" is set forth in 10 CFR 50.10(a)(1), and the list of activities not included in the definition of "construction" is set forth in 10 CFR 50.10(a)(2). These definitions are incorporated into NRC's environmental regulations in 10 CFR 51.4, and 10 CFR 51.45(c) uses the term "preconstruction" to refer to those activities excluded from the definition of "construction." As explained in the 2007 revisions to 10 CFR 50.10, 72 FR 57416 (Oct. 9, 2007), NRC authorization is required only before undertaking activities that have a reasonable nexus to radiological health and safety and/or common defense and security.

In its review of SHINE's application, the Staff determined that the impacts from preconstruction and construction would be the same. For example, preconstruction would include the potential impacts from clearing, grading, and excavation. No clearing would occur on the site because it is currently agricultural land and no trees presently exist on the site. Grading and excavation would have minimal impacts on environmental resources because a relatively limited area would be graded, and the footprint of the proposed buildings are also relatively minimal. As discussed in the Final EIS, SHINE would be required to obtain environmental permits and authorizations from the State of Wisconsin prior to these activities. Part of the permit process would include the State's approval of an associated stormwater management plan, which would further minimize potential impacts from grading and excavation.

The EIS presents the impacts of both preconstruction and construction in Sections 4.1 through 4.12, which describe the impacts from construction, operations, and decommissioning. Given that the impacts are the same for preconstruction and construction, the Staff presented a single impact level to increase the readability of the document. In addition, this method follows a similar approach used in the review of the Fermi 3 COL application, whereby a review team representing both the U.S. Army Corps of Engineers (USACE), a cooperating agency on the EIS, and the NRC first determined the overall impact level of combined construction and preconstruction activities. When the Staff determined the impacts to be SMALL for both construction and preconstruction, the EIS associated with the Fermi 3 COL application did not further breakdown the impacts between construction and preconstruction because they were the same.

Another reason for presenting the impacts of preconstruction and construction in Sections 4.1 through 4.12 was to address the regulatory requirements of DOE, which was a cooperating agency on the EIS, similar to the USACE for the Fermi COL EIS. For the Fermi COL EIS, the impacts from preconstruction are discussed in detail in Chapter 4 of the EIS to satisfy the USACE's needs. Similarly, the NRC discussed the impacts of preconstruction in Chapter 4 to satisfy the DOE's requirement to describe the potential impacts from both preconstruction and construction. The impacts of preconstruction are also considered in the cumulative impacts analysis in Section 4.13 of the SHINE EIS to satisfy NRC's regulatory requirements.

**56. Explain why the Proposed Action and Purpose and Need statement changed between the Draft and Final EISs.**

**In Section 1.2 of the Draft EIS (FEIS at 1-2), the proposed action is "for the NRC to decide whether to issue a construction permit under 10 CFR Part 50 that would allow construction of a medical radioisotope production facility (which would include utilization facilities)." In the Final EIS, the proposed action reads, "for the NRC to decide whether to issue a construction permit under 10 CFR Part 50 that would allow construction of the SHINE facility, which would include up to eight utilization facilities and a production facility."**

**In Section 1.3 of the Draft EIS (FEIS at 1-3), the purpose and need was to "evaluate the applicant's proposal to construct a facility that would ultimately produce medical isotopes" while in the Final EIS, the purpose and need statement was changed to read "…provide a medical radioisotope production option that could help meet the need for a domestic source of molybdenum-99."**

**Staff Response:** The Staff revised the proposed action statement to more accurately characterize the SHINE facility as it would be licensed under 10 CFR Part 50. For example, the initial language used in the draft EIS generally referred to a production facility that included utilization facilities. In the final EIS, the Staff clarified that the proposed action would include up to eight utilization facilities (i.e., each irradiation unit) and a single production facility (i.e., the radioisotope production facility).

