UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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

ORDER

(Transmitting Pre-Hearing Questions)

On October 27, 2015, the Commission issued a notice that it would convene an evidentiary hearing at its Rockville, Maryland headquarters on December 15, 2015, pursuant to section 189a. of the Atomic Energy Act of 1954, as amended, to receive testimony and exhibits in this uncontested proceeding.[1] In connection with that hearing, pursuant to my authority under 10 C.F.R. § 2.346(a) and (j), SHINE Medical Technologies, Inc. and the NRC Staff should file written responses to the questions provided in the table below. Responses should be filed by **November 24, 2015**.[2]

[1] *See* SHINE Medical Technologies, Inc.; Notice of Hearing, 80 Fed. Reg. 67,435 (Nov. 2, 2015).

[2] Today I am also issuing a separate order with additional questions for SHINE and the Staff. This order is being filed on the non-public docket for this proceeding because it contains security-related sensitive unclassified non-safeguards information (SUNSI).

No.	Category	Subject	Directed to	Question
1	Safety	Scope of Review	Staff	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.
2	Safety	Scope of Review, SECY-15-0130, SER Chapters 1, 3 and 7	Staff/ Applicant	On page 11 of the Staff's Statement in Support of the Uncontested Hearing (SECY-15-0130), the Staff discusses why it chose to apply Part 50 in reviewing the SHINE facility, and the paper states that "the NRC staff used its technical judgement in determining the acceptance criteria for SHINE's construction permit application and the applicable regulations." a. Once the Staff decided to license the facility under Part 50, what was the basis for the Staff using its technical judgement on whether to review the application under every applicable section of Part 50? Why was it not necessary to take exemptions from regulations in Part 50 that apply to construction permits that the applicant did not address? b. Similarly, the SER states (page 1-5) that SHINE applies several of the General Design Criteria to the preliminary design, and that the Staff based its review, in part, on some of the GDC. Why were these particular GDC chosen for the design and review? Was a systematic process used to identify potentially applicable GDC? For example, why did the Staff and SHINE use GDC 16, "Containment Design," when there is no containment used in this design, but not GDC 1 "Quality Standards and Records?"

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				c. Further, how did the Staff use its judgement in determining which regulatory guidance and acceptance criteria to apply? d. Is an exemption from NRC regulations required to alter the definition of safety-related SSCs in 10 C.F.R. 50.2, as discussed in Section 3.4.5 in the SER?
3	Safety	Scope of Review, SER Appendix A	Staff/ Applicant	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?
4	Safety	Scope of Review, ACRS Letter, SER Chapter 1	Staff/ Applicant	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?
5	Safety	Accident Analysis and Dose Assessment	Staff/ Applicant	PSAR Section 13a2.1.1 describes the Maximum Hypothetical Accident (MHA) for the irradiation facility. a. For SHINE and the Staff: Please describe the reasoning underlying the selection of the MHA for the SHINE facility and how it represents the accident whose dose consequences would not be exceeded by any other accident considered credible. b. For the Staff: In RAI 13a2.1-1 the Staff asked SHINE to provide the basis for rejecting multiple Target Solution Vessel (TSV) failures. Please provide additional details about why the Staff

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				ultimately agreed with the SHINE response that there were no credible events involving multiple TSV failures.
6	Safety	Accident Analysis and Dose Assessment, SER Chapter 13	Staff/ Applicant	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.
7	Safety	Accident Analysis and Dose Assessment	Staff/ Applicant	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.
8	Safety	Accident Analysis and Dose Assessment	Staff/ Applicant	The dispersion coefficients used in the dose consequence accident analyses appear to be based on the 50th percentile estimates (as stated in PSAR Tables 13a2.2.1-2 and 13b.2.1-2, both of which are entitled, "Parameters Used in the Dose Consequence Assessment"). NUREG-1537, Part 2, Section 2.3 "Meteorology," states that: The information on meteorology and local weather conditions is sufficient to support dispersion analyses for postulated airborne releases. The analyses should support realistic dispersion estimates of normal releases for Chapter 11 analyses and conservative dispersion estimates of projected releases for Chapter 13 analysis of accidental releases at locations of

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				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.
9	Safety	Accident Analysis and Dose Assessment	Staff/ Applicant	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.
10	Safety	Accident Analysis and Dose Assessment	Staff/ Applicant	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."

