UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE COMMISSION

In the Matter of	)	Docket No. 50-608-CP
SHINE MEDICAL TECHNOLOGIES, INC.	)	
(Medical Radioisotope Production Facility)	)	November 24, 2015

APPLICANT'S PRE-FILED TESTIMONY OF JAMES COSTEDIO FOR THE MANDATORY HEARING ON UNCONTESTED ISSUES FOR THE SHINE MEDICAL TECHNOLOGIES, INC.'S MEDICAL RADIOISOTOPE PRODUCTION FACILITY

I. WITNESS BACKGROUND

Q1. Please state your name.

A1. My name is James Costedio.

Q2. By whom are you employed?

A2. I am employed by SHINE Medical Technologies, Inc. (SHINE).

Q3. What is your position at SHINE?

A3. I am the Licensing Manager. I have served in that position since 2012. I am responsible for providing direction and oversight for the Licensing Department and overall responsibility for the Construction Permit (CP) Application.

Q4. Please describe your educational and professional background.

A4. I have Bachelor of Science degrees in both Applied Science and Technology and Human Resources Management. Prior to joining SHINE, I worked at nuclear power plants since 1993. As part of that experience, I worked in a variety of engineering, training, and licensing roles at the FitzPatrick Nuclear Power Plant in Oswego, New York from 1993

to 2008, including a position as the Licensing Manager. I also worked as the Licensing Manager from 2008 to 2012 at Point Beach Units 1 and 2 in Two Rivers, Wisconsin.

Q5. What is the purpose of your testimony?

A5. The purpose of my testimony is to support the findings the U.S. Nuclear Regulatory Commission (NRC) must make as part of the hearing on uncontested issues for the CP for SHINE's Medical Radioisotope Production Facility (SHINE Facility) that would be located in Wisconsin.

Q6. Please describe the structure of your testimony.

A6. Section II provides a description of the CP Application, including background information on the project, SHINE, and the NRC staff's review of the Application. Sections III and IV address the safety and environmental findings, respectively, for issuing a CP for the SHINE Facility. Section V discusses conclusions. Attachment 1 to this testimony provides a list of abbreviations and acronyms used in the testimony.

II. DESCRIPTION OF THE CP APPLICATION

A. Project Background

Q7. Please briefly describe the project related to the SHINE Facility.

A7. SHINE has developed a new method for the manufacture of medical isotopes and seeks to construct and operate a facility for the purpose of producing molybdenum-99 (Mo-99).

Q8. Why is the SHINE Facility needed to produce Mo-99?

A8. The decay product of Mo-99, technetium-99m (Tc-99m), is used to perform approximately 40 million imaging procedures worldwide each year, and accounts for 80% of all nuclear medicine procedures. Tc-99m is used in a wide variety of imaging procedures, including cardiac perfusion imaging (to detect and treat heart disease) and

bone scans (to detect cancer metastases). Technetium becomes a "light source" within the body to provide a high quality view of internal organs.

Q9. Are there other sources of Mo-99 in the United States?

A9. Despite being the world's largest consumer of Tc-99m, the United States has no domestic production of Mo-99. The vast majority of the world's supply of Mo-99 comes from seven nuclear reactors, which are greater than 40 years old. As these reactors age, they must be shut down for repairs and maintenance with increasing frequency, thereby creating supply disruptions. Mo-99, with a half-life of just 66 hours, cannot be stockpiled, and must be produced continuously. Over time, unless a new, reliable production capacity is brought on-line, supply disruptions will become increasingly more frequent. Without new production capacity, the United States will certainly face a Mo-99 shortage, potentially impacting the health of hundreds of thousands of patients every week.

Q10. Please provide a high-level description of the SHINE Facility.

A10. SHINE's technology involves the use of a non-reactor based, subcritical fission process. The process includes the combination of a high-output deuterium-tritium gas-target neutron source with a low enriched uranium (LEU) target in a target solution vessel (TSV). Neutrons created by simple, accelerator-driven neutron sources induce fission in the LEU, creating Mo-99 as a byproduct. The combination of the neutron driver, subcritical assembly, light water pool, TSV off-gas system (TOGS), and other supporting systems are known as the irradiation unit (IU). Eight IUs and their supporting systems comprise the irradiation facility (IF).

