January 6, 2015

Richard Vann Bynum, Ph.D.
Chief Operating Officer
SHINE Medical Technologies, Inc.
2555 Industrial Drive
Monona, WI 53713

SUBJECT: SHINE MEDICAL TECHNOLOGIES, INC. – REQUEST FOR ADDITIONAL INFORMATION REGARDING APPLICATION FOR CONSTRUCTION PERMIT (TAC NOS. MF2305, MF2307, AND MF2308)

Dear Dr. Bynum:

By letter dated October 15, 2014 (SMT-2014-033, Agencywide Documents Access and Management System (ADAMS) Accession No. ML14296A190), SHINE Medical Technologies, Inc. (SHINE) responded, in part, to the U.S. Nuclear Regulatory Commission (NRC) staff's September 19, 2014 request for additional information (RAI) (ADAMS Accession No. ML14195A159) to complete the review of SHINE's preliminary safety analysis and environmental reports supporting a construction permit application. In this letter, SHINE committed to providing the remainder of its responses to the NRC staff's request for additional information by December 18, 2014.

In the course of reviewing SHINE's RAI responses submitted on October 15, 2014, the NRC staff has determined that additional information is required to complete the review of SHINE's preliminary safety analysis and environmental reports in order to prepare a safety evaluation report and environmental impact statement, respectively.

This request for additional information supplements the NRC's previous requests for additional information related to SHINE's construction permit application dated September 11, 2013 and September 19, 2014 (ADAMS Accession Nos. ML13231A041 and ML14195A159). The specific information requested is addressed in the enclosure to this letter. It is requested that SHINE respond to this request within 30 days of the date of this letter. Timely responses to RAIs contribute toward an efficient and effective review of the submitted application.

In accordance with 10 CFR Section 50.30(b), SHINE must execute its response in a signed original document under oath or affirmation. SHINE's response must be submitted in accordance with 10 CFR 50.4, "Written communications." Information included in this response that SHINE considers sensitive or proprietary must be marked in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." Any information related to security should be submitted in accordance with 10 CFR 73.21, "Protection of Safeguards Information: Performance requirements." Following receipt of the additional information, NRC staff will continue its evaluation of SHINE's construction permit application.

If you have any questions, please contact Steven Lynch at 301-415-1524 or by email at Steven.Lynch@nrc.gov.

Sincerely,

/Duane Hardesty for RA/

Alexander Adams, Jr., Chief
Research and Test Reactors Licensing Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Docket No.: 50-608

Enclosure:
Request for Additional Information

cc: See next page

cc:

Jim Costedio
Licensing Manager
SHINE Medical Technologies, Inc.
2555 Industrial Drive
Monona, WI 53713

Kirsten Cutler, Ph.D.
National Security and International Affairs
Office of Science and Technology Policy
Executive Office Building
1650 Pennsylvania Avenue
Washington, DC 20503

Rilla Hamilton
National Nuclear Security Administration,
NA-212
U.S. Department of Energy
1000 Independence Ave SW
Washington, DC 20585

Cheryl Rogers
Supervisor
Radiation Protection Section
Wisconsin Department of Health Services
P.O. Box 2659
Madison, WI 53701-2659

Amanda Cushman
Environmental Analysis and Review
Specialist
State of Wisconsin
Department of Natural Resources
3911 Fish Hatchery Road
Fitchburg, WI 53711

TRTR Newsletter
University of Florida
Department of Nuclear
Engineering Sciences
202 Nuclear Sciences Center
Gainesville, FL 32611

Mark Freitag
City Manager
P.O. Box 5005
Janesville, WI 53547-5005

Bill McCoy
1326 Putnam Avenue
Janesville, WI 53546

Alfred Lembrich
541 Miller Avenue
Janesville, WI 53548

Gerald and Muriel Bumgarner
1735 S Osborne Ave
Janesville, WI 53546

If you have any questions, please contact Steven Lynch at 301-415-1524 or by email at Steven.Lynch@nrc.gov.