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11	Safety	Accident Analysis, SER Chapter 2	Staff/ Applicant	Section 2.4.2, "Nearby Industrial, Transportation, and Military Facilities," of the SER discusses three different sources of potential acceptance criteria for evaluating the aircraft accident probability. NUREG-0800, the Standard Review Plan, states that the probability of aircraft hazards with greater than an order of magnitude of 10^{-7} per year should be considered for nuclear power plants. International Atomic Energy Agency IAEA-TECDOC-1347 has an acceptance criteria for aircraft accident probability of less than 10^{-5} per year. The third source was the NRC precedent of an aircraft accident threshold probability of 10^{-6} per year in the case of *Private Fuel Storage, L.L.C.* a. Which aircraft accident probability was used for the SHINE construction permit application and what is the technical basis for this probability? b. Please explain if the probability selected for the design basis aircraft accident is consistent with the probability of other internal and external design bases events, such as explosions, flammable vapor clouds (delayed ignition), toxic chemicals, and fires, analyzed for SHINE.
12	Safety	Accident Analysis, SER Chapter 13	Staff/ Applicant	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?

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13	Safety	Accident Analysis, SER Chapter 13	Staff/ Applicant	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.
14	Safety	Accident Analysis, SER Chapter 13	Staff/ Applicant	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.
15	Safety	Conduct of Operations, SER Chapter 12	Staff/ Applicant	Has SHINE defined how many irradiation units a single operator will be assigned or will this information be provided in the FSAR?
16	Safety	Criticality Safety	Staff/ Applicant	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.

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17	Safety	Criticality Safety	Staff/ Applicant	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.

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18	Safety	Criticality Safety	Staff/ Applicant	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.

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19	Safety	Criticality Safety	Staff/ Applicant	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.
20	Safety	Criticality Safety	Staff/ Applicant	Please explain the approach SHINE plans to use for determining reactivity coefficients and the k_{eff}.
21	Safety	Criticality Safety	Staff/ Applicant	Please explain how the neutron flux distribution in the vessel/solution is determined.
22	Safety	Criticality Safety	Staff/ Applicant	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.

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23	Safety	Criticality Safety, SER Chapter 4	Staff/ Applicant	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.
24	Safety	Criticality Safety, SER Chapter 4	Staff/ Applicant	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."
25	Safety	Criticality Safety, SER Chapter 4	Staff/ Applicant	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.
26	Safety	Criticality Safety	Staff/ Applicant	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?
27	Safety	Criticality Safety, SER Chapter 4	Staff/ Applicant	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.

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				Please explain if the shutdown will include independent and diverse means of terminating the reaction.
28	Safety	Emergency Planning, SER Chapter 12	Staff	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).
29	Safety	Engineered Safety Features, SER Chapter 6	Staff/ Applicant	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?
30	Safety	Facility Design, SER Chapter 4	Staff/ Applicant	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.
31	Safety	Facility Design, SER Chapter 4	Staff/ Applicant	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.

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				Please explain why system pressure is not another parameter necessary to shut down the Irradiation Unit to ensure safe operation of the facility.
32	Safety	Facility Design, SER Chapter 4	Applicant	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?
33	Safety	Meteorology, SER Chapters 2 and 3	Staff/ Applicant	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.
34	Safety	Meteorology, SER Chapter 3	Staff/ Applicant	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?

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				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?
35	Safety	Seismic Damage, SER Chapter 3	Staff/ Applicant	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?
36	Safety	Seismic Damage, SER Chapter 3	Staff/ Applicant	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?
37	Safety	Seismic Damage, SER Chapter 3	Staff/ Applicant	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?
38	Safety	Thermal-Hydraulics	Applicant	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

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				design. Please describe the planned efforts to validate the thermal-hydraulic models.
39	Safety	Thermal-Hydraulics	Applicant	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?
40	Safety	Thermal-Hydraulics	Staff/ Applicant	PSAR Section 4a2.7.4, "Thermal-Hydraulic Methodology," states that CFD software will be used for detailed thermal hydraulic design and optimization. However, the only validation presented by the applicant used University of Wisconsin-Madison experiments. These are separate effects experiments that may not capture many important aspects of the actual solution. For SHINE: Does SHINE plan to perform any additional experiments to validate the codes used in the current methodology? For the Staff: Does the Staff have any comments about the proposed methodology?
41	Safety	Thermal-Hydraulics	Applicant	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