The SHINE Facility also includes the radioisotope production facility (RPF). The RPF is where the irradiated material is processed to separate medical isotopes, and includes packaging of the resulting materials for shipment to customers.

Q11. Where would the SHINE Facility be located?

A11. SHINE intends to build its production facility on previously-undeveloped property in the City of Janesville, Rock County, Wisconsin. This location was chosen for many reasons, including local government and community support, access to a skilled workforce, proximity to potential future customers, and proximity to local transportation, such as an airport and interstate highway.

Q12. Please identify the license being sought for the SHINE Facility.

A12. SHINE submitted an Application seeking a CP under 10 CFR Part 50 to construct the SHINE Facility.

B. Applicant for the SHINE Facility

Q13. Please identify the applicant for the SHINE Facility and its roles and responsibilities.

A13. SHINE is the applicant for the CP for the SHINE Facility. SHINE will own and operate the facility. SHINE is a private organization that was created for the purpose of designing, constructing, and operating the Facility. SHINE was organized in the State of Wisconsin. The business and affairs of SHINE are managed under the direction of a Board of Directors and through the officers of SHINE.

Q14. When did SHINE submit the CP Application?

A14. SHINE submitted the CP Application in two parts, pursuant to an exemption to 10 CFR § 2.101(a)(5), which is discussed below. SHINE submitted Part One (ML13088A192) to

the NRC on March 26, 2013. Part One consisted primarily of Preliminary Safety Analysis Report (PSAR) Chapter 2 (Site Characteristics), PSAR Chapter 19 (Environmental Review), and financial and general information. SHINE submitted Part Two (ML13172A361) on May 31, 2013. Part Two provided the remaining portions of the PSAR. Finally, on September 25, 2013, SHINE provided a discussion of preliminary plans for coping with emergencies in accordance with 10 CFR § 50.34(a)(10) (ML13269A378).

Q15. Did the CP Application address all applicable NRC regulations?

A15. Yes. The CP Application provided the information required by applicable NRC regulations, including 10 CFR §§ 50.30 (Filing of applications for licenses; oath or affirmation), 50.33 (Contents of applications; general information), 50.34 (Contents of applications; technical information), and Part 51 (Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions). The NRC accepted Part One of the CP Application for docketing on June 25, 2013 (78 Fed. Reg. 39,342) and Part Two for docketing on December 2, 2013 (78 Fed. Reg. 73,897). SHINE submitted the most recent update to the PSAR on August 27, 2015 (ML15258A431). SHINE most recently updated its CP Application on October 1, 2015 to include a description of the SHINE process for preparing consolidated liquid waste streams for disposal (ML15274A539).

Q16. Please describe the exemption that was required to submit the CP Application in two parts.

A16. The NRC regulations, 10 CFR § 2.101(a)(5), allow certain applications, including CP applications, to be submitted in two parts if they fall within the category of actions that

require an Environmental Impact Statement (EIS) under 10 CFR § 51.20(b). Because construction and operation of a medical isotope production facility does not require an EIS under Section 51.20(b), SHINE could not submit its CP Application in two parts. SHINE desired to submit the Application in two parts to allow the NRC to commence its environmental review earlier, potentially resulting in earlier issuance of the CP. Therefore, SHINE submitted a 10 CFR § 50.12 request to the NRC on February 18, 2013 (ML13051A007) seeking an exemption from the requirements of 10 CFR § 2.101.

The NRC staff granted the exemption request on March 20, 2013 (78 Fed. Reg. 19,537). The NRC staff agreed with SHINE that the exemption satisfied the 10 CFR § 50.12 requirements because it was authorized by law, does not present an undue risk to public health or safety, is consistent with the common defense and security, and reflects special circumstances. The NRC staff concluded that the special circumstances described in 10 CFR § 50.12(a)(2)(ii) are present because the underlying purpose of the rule (10 CFR § 2.101(a)(5)), to facilitate the application submittal process for CP applicants when in the interest of the public, was achieved based on the SHINE Facility's contribution to meeting domestic demands for Mo-99.