Likewise, the Staff revised the purpose and need statement to more accurately characterize the purpose and need of the proposed action. For example, in the final EIS, the purpose and need statement was broadened to account for the multiple options, or methods in which an entity may be able to create a domestic supply of Mo-99 using LEU to satisfy the need for Mo-99 in the United States. In addition, the alternatives analysis, other than the no-action alternative, should consider other ways to meet the stated purpose and need. The Staff clarified the purpose and need statement to ensure that all the alternatives, other than the no-action alternative, described other ways to achieve the stated purpose and need.

**57. Explain the Staff's reasoning for evaluating the impacts from operation and decommissioning as a direct effect of the proposed action even though SHINE is applying for a construction permit. The Record of Decision states that if "SHINE were to submit an application for an operating license, the Staff would prepare a supplement to this EIS in accordance with 10 CFR 51.95(b)." What would the Staff evaluate in that supplement?**

**Staff Response:** The EIS for SHINE's construction permit evaluated potential impacts from the proposed action as well as related or connected actions. As described in Section 1.2 of the EIS, the proposed Federal action is for the NRC to decide whether to issue a construction permit under 10 CFR Part 50 that would allow construction of the SHINE facility, which would include up to eight utilization facilities and a production facility. If the NRC were to issue a construction permit, SHINE could build the proposed facility on a 91-acre (37-hectare) site in Rock County, which is located about 4 mi (6 km) south of the city center of Janesville, Wisconsin.

As noted in response to Question 44, in addition to the potential impacts from the proposed action, the Council on Environmental Quality's regulations implementing NEPA state that the NEPA analysis should also include connected actions (40 CFR 1508.25). Connected actions include closely related actions that cannot or will not proceed unless other actions are taken previously or simultaneously and related actions that are interdependent parts of a larger action and depend on the larger action for their justification. Therefore, the Staff determined that it was appropriate to evaluate the potential impacts from operations and decommissioning given that such activities are connected to construction because such activities cannot proceed unless other actions (e.g., issuance of a construction permit) are taken previously. Also, a discussion of potential impacts from operations is consistent with previous environmental reviews conducted by the Staff for construction permit applications (e.g., Final Environmental Statement related to the Arkansas Nuclear One Unit 2, Docket No. 50-368; Final Environmental Statement related to the construction of Washington Public Power Supply System Nuclear Projects 1 and 4, NUREG-75/012).

The issuance of a construction permit is a separate licensing action from the issuance of an operating license. If the NRC issues a construction permit, then SHINE must submit a separate application for an operating license, pursuant to the NRC's requirements. If SHINE were to submit an application for an operating license, the Staff would prepare a supplement to the EIS for the construction permit in accordance with 10 CFR 51.95(b). The supplement to the final EIS would cover matters that differ from the final EIS or that reflect significant new information concerning matters discussed in the final EIS.

As described in 10 CFR 51.53(b), an operating license applicant must submit with its application a separate document entitled "Supplement to Applicant's Environmental Report – Operating License Stage." In this supplement, the applicant shall discuss the same matters described in 10 CFR 51.45, 51.51, and 51.52, but only to the extent that they differ from those discussed or reflect new information in addition to that discussed in the final EIS in connection with the construction permit.

As required by 51.95(b), the Staff would independently evaluate the information provided in the supplemental environmental report to prepare a supplement to the final EIS. In addition, the Staff would conduct its own independent evaluation of any new significant information that has become available since publication of the final EIS to be included in the supplement.

**58. Because the NRC and DOE have different agency missions, describe any regulatory challenges that arose during the preparation of the EIS.**

**Staff Response:** As described in the response to Question 55, the NRC and DOE Staff encountered one regulatory challenge due to the NRC's definitions of "preconstruction" and "construction." To address this challenge, the Staff presented the impacts of both "preconstruction" and "construction" in Sections 4.1 through 4.12 in the EIS to help satisfy DOE's need to describe the impacts from both activities. Section 4.13 of the EIS incorporates the impacts from "preconstruction" to satisfy NRC's regulatory requirements.