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				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 ^{o}F (42 ^{o}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?
42	Safety	Quality Assurance	Staff/ Applicant	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.
43	Safety	Water Damage, SER Chapter 3	Staff/ Applicant	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.
44	Environmental	Scope of Review	Staff	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).
45	Environmental	Accidents	Staff	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?

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46	Environmental	Accidents, EIS Chapter 4	Staff/ Applicant	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)?
47	Environmental	Alternatives, EIS Chapter 5	Staff/ Applicant	Section 5.3 of the EIS analyzes the environmental impacts from alternative technologies. After identifying three technologies as reasonable alternatives, the EIS states that there is only sufficient information available to analyze the environmental impacts from one of those technologies in depth. a. Describe in more detail how the Staff and SHINE identified which technologies were reasonable alternatives and how they determined whether there was sufficient information available to do a more in-depth environmental review. b. Why did the Staff not include any of the technologies currently being used in other countries to produce molybdenum-99 as a reasonable alternative?
48	Environmental	Conclusions, EIS Chapter 6	Staff/ Applicant	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?

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49	Environmental	Consultation	Staff	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.
50	Environmental	Consultation	Staff	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?
51	Environmental	Consultation, EIS Chapter 3	Staff	How did the Staff define the action area with respect to its review under the Endangered Species Act? (FEIS at 3-35)
52	Environmental	Cumulative Impacts, Accidents	Staff	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.
53	Environmental	Cumulative Impacts	Staff	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?
54	Environmental	General	Staff/ Applicant	Did SHINE propose any novel review approaches in the environmental portion of its application? How did the Staff address these approaches?
55	Environmental	General	Staff	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.

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56	Environmental	General, EIS Chapter 1	Staff	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."
57	Environmental	General	Staff	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?
58	Environmental	General	Staff	Because the NRC and DOE have different agency missions, describe any regulatory challenges that arose during the preparation of the EIS.

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59	Environmental	General	Staff	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?
60	Environmental	General, EIS Appendix B	Applicant	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?
61	Environmental	General	Staff/ Applicant	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?
62	Environmental	General, EIS Chapter 2	Staff/ Applicant	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?
63	Environmental	Historic and Cultural Resources, EIS Chapters 3 and 4	Staff	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?
64	Environmental	Human Health, EIS Chapter 4	Staff	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

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				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?
65	Environmental	Mitigation Measures	Staff	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."
66	License Conditions	License Conditions, Appendix B	Staff/ Applicant	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?
67	License Conditions	License Conditions 3.D.2, 3.D.3, 3.D.4, and Appendix B	Staff	Please discuss whether any previously-issued construction permits have contained a similar preliminary license amendment request process.
68	License Conditions	License Conditions	Staff	Please discuss the need for the preliminary license amendment request process when 10 C.F.R. § 50.90, "Application for amendment of

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		3.D.2, 3.D.3, 3.D.4, and Appendix B		license, construction permit, or early site permit," already applies to "a holder of a license, including a construction permit."
69	License Conditions	License Conditions 3.D.2, 3.D.3, 3.D.4, and Appendix B	Staff	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?
70	License Conditions	License Conditions 3.D.2, 3.D.3, 3.D.4, and Appendix B	Staff	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.

IT IS SO ORDERED.

For the Commission

NRC SEAL

/RA/

Annette L. Vietti-Cook
Secretary of the Commission

Dated at Rockville, Maryland,
this 10th day of November, 2015.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
SHINE Medical Technologies, Inc.	)	Docket No. 50-608-CP
	)	
(Mandatory Hearing)	)	

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing **ORDER (Transmitting Pre-Hearing Questions)** have been served upon the following persons by the Electronic Information Exchange.

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[Original signed by Herald M. Speiser]
Office of the Secretary of the Commission

Dated at Rockville, Maryland
this 20th day of November, 2015