Q17. Were there other companies or organizations that provided significant contributions in preparing the CP Application or supporting SHINE's response to the NRC's review of the CP Application?

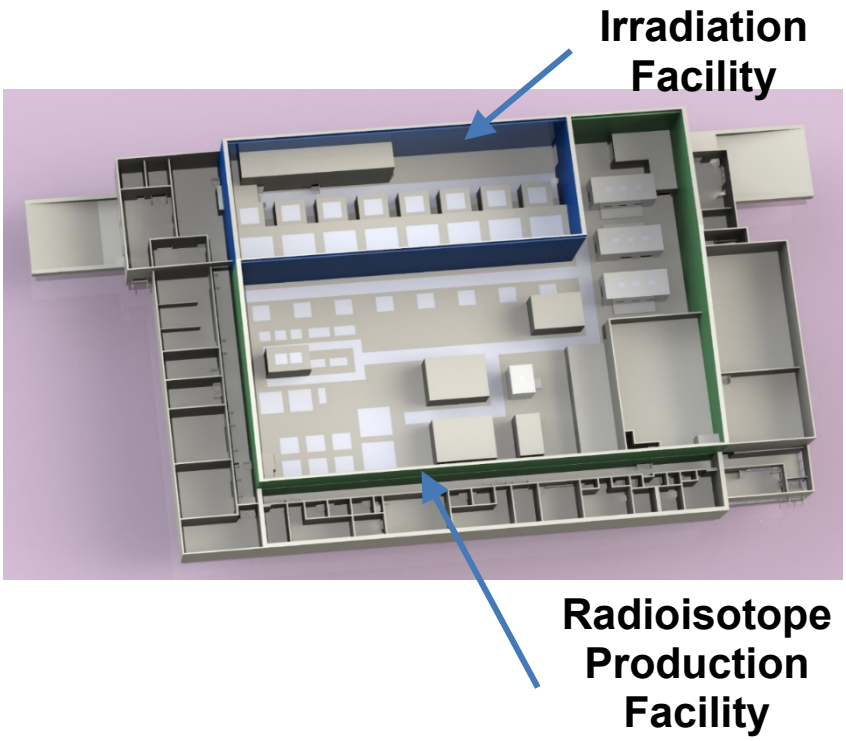
A17. Yes. Several other companies and organizations provided significant contributions in preparing the CP Application or supporting SHINE's response to the NRC's review of the CP Application, including: AECOM Technical Services (providing support for reviewing documents prepared by third parties); AMEC E&I, Inc. (providing support for

the environmental review); Atkins Nuclear Solutions US (formerly Nuclear Safety Associates, Inc.) (providing support for the accident, preliminary hazards, and integrated safety analyses, and calculations related to offsite dose, criticality safety, reactivity, and hazardous chemicals); Golder Associates Inc. (providing support for the environmental site assessment, and geotechnical, hydrological, and seismological assessments and calculations); Merrick & Company (providing support for the design of hot cells and various facility systems); Morgridge Institute for Research, Inc. (providing support for the conceptual design of the facility); Mortenson Construction (providing support for construction-related estimates and inputs into the environmental review); Phoenix Nuclear Labs, LLC (providing support for the design and development of the neutron driver); and Sargent & Lundy, LLC (providing support for the structural and seismic design and related calculations, external event and accident analyses, population estimates, and the design of electrical, instrument and control, fire protection and various auxiliary systems).

C. General Description of SHINE Facility

Q18. Please provide a general description of the SHINE Facility.

A18. As discussed in PSAR Section 1.3, the SHINE production facility building consists of an IF, RPF, shipping and receiving area, and other areas that contain various support systems and equipment. Floor plan and section drawings of the Facility showing the arrangements of the major structures and equipment are provided in PSAR Figures 1.3-1, 1.3-2, and 1.3-3. The SHINE Facility site layout is provided in PSAR Figure 1.3-4. The radiologically controlled area (RCA) of the SHINE Facility consists of the IF and the RPF (see PSAR Figure 1.3-5). The high-level layout of the Facility is provided below:



Q19. What are the principal characteristics of the site?