The NRC and DOE Staff minimized regulatory challenges by developing a Memorandum of Agreement (MOA) (ADAMS Accession No. ML13304B666). The purpose of the MOA was to establish a framework for early coordination and participation among the signatories to this agreement to support common goals in furthering each agency's regulatory responsibilities.

The intent of the MOA was to designate NRC as the lead agency and DOE-NNSA as a cooperating agency in the development of a single EIS for both agencies' reviews.

The MOA established a process to facilitate timely preparation of the environmental review document in connection with the SHINE facility, whereby both agencies satisfied the following goals:

- Work together and consider input from the applicant and other stakeholders, as appropriate.
- Identify and resolve issues as quickly as possible.
- Attempt to build a consensus among governmental agencies and their stakeholders.
- Provide for the effective and efficient environmental review for the SHINE facility.

As stated in the MOA, each agency has responsibility for its own decision document. Upon completion of the final NEPA analysis, DOE will commence its process for considering adoption of the EIS, after which a DOE record of decision may be prepared.

**59. What comments generated the most significant revisions to the EIS? Did any comments lead the Staff to rethink its approach? If so, in what way?**

**Staff Response:** The NRC did not receive any comments that generated significant revisions to the draft EIS nor did it receive comments that led the Staff to rethink its approach. However, the Staff did receive and consider several comments during the public comment period.

For example, the Staff held two public meetings in Janesville, Wisconsin, on June 10, 2015, to describe the preliminary results of the environmental review and take public comments. Approximately 25 people attended the afternoon meeting and 25 people attended the evening meeting. One person made a public comment which was transcribed by a certified court reporter. In addition, the NRC received eight written comments on the draft EIS during the public comment period. Many of the comments received were outside the scope of the NRC's environmental analysis, or the Staff determined that sufficient information existed within the EIS to provide the public with a clear description of the affected environmental, potential environmental impacts, and alternatives to the proposed action.

In addition, SHINE provided 55 individual comments on the draft EIS. Most of these comments suggested minor revisions to clarify statements within the EIS, or to update data or analyses in the EIS based on revised assumptions or newly available data. The Staff updated the final EIS appropriately. None of the revisions resulted in changes to the Staff's findings.

**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?**

**Staff Response**: None. This question was for the applicant only.

**61. 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?**

**Staff Response:** The estimated volume of radioactive waste is described in SHINE's environmental report. Specifically, Table 19.2.5–1 in the SHINE environmental report describes the estimated type and quantity of radioactive wastes associated with the operation of the SHINE facility. Table 19.2.5-1 in the environmental report describes the volume of solid radioactive waste generated per year. SHINE stated in its environmental report that the wastes listed in Table 19.2.5-1 would be stored on-site for a period of time before they are shipped off-site. Table 19.2.5-1 in the environmental report describes where each type of waste would be transported offsite.

In Table 19.2.5-1 in the environmental report, SHINE stated that it would generate greater than Class C (GTCC) waste during operation of the SHINE facility. SHINE would transport GTCC to Waste Control Specialists for treatment and storage. However, as of November 2015, no disposal pathway exists for GTCC.

In Sections 2.7.1, 4.9.1, and Appendix A.2 of the EIS, the Staff states that no disposal pathway exists for GTCC. Further, the Staff explains that DOE may have a role in final disposition of GTCC wastes, due to a mandate in the American Medical Isotopes Production Act of 2012 (AMIPA). The AMIPA requires DOE to establish a Uranium Lease and Take Back (ULTB) Program, which includes, among other things, a requirement that DOE be responsible for the final disposition of radioactive waste generated in medical isotope production using DOE-leased uranium, for which DOE determines a producer does not have access to a disposal path. Therefore, if a commercial disposal pathway does not exist for GTCC, DOE would be responsible for this waste.