Sincerely,

/Duane Hardesty for RA/

Alexander Adams, Jr., Chief
Research and Test Reactors Licensing Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Docket No.: 50-608

Enclosure:
Request for Additional Information

cc: See next page

DISTRIBUTION:

Public	AAdams, NRR	MRodriguez, NSIR	MYoung, OGC	VHuckabay, NRO
DHowe, FSME	LTran, NRR	JFisher, RII	TZaki, RES	SHarwell, NRR
MAdams, NMSS	SLynch, NRR	JLynch, RIII	MConley, OPA	RLukes, NRO
MMoser, NRR	DBarss, NSIR	CFrazier, RIII		

ADAMS Accession No.: ML15005A407 **NRR-088**

OFFICE	NRR/DPR/PRLB/PM	NRR/DPR/PRLB/BC	NRR/DPR/PRLB/PM
NAME	SLynch	(DHardesty for) AAdams	SLynch
DATE	01/05/2015	01/06/2015	01/06/2015

OFFICIAL RECORD COPY

REQUEST FOR ADDITIONAL INFORMATION
SHINE MEDICAL TECHNOLOGIES, INC.
REGARDING PRELIMINARY SAFETY ANALYSIS REPORT
AND ENVIRONMENTAL REPORT
CONSTRUCTION PERMIT APPLICATION
DOCKET NO. 50-608
TAC NOS. MF2305, MF2307, AND MF2308

By letter dated May 31, 2013 (SMT-2013-023, Agencywide Documents Access and Management System (ADAMS) Accession No. ML13172A361), SHINE Medical Technologies, Inc. (SHINE) submitted the second and final part of its two-part application for a construction permit. Part one of SHINE's construction permit application, primarily consisting of SHINE's environmental report, was submitted by letter dated March 26, 2013 (SMT-2013-012, ADAMS Accession No. ML13088A192). By letter dated September 25, 2013 (SMT-2013-033, ADAMS Accession No. ML13269A378), SHINE supplemented this submission with a discussion of preliminary plans for coping with emergencies, as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 50.34(a)(10), completing its application for a construction permit.

In the course of reviewing SHINE's construction permit application, the U.S. Nuclear Regulatory Commission (NRC) staff has determined that additional information is required to complete the review of the SHINE Preliminary Safety Analysis Report (PSAR) submitted on May 31, 2013 (ADAMS Package No. ML13172A324), in support of the development of its safety evaluation report. Additionally, the NRC staff has determined that additional information is required to complete the review of the SHINE environmental report in support of the development of its environmental impact statement.

By letter dated September 19, 2014 (ADAMS Accession No. ML14195A159), NRC staff issued a request for additional information. SHINE responded, in part, to the NRC staff's request by letter dated October 15, 2014 (SMT-2014-033, ADAMS Accession No. ML14296A190), committing to provide the remainder of its responses to the NRC staff's request by December 18, 2014.

In the course of reviewing SHINE's RAI responses submitted on October 15, 2014, the NRC staff determined that additional information is required to complete the review of SHINE's preliminary safety analysis and environmental reports in order to prepare a safety evaluation report and environmental impact statement, respectively.

The SHINE irradiation facility, including the irradiation units, and radioisotope production facility, as described in the SHINE PSAR, are primarily evaluated using the appropriate 10 CFR regulations, as well as the guidance contained in NUREG-1537 Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (ADAMS Accession No. ML042430055), and NUREG-1537 Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (ADAMS Accession No. ML042430048), as well as the "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ADAMS Accession No. ML12156A069), and "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 2,

ENCLOSURE

'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ADAMS Accession No. ML12156A075). As applicable, additional guidance referenced in NUREG-1537, Parts 1 and 2, as well as the ISG Augmenting NUREG-1537, Parts 1 and 2, has been utilized in the review of the SHINE PSAR.

For the purposes of this review, the term "reactor," as it appears in the relevant guidance listed above, can be interpreted to mean "irradiation unit," "irradiation facility," or "radioisotope production facility," as appropriate. Similarly, for the purposes of this review, the term "reactor fuel," as it appears in the relevant guidance listed above, may be interpreted to mean SHINE's "target solution."

In order to avoid repeating reference numbers for specific information requests, the reference numbers used in this this request for additional information are a continuation of the numbering used in the previous request for additional information issued on September 19, 2014.

This request for additional information supplements the NRC's previous requests for additional information dated September 11, 2013 and September 19, 2014 (ADAMS Accession Nos. ML13231A041 and ML14195A159).

Responses to the following RAIs are needed to continue the review of the SHINE construction permit application.