A19. The SHINE site consists of an undeveloped, approximately 91-acre parcel that has historically been farmed. Safety-related structures are located within a rectangular area located near the center of the property. The region of the SHINE site is entirely contained within Rock County, Wisconsin. The dominant land use in the region is agricultural/cultivated crops. The northern limits of the City of Beloit are located approximately 3.7 miles to the south. Principal characteristics of the site are further described in PSAR Chapter 2.

Q20. Where are the principal design criteria for the SHINE Facility identified?

A20. Design criteria for the SHINE Facility are addressed in PSAR Section 3.1. Design criteria for systems and components are addressed in PSAR Section 3.5.

Q21. What are the operating characteristics for the SHINE Facility?

A21. The IUs are operated in a batch mode (*i.e.*, one batch of target solution is irradiated in a TSV at a time) with an approximate week-long operating cycle. An operating cycle includes the following steps: receipt of uranyl sulfate target solution from the RPF, transfer to the TSV, operation of the subcritical assembly at full power for approximately 5.5 days, shut down, and transfer of the irradiated target solution to the RPF for isotope extraction. The target solution always is maintained in a subcritical state.

The RPF operates in a batch mode. The major operating steps include the following: preparation of uranyl sulfate solution from recycled materials (*i.e.*, target solution that had already been through the IU and RPF) and/or from raw feed materials, extraction of Mo-99 from irradiated target solution, purification of extracted Mo-99, and packaging of Mo-99 for shipment to customers. The RPF also contains systems and components for the cleanup of irradiated target solution to separate uranium from fission products and transuranics and for handling and storing wastes generated during this process. Operating characteristics of the IUs are discussed in more detail in PSAR Section 4a2. Operating characteristics of the RPF are discussed in more detail in PSAR Section 4b.

Q22. Please describe the Facility systems in more detail, starting with the IF.

A22. The IF consists of eight IUs. Each IU consists of a neutron driver assembly system (NDAS), a subcritical assembly system (SCAS), a light water pool system (LWPS), TOGS, and related support systems.

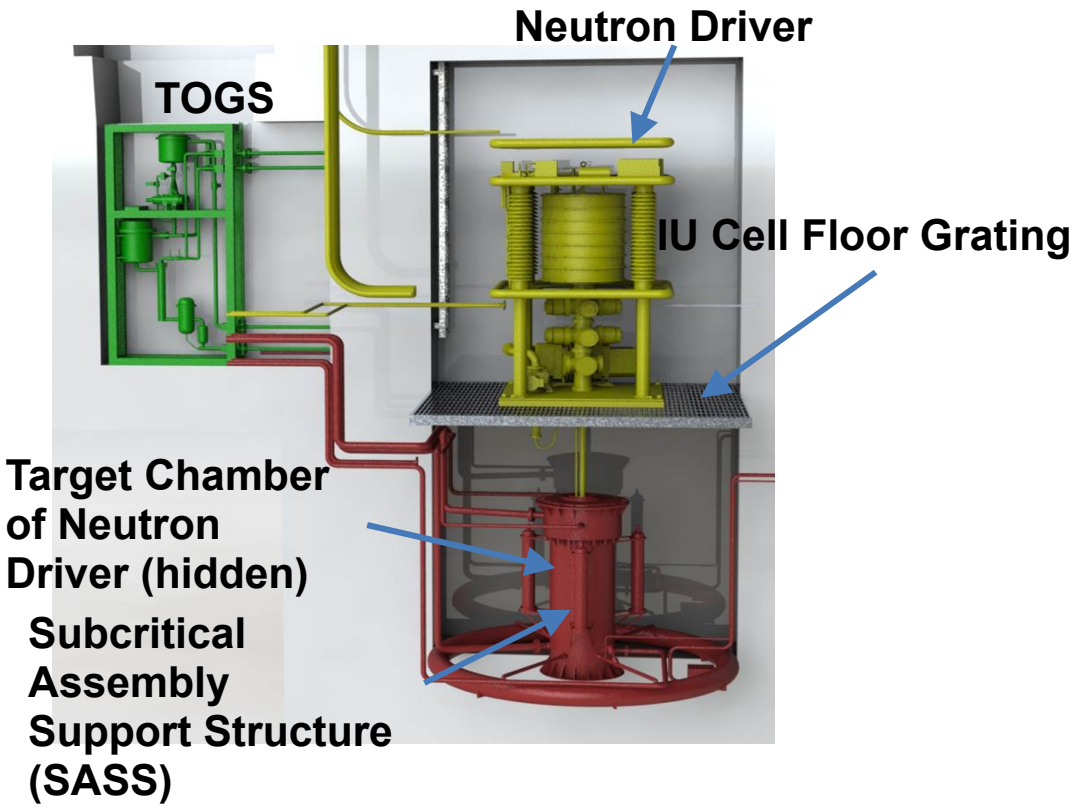
The neutron driver is an accelerator-based assembly that accelerates a deuterium beam into a tritium gas target chamber. The resulting fusion reaction produces 14 MeV