The Staff concluded that the impacts from the generation of radioactive waste would be SMALL given: the provisions within AMIPA for DOE to establish a Uranium Lease and Take Back Program; that disposal pathways currently exist for Class A, Class B, and Class C wastes; SHINE's proposed waste management systems would minimize waste generation; engineered designs features would minimize radioactive contamination; and that SHINE would operate within the NRC's, Department of Transportation's, and State of Wisconsin's radiation protection requirements.

If SHINE submits an operating license application, further evaluation of the programs and controls related to SHINE's waste management would occur during the review of SHINE's FSAR and environmental report in support of an operating license application. In addition, 10 CFR 51.95(b) requires that the Staff prepare a supplement to the EIS that would update the prior review based on any new or updated information provided in the operating license application or identified during the Staff independent review. Therefore, the Staff would update the supplement regarding any new, significant information related to the generation and disposal of GTCC.

**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?**

**Staff Response:** As described in the response to Question 61, SHINE stated in its environmental report that all radioactive wastes, including GTCC, would be stored on-site for a period of time before they are shipped off-site. SHINE stated in its environmental report that it would transport GTCC to Waste Control Specialists for treatment and storage.

**63. The EIS states at 3-40 that the applicant performed an archeological survey. What methods did the Staff use to verify the applicant's results?**

**<u>Staff Response</u>:** The Staff reviewed Section 19.3.6.3 of SHINE's environmental report, which described the methodology and results of the Phase I archaeological survey (ADAMS Accession No. ML15175A254). No archaeological sites or evidence of cultural resources were identified within the survey area, and no further archaeological investigations were recommended by the investigator, a contractor hired by SHINE. As stated in the environmental report, SHINE submitted the Phase I report to the Wisconsin Historical Society for review and comment. In July 2015, the NRC received notification that the Wisconsin Historical Society concurred with the determination that no historic properties would be affected (ADAMS Accession No. ML15191A323).

As described in Section 4.6.3 of the EIS, the Staff independently verified the information in the survey by visiting the Wisconsin Historical Society (which operates the State Historic Preservation Office) to perform a cultural resource review of the proposed site. During the visit, the Staff queried the Archaeological Sites Inventory and Architectural History Inventory, Burial Sites Inventory, and the Bibliography of Archaeological Reports. The Staff did not identify any known historic or cultural resources or historic properties at the proposed project site or alternative sites (ADAMS Accession No. ML13226A537).

**64. In FEIS Section 4.8 on Human Heath, the Staff finds that radiological impacts for different phases of the SHINE facility's lifecycle would be SMALL "assuming that" the Staff's SER shows that public and worker doses will be within the dose limits in 10 CFR Part 20. It appears that these statements refer to the SER(s) to be developed for the subsequent licensing actions required before SHINE can possess and use radioactive material and operate the facility. Does the Staff plan to include a summary of these relevant findings from the SER(s) in the supplemental EIS(s) that will be prepared for the SHINE facility?**

**<u>Staff Response</u>:** In Section 4.8 of the EIS, the Staff finds that radiological impacts would be SMALL based on the Staff's review of SHINE's analysis of the maximum dose to a member of the public; the design of the facility that incorporates measures to minimize radiation exposure to workers and members of the public by limiting the release of radioactive gaseous effluents; and given that SHINE would operate the proposed facility in accordance with all applicable Federal and State of Wisconsin regulatory requirements. The Staff also stated in the EIS that the radiological impacts would be SMALL if the Staff determines in its SER related to the construction permit application that the maximum dose to workers and the public is within the dose limits in 10 CFR Part 20. In the SER for the construction permit which was published in October 2015, the Staff determined that the maximum dose to workers and the public would be within the dose limits in 10 CFR Part 20. Therefore, the EIS accurately states that the radiological impacts would be SMALL.