General Information Request

RAI G-2 Title 10 of the *Code of Federal Regulations* (10 CFR 50.34(a)(8)), requires that a PSAR include:

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

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

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

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

---

1 Kalensky, M. et. al. "Measuring Radiolytic- and Fission-Gas Generation in an Aqueous Uranium-Sulfate Target Solution in Accelerator-Based Mo-99 Production." *2014 Mo-99 Topical Meeting, Washington D.C., 24 - 27 June 2014.* Argonne National Laboratory, 2014.

Chemerisov, S. et. al. "Experimental Setup for Direct Electron Irradiation of the Uranyl Sulfate Solution: Bubble Formation and Thermal Hydraulics Studies." *2014 Mo-99 Topical Meeting, Washington D.C., 24 - 27 June 2014.* Argonne National Laboratory, 2014.

CHAPTER 2 – SITE CHARACTERISTICS

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

Section 2.2 – Nearby Industrial, Transportation, and Military Facilities

RAI 2.2-3 NUREG-1537, Part 2, Section 2.2, "Nearby Industrial, Transportation, and Military Facilities," states that the information contained in this section should be "complete enough to support evaluations of potential risks posed by these facilities to the safe operation and shutdown of the reactor during its projected lifetime."

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

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

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

RAI 2.2-4 NUREG-1537, Part 2, Section 2.2, "Nearby Industrial, Transportation, and Military Facilities," states in part, "[t]he reviewer should focus on facilities, activities, and materials that may reasonably be expected to be present during the projected lifetime…."

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

gnee_types/ame/tutorial/section2/aeromedical_issues/), aerobatic accidents tend to occur during performance, as opposed to during takeoffs and landings.

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

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

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

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

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

CHAPTER 4 – IRRADIATION UNIT AND RADIOISOTOPE PRODUCTION FACILITY DESCRIPTION

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

Section 4a2.2 – Subcritical Assembly

RAI 4a2.2-10 The ISG Augmenting NUREG-1537, Part 2, Section 4a2.2.1, "Reactor Fuel," Acceptance Criteria, states, in part, that the PSAR should consider "various phenomena that result in changes to the initial fuel composition and properties…[including] information on radiolytic gas formation" in the target solution.

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

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

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

CHAPTER 11 – RADIATION PROTECTION PROGRAM AND WASTE MANAGEMENT

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

Section 11.1 – Radiation Protection

RAI 11.1-9 As required by 10 CFR 50.34(a)(3)(i), the preliminary design information provided for the facility should include principal design criteria.

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

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

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

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

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

goat milk from the two dairy operations noted in PSAR Section 11.1.7.2.3.

CHAPTER 12 – CONDUCT OF OPERATIONS

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

Section 12.7 – Emergency Planning

RAI 12.7-35 NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors," Section 3.0, "Organization and Responsibilities," Evaluation Item 1.b., states that the emergency plan should describe "[t]he reactor's emergency organization, including augmentation of the reactor staff to provide assistance for coping with the emergency situation, recovery from the emergency, and maintaining emergency preparedness."

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

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

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

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

APPENDIX 12C – QUALITY ASSURANCE PROGRAM DESCRIPTION

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

Appendix 12C Section 1 – Introduction

RAI 12C.1-3 As required by 10 CFR 50.34(a)(7), each applicant for a construction permit to build a production or utilization facility must include, in its preliminary safety analysis report, a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Regulatory Guide 2.5, Revision 1, states that the general requirements for establishing and executing a quality assurance program for the design, construction, testing, modification, and maintenance of research and test reactors in the American National Standards Institute/American Nuclear Society Standard (ANSI/ANS) 15.8-1995 provide an acceptable method for complying with the program requirements of 10 CFR 50.34, "Contents of Applications; Technical Information."

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

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

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

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

RAI 12C.1-4 ANSI/ANS-15.8-1995, Section 1.3, "Definitions," defines safety-related items as: "Those physical structures, systems, and components whose intended functions are to prevent accidents that could cause undue risk to the health and safety of workers and the public, or to the research reactor's programs; and to control or mitigate the consequences of such accidents."

The SHINE Quality Assurance Program Description (QAPD), "Executive Summary" and Section 1, "Introduction," the last paragraph, state that SHINE

utilizes a definition of safety-related systems, structures, and components (SSCs) for the Quality Level 1 SSCs. Further, Section 1.3, Definitions, of the QAPD states that definitions for use at SHINE are located in a stand-alone document and are under document control.