neutrons, which move outward from the tritium target chamber in all directions. The neutron driver is addressed in PSAR Section 4a2.3.

The neutron driver is located directly above the SCAS. Most of the neutrons enter the SCAS, where they are slowed down to thermal energy. The resulting thermal neutron flux interacts with the uranium-235 atoms in the target solution, causing the atoms to fission. Each SCAS has four major components: the TSV, the neutron multiplier, the subcritical assembly support structure (SASS), and the TSV dump tank. The SCAS and its subcomponents are described in PSAR Section 4a2.2.

The SCAS is located inside of the light water pool, part of the LWPS. The LWPS, which provides shielding and cooling, is addressed in PSAR Sections 4a2.4 and 5a2.2. The TOGS handles the off-gas from the TSV and is described in PSAR Section 4a2.8.

A figure illustrating an IU is provided below:



Q23. Please describe the RPF and related systems in more detail.

A23. The function of the RPF is to extract, purify, and package Mo-99 for the end users. Additionally, the RPF prepares feed target solution for the IUs. The RPF includes facility features and systems where the processes that support the IUs are performed, and where processing of the irradiated target solution occurs. Some of the key systems associated with the RPF are discussed below and are discussed further in PSAR Section 4b.

The target solution preparation system (TSPS) prepares target solution from either fresh uranium or recycled uranium from the target solution cleanup processes, and transfers the target solution to the TSV. The TSPS is described in PSAR Section 4b.1.3.1.

The molybdenum extraction and purification system (MEPS) receives irradiated target solution, processes the target solution to extract the Mo-99, then purifies the Mo-99

product into its final form prior to packaging and shipping. The MEPS is described in PSAR Section 4b.1.3.2.

The uranyl nitrate conversion system (UNCS) periodically performs additional processing of the irradiated target solution after the Mo-99 has been extracted. This processing includes conversion of the uranyl sulfate target solution to uranyl nitrate, cleanup of the target solution by removal of fission products, and conversion of the cleaned up target solution to uranium oxide that is then supplied to the TSPS as a feed material to produce new target solution. The UNCS is described in PSAR Section 4b.1.3.3.

The process vessel vent system (PVVS) collects and processes gases from the vents of process vessels that handle the main process fluids. This system is briefly discussed in PSAR Section 4b.1.3.5 (which identifies the relevant process vessels) and discussed in detail in PSAR Section 9b.6.

The molybdenum isotope product packaging system (MIPS) receives the Mo-99 from MEPS and packages it for shipment to the customers. This system is addressed briefly in PSAR Section 4b.1.3.4 and in detail in PSAR Section 9b.7.1.

Q24. What are the engineered safety features for the Facility?

A24. Engineered safety features (ESFs) are structures, systems, and components (SSCs) of the Facility that mitigate design basis events or accidents. ESFs for the IF are related to confinement of radiological material and are addressed in PSAR Section 6a2.2 and Table 6a2.2-2.