If SHINE submits an application for an operating license, further evaluation of the doses to the public would occur during the review of SHINE's FSAR and environmental report in support of an operating license application. In addition, as required by 10 CFR 51.95(b), the Staff would prepare a supplement to the EIS that would update the prior review based on any new or updated information provided in the operating license application or identified during the Staff's independent review. Therefore, the Staff would include in the supplement any information that differs from that presented in the final EIS or is new, significant information related to radiological impacts to workers and the public.

**65. Explain what the Staff did to ensure that it "has taken all practicable measures within its jurisdiction to avoid or minimize environmental harm from the proposed action."**

**Staff Response:** The Staff followed the procedures described in 10 CFR Part 51 and the ISG to NUREG-1537, and completed all of the required consultations to ensure that it has taken all practicable measures within its jurisdiction to avoid or minimize environmental harm from the proposed action.

As described in Sections 6.1 and 6.2 of the EIS, the Staff determined that impacts to all resource areas would be SMALL with the exception of transportation. For those resource areas that would have SMALL impacts, the environmental effects would not be detectable or would be so minor that they would neither destabilize nor noticeably alter any important attribute of the resource. For transportation, the Staff determined that the proposed action could noticeably alter traffic conditions on U.S. Highway 51 as described in Section 6.1 of the EIS. To mitigate the increase in traffic and to help reduce traffic congestion, SHINE plans to use a staggered construction work-shift schedule to reduce the hourly traffic flow onto U.S. Highway 51 and to schedule truck deliveries early in the day. In addition, SHINE would ensure that delivery routes would avoid residential and sensitive areas. These potential mitigations are beyond NRC's jurisdiction to avoid or minimize environmental harm.

In Section 6.3.1 of the EIS, "Unavoidable adverse environmental impacts," the Staff presents the unavoidable adverse impacts from construction, operations, and decommissioning of the proposed SHINE facility and presents mitigations and controls intended to lessen the adverse impact for each resource area. For example, for accidents, the Staff determined that SHINE's administrative controls as well as proposed structures, systems, and components to control the likelihood of accidents would adequately provide for the prevention and the mitigation of the consequences of accidents, such that the likelihood of accidents would be reliably controlled, and that doses to members of the public from the MHAs would be within the dose limits in 10 CFR 20.1301. Similarly, the Staff determined that the radiological dose exposures from routine operations and accidents would be within the dose limits in 10 CFR 20.1301. Potential mitigation for non-radiological impacts identified in Section 6.3.1 of the EIS are beyond NRC's jurisdiction to avoid or minimize environmental harm.

As described in the response to Question 50, the Staff completed the consultation with the FWS as required by the ESA. As part of this assessment of impact to Federally-listed species, the Staff initially requested information from FWS on Federally listed, proposed, and candidate species and critical habitat that may be in the vicinity of the SHINE site and the two alternative sites, in accordance with the ESA section 7 regulations at 50 CFR 402.12(c) in a letter dated July 1, 2013 (ADAMS Accession No. ML13134A385). The FWS responded to the Staff's request in a letter dated August 15, 2013, and stated that "no Federally-listed, proposed, or candidate species would be expected within the project area. No critical habitat is present. If any construction is to take place within these sites [Chippewa Falls or Janesville], there is no need for further action as required by the 1973 Endangered Species Act, as amended" (ADAMS Accession No. ML13234A020). In Section 3.5 of the EIS, the Staff concludes that no ESA-protected species or critical habitats occur in the action area, and Section 4.5 concludes that the proposed action would have no effect on any ESA-protected species or critical habitats. The FWS does not typically provide its concurrence with "no effect" determinations by Federal agencies. Thus, the ESA did not require further informal consultation or the initiation of formal consultation with the FWS for the proposed SHINE construction permit. Nonetheless, because the EIS constitutes the NRC's biological assessment, the Staff submitted a copy of the draft EIS to the FWS for its review in accordance with 50 CFR 402.12(j) in a letter dated May 13, 2015. In response, the U.S. Department of the Interior (DOI) Office of Environmental Policy and Compliance stated in a letter dated July 6, 2015, that the DOI, which includes the FWS, had no comments on the draft EIS (ADAMS Accession No. ML15191A322).