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

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

Appendix 12C Section 2.1 - Organization

RAI 12C.2.1-5 ANSI/ANS-15.8-1995, Section 2.1, "Organization," states, in part, that "[p]ersons responsible for ensuring that appropriate controls have been established, and for verifying that activities have been correctly performed, need sufficient authority, access to work areas, and freedom to: (a) identify problems; (b) initiate, recommend, or provide corrective action; and (c) ensure corrective action implementation."

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

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

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

Appendix 12C Section 5 – Decommissioning

RAI 12C.5-1 ANSI/ANS-15.8-1995, Section 5, "Decommissioning," states: "The quality assurance requirements for a facility during the decommissioning phase are addressed by the appropriate sections of this standard, and American National

Standard for Decommissioning of Research Reactors, ANSI/ANS-15.10-1994 [4]."

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

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

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

Appendix 12C Enclosure 2 – Graded Approach to Quality

RAI 12C.E2-5 The SHINE QAPD Enclosure 2 – Graded Approach to Quality, states, in part: "The graded approach to quality is a process by which the level of analysis, documentation, and actions necessary to comply with a requirement is commensurate with the safety significance." It also further states: "QL-2 will include the non-safety related quality activities performed by the licensee, that are deemed necessary by SHINE to ensure the manufacture and delivery of highly reliable products and services to meet or exceed customer expectations and requirements."

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

a) Clarify the meaning of the phrase "to the extent necessary" in SHINE's response to RAI 12C.E2-3;

b) Clarify whether QL-2 classification is applicable to all or only selected non-safety related SSCs and activities; if QL-2 is applicable to selected non-safety related SSCs and activities, describe the process used to identify those SSC and activities to which QL-2 classification applies; if QL-2 is considered to be a voluntary application of the SHINE QAPD requirements to selected non-

safety related SSCs and activities, explain how this approach fits the framework of the graded approach to quality (“commensurate with the safety significance,”) as defined in the first sentence of Enclosure 2.

CHAPTER 19 – ENVIRONMENTAL REVIEW (ER)

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

Section 19.1 – Introduction of the Environmental Report

RAI 19.1-1 The ISG augmenting NUREG-1537, Part 1, Section 19.1.2, "Regulatory Provisions, Permits, and Required Consultations," and 10 CFR 51.45(d) state that an applicant should list and summarize the status of all applicable federal, state, local, and other regulatory requirements, permits, and consultations that would be required for the proposed facility to be constructed and operated.

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

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

Section 19.2 – Proposed Action

RAI 19.2-6 The ISG augmenting NUREG-1537, Part 1, Section 19.2, "Proposed Action," states that the applicant should provide a description of the activities that would occur during the major phases of the proposed action, including construction, operational, and decommissioning activities.

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

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

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

(Applies to RAIs 19.2-7 through 8)

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

RAI 19.2-7 SHINE's response to RAI 19.2-5(b) regarding deliveries of materials and off-site shipment of wastes during operation stated there would be 36 truck deliveries and one off-site waste shipment per month during the operations phase.

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

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

RAI 19.2-8 In Section 19.2 of the environmental report, Table 19.2.5-1, "Estimated Type and Quantity of Radioactive Wastes Associated with the SHINE Facility," describes that estimated types and quantities of radioactive wastes. In this table, SHINE provided an estimate of the volume of waste to be produced each category; however, SHINE did not provide the units for the volume of technetium columns and cesium/cerium media.

Provide the units for the volume of technetium columns and cesium/cerium media, as described in Table 19.2.5-1, "Estimated Type and Quantity of

Radioactive Wastes Associated with the SHINE Facility."

Section 19.3 – Description of the Affected Environment

RAI 19.3-2 The ISG augmenting NUREG-1537, Part 1, Section 19.3.2, "Air Quality and Noise" states that the applicant should estimate onsite and offsite vehicle and other emissions resulting from construction, operations and decommissioning.

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

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

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

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

RAI 19.4-2 The ISG augmenting NUREG-1537, Part 1, Section 19.4.11, "Postulated Accidents," states that the applicant should describe the radiological impacts from potential accidents.

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

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