Confinement is the term used to describe the low-leakage boundary that surrounds radioactive materials released during a hypothetical accident and the associated RCA

ventilation system (RV). Confinement systems are designed to localize release of radioactive material to controlled areas in normal operational states and mitigate the consequences of design basis accidents. Radiation protection control features such as adequate shielding and the RV minimize hazards associated with radioactive materials. The principal design and safety objective of the confinement systems is to protect on-site personnel, the public, and the environment. The second design objective is to minimize reliance on administrative or complex active engineering controls to provide a confinement system that is as simple and as fail-safe as reasonably possible.

The TSV, TSV dump tank, TOGS, and associated components act as the primary pressure boundary and are safety-related SSCs. These components act as the primary fission product boundary and are referred to as the primary system boundary (PSB). The confinement boundary of the IU cell and TOGS shielded cell encloses the PSB.

Confinement of the IU cells is achieved through the RV, the engineered safety feature actuation system (ESFAS), and the biological shielding provided by the steel and concrete structures comprising the walls, roofs, and penetrations of the IU cell and TOGS shielded cell. Shielding of the IU cells is discussed in detail in PSAR Section 4a2.5.

ESFs outside the IF are related to confinement of radiological material and hazardous material and are addressed in PSAR Section 6b.2 and Table 6b.2-2. The RPF confinement areas include hot cell enclosures and gloveboxes for process operations and trench and vault enclosures for process tanks and piping.

Confinement for the RPF is achieved through the RV, radiological integrated control system (RICS), and biological shielding provided by the steel and concrete

structures comprising the walls, roofs, and penetrations of the hot cells. Shielding of the hot cells is discussed in detail in PSAR Section 4b.2.2.

Q25. Please describe the instrumentation, control, and electrical systems.

A25. The TSV process control system (TPCS) is used for control of normal operations, startup, and shutdown of the neutron driver and the TSV residing in the IU cell. The TSV is protected by the TSV reactivity protection system (TRPS). The TRPS is responsible for monitoring various essential inputs and has the ability to mitigate abnormal or accident conditions through automated protective actions. The protective actions include opening the TSV dump valves, deenergizing the neutron driver, closing the TSV fill valves, and closing the TSV dump tank outlet valves. The TPCS and the TRPS are addressed in PSAR Sections 7a2.3 and 7a2.4, respectively.

Control and protection systems associated with the RPF are addressed in Section 7b. The RICS provides for monitoring and control of safety-related components (including ESFs) within the RPF. The RICS also provides process monitoring and control of the non-safety-related systems within the RPF.

Design features of the control consoles and display instrumentation, and the radiation monitoring systems for both the IU and the RPF, are addressed in PSAR Chapter 7. Radiation monitoring systems include the criticality accident and alarm system (CAAS), the radiation area monitoring system (RAMS), and the continuous air monitoring system (CAMS). The CAAS provides for continuous monitoring, indication, and recording of neutron or gamma radiation levels in areas where personnel may be present and wherever an accidental criticality event could result from operational processes. The IF and RPF utilize the CAMS and RAMS for continuous radiological

monitoring. The RAMS and CAMS are strategically placed throughout the facility to alert personnel of any potential radiation hazards.

The SHINE Facility has one common non-safety electrical supply system, which provides power to the IF, the RPF, and other support buildings. Power service is provided by the local utility via an off-site feed. A standby diesel generator provides power for asset protection to selected loads in the event of a loss of off-site power. These systems are described in PSAR Section 8a2.1.

Emergency electrical power for the SHINE facility is provided by a Class 1E uninterruptible electrical power supply system (UPSS). This system consists of two independent trains, each consisting of a 250 volts direct current battery system with associated charger, inverter, and distribution system. This system is described in PSAR Section 8a2.2.

Q26. Please describe the TSV cooling and other auxiliary systems.