The Staff also included an Environmental Protection Plan (Appendix A of the construction permit) in the construction permit to ensure compliance with the ESA, and to ensure that the Commission is kept informed of other environmental matters. The Environmental Protection Plan describes reporting requirements regarding potential impacts to protected environmental resources during construction activities. The Environmental Protection Plan is intended to be consistent with Federal, State, and local requirements for environmental protection.

In July 2013, the Staff initiated NHPA Section 106 consultations regarding the proposed licensing action to identify potential impacts to historic and cultural properties. As described in the response to Question 49, the Staff determined that no historic properties would be affected by the proposed undertaking. In July 2015, the NRC received a notification that the Wisconsin Historical Society concurred with the Staff's determination that no historic properties would be affected (ADAMS Accession No. ML15191A323).

As described in the response to Question 54, the Staff identified and discussed in the final EIS the relevant environmental permits and authorizations that the applicant will be required to obtain from the State of Wisconsin with respect to construction-related and post-construction stormwater runoff, which include a Wisconsin General Permit to Discharge Construction Site Storm Water Runoff (Wisconsin Pollutant Discharge Elimination System (WPDES) Permit No. WI-S067831-4) and approval of an associated stormwater management plan.

Thus, the EIS discusses mitigation in sufficient detail so that both the decisionmaker and the public are informed of the environmental consequences of SHINE's proposal to construct a medical radioisotope production facility. Further, the Staff's mitigation discussion demonstrates that the Staff has taken all practicable measures within its jurisdiction to avoid or minimize environmental harm from the proposed action.

**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?**

**<u>Staff Response</u>:** The Staff initially envisioned that the preliminary license amendment request process would reduce uncertainty and avoid unnecessary delays in construction that could result if there are significant changes to the proposed facility. As a result of Questions 66-70, however, the Staff has determined that both the preliminary amendment process and the use of criteria similar to those in 10 CFR 50.59 are better suited to instances where a construction permit applicant has sought approval of a final design.

As noted in COL-ISG-025, the preliminary amendment request process was intended for changes or modifications to a final design requiring a license amendment during construction, following the issuance of a combined license under 10 CFR Part 52. Because SHINE has neither proposed a final facility design nor developed technical specifications, a preliminary amendment request process, which controls changes made to a final facility design and addresses changes that impact technical specifications, should not be included as a condition in the SHINE construction permit.

The Staff agrees that the existing regulations in 10 CFR Part 50 are sufficient to accommodate changes to the SHINE facility as its design matures. As indicated in 10 CFR 50.35(b), a construction permit allows an "applicant to proceed with construction but will not constitute approval of the safety of any design feature or specification unless" such approval is specifically requested by the applicant and it is incorporated in the permit. An applicant, "at his option," may request such approval in the construction permit or, from time to time, by amendment of [the] construction permit." As stated in 10 CFR 50.35(c), a construction permit, if issued, "will be subject to the limitation that a license authorizing operation of the facility will not be issued … until (1) the applicant has submitted to the Commission, by amendment of the application, the complete final safety analysis report, portions of which may be submitted and evaluated from time to time, and (2) the Commission has found that the final design provides reasonable assurance that the health and safety of the public will not be endangered …."

In addition, the proposed draft construction permit would only authorize construction of the eight utilization facilities and one production facility in a single building as described in the SHINE application. The findings in 10 CFR 50.35(a)(2) for issuance of a construction permit also indicate that a determination has been made that further technical information, not initially supplied in the PSAR, may be reasonably left for later consideration in the FSAR. The Staff expects that SHINE will submit amendment request(s) under 10 CFR 50.90, addressing the criteria in 10 CFR 50.92. Such amendment requests would request the approval of either the complete final safety analysis report or a specific final design feature. The Staff's construction inspection program will confirm that the facility is constructed as described in SHINE's application, including any approved amendments to the application.