A26. The main source of cooling for the TSV and related components is provided by the LWPS and the primary closed loop cooling system (PCLS). The TSV and related components are submerged in the light water pool. The LWPS is addressed in PSAR Sections 5a2.2 and 4a2.4. The PCLS is addressed in PSAR Section 5a2.2. The light water pool and primary closed loop cooling make-up system (MUPS) supports the LWPS and the PCLS. This system is addressed in PSAR Section 5a2.5.

Primary cooling for the RPF and removal of heat from both the LWPS and the PCLS is provided by the radioisotope process facility cooling system (RPCS). This system is discussed in PSAR Section 5a2.3.

Ventilation for both the IF and the RPF is provided by the RV. This ventilation system is described in PSAR Section 9a2.1.

Equipment and processes related to handling and storage of target solution in the IF are addressed in PSAR Section 9a2.2. Equipment and processes related to handling and storage of byproduct material and special nuclear material are addressed in PSAR Section 9a2.5.

The tritium purification system (TPS) is provided to process gas from the tritium target of the neutron drivers. This system separates the deuterium from the tritium, and returns a purified tritium stream. This system is addressed in PSAR Section 9a2.7.1.

Finally, fire protection systems and programs are addressed in PSAR Section 9a2.3. Communications systems are addressed in PSAR Section 9a2.4. Other auxiliary systems are also addressed in PSAR Sections 9a2 and 9b.

Q27. Please describe radioactive waste management and radiation protection programs for the Facility.

A27. The SHINE Facility has a radiation protection program to protect the radiological health and safety of its workers. The program complies with the regulatory requirements of 10 CFR Parts 19, 20, and 70. This program includes the elements of an as low as reasonably achievable (ALARA) program, radiation monitoring and surveying, exposure control, dosimetry, contamination control, and environmental monitoring. This program is addressed in PSAR Section 11.1.2.

The SHINE Facility also has a respiratory protection program to protect its workers from airborne contamination. This program is described in PSAR Section 11.3.

Control of gaseous, liquid, and solid radioactive wastes generated during operation of the SHINE Facility is provided by the PVVS, the aqueous radioactive liquid waste storage system (RLWS), the radioactive liquid waste evaporation and immobilization system (RLWE), the noble gas removal system (NGRS), and the solid radioactive waste packaging system (SRWP). These systems are described in PSAR Sections 9b.6 and 9b.7.

D. Structure of the CP Application for the SHINE Facility

Q28. Please describe the structure of the CP Application for the SHINE Facility.

A28. The CP Application is organized as follows. Part One of the Application included an Enclosure 4 with General and Financial Information, which provides general information in accordance with 10 CFR § 50.33; fee information in accordance with 10 CFR §§ 50.30(e) and 170.21; and a Classified Information Agreement in accordance with 10 CFR § 50.37. Parts One and Two of the Application included the PSAR, which provides the technical information in accordance with 10 CFR § 50.34 and the environmental review in accordance with 10 CFR Part 51. Finally, on September 25, 2013, SHINE provided a discussion of preliminary plans for coping with emergencies in accordance with 10 CFR § 50.34(a)(10).

Q29. Please describe the structure of the PSAR.

A29. The PSAR for the CP Application for the SHINE Facility is organized as follows:

- Chapter 1 – The Facility
- Chapter 2 – Site Characteristics
- Chapter 3 – Design of Structures, Systems, and Components
- Chapter 4 – Irradiation Unit and Radioisotope Production Facility Description
- Chapter 5 – Cooling Systems
- Chapter 6 – Engineered Safety Features

- Chapter 7 – Instrument and Control Systems
- Chapter 8 – Electrical Power Systems
- Chapter 9 – Auxiliary Systems
- Chapter 10 – Experimental Facilities
- Chapter 11 – Radiation Protection Program and Waste Management
- Chapter 12 – Conduct of Operations
- Chapter 13 – Accident Analysis
- Chapter 14 – Technical Specifications
- Chapter 15 – Financial Qualifications
- Chapter 16 – Other License Considerations
- Chapter 17 – Decommissioning and Possession-Only License Amendments
- Chapter 18 – Highly Enriched to Low Enriched Uranium Conversion
- Chapter 19 – Environmental