The Staff will provide a revised draft construction permit that deletes conditions for establishing a screening and evaluation process and preliminary amendment request process and the related appendix (i.e., conditions 3.D.(2), 3.D.(3) and Appendix B to the permit). Also, the SECY-15-0130, "Staff Statement in Support of the Uncontested Hearing for Issuance of Construction Permit for the SHINE Medical Technologies, Inc. Medical Radioisotope Production Facility," and construction permit condition 3.D.(4) will be modified to reflect these deletions.

The Staff's SER will also be revised by removing the last paragraph of Section 1.1.4, paragraph 5 of Section 1.2, and Appendix E from the SER.

**67. Please discuss whether any previously-issued construction permits have contained a similar preliminary license amendment request process.**

**<u>Staff Response</u>:** The Staff has not identified any previously issued 10 CFR Part 50 construction permits that contain similar conditions.

**68. Please discuss the need for the preliminary license amendment request process when 10 C.F.R. § 50.90, "Application for amendment of license, construction permit, or early site permit," already applies to "a holder of a license, including a construction permit."**

**<u>Staff Response</u>:** A preliminary license amendment request process has the potential to avoid unnecessary delays in construction of a facility that is based on a certified design and is used by COLs, which are also subject to 10 CFR 50.90. If certain criteria are met, construction changes can proceed before the Staff has completed its review of the license amendment request. If the Staff ultimately denies the amendment request, the licensee must return to the original licensing basis.

As noted in response to Question 66, above, the Staff is no longer proposing that the process apply to the SHINE construction permit, if issued.

**69. The preliminary amendment request process appears to provide a 10 C.F.R. § 50.59 – like process for making changes to the PSAR. However, the agency has historically declined to apply § 50.59 to construction permits. Miscellaneous Amendments; Correction, 27 Fed. Reg. 8825 (1962) (removing the words "construction or" from 10 C.F.R. §50.59). In light of this policy, what is the Staff's justification for this proposed departure from established practice? Did the Staff consider proposing a change to this policy to the Commission as a separate policy notation voting matter in advance of proposing its insertion into the SHINE construction authorization as a license condition? If not, why not?**

**<u>Staff Response</u>:** The Staff initially included the preliminary amendment process and requirement for an associated screening process in the draft construction permit as a facility-specific proposal. The Staff was not proposing a generic change. The Staff expected the Commission would review its proposal in the context of the mandatory hearing on the SHINE construction permit application.

However, as indicated in the response to Question 66, above, the Staff plans to submit a revised draft permit that reflects deletion of the condition.

**70. Please explain why including the preliminary amendment request process in the SHINE Construction Permit is necessary for providing a reasonable assurance of public health and safety or the common defense and security.**

**<u>Staff Response</u>:** As indicated in response to Question 66, above, because SHINE is not seeking approval of a final design, the condition is not required to provide reasonable assurance of public health and safety or the common defense and security. The Staff expects any changes to the design will be fully described in the FSAR or that SHINE will seek approval of changes reflected in its final design via the construction permit amendment process referred to in 10 CFR 50.35(b) and (c), 50.90 and 50.92(a).

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE COMMISSION

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

CERTIFICATE OF SERVICE

Pursuant to 10 C.F.R. § 2.305, I hereby certify that copies of the foregoing "NRC STAFF RESPONSES TO COMMISSION PRE-HEARING QUESTIONS," dated November 24, 2015, as corrected December 8, 2015, have been served upon the Electronic Information Exchange, the NRC's E-Filing System, in the above-captioned proceeding, this 8th day of December, 2015.

***/Signed (electronically) by/***

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Dated at Rockville, Maryland
this 8th day of December, 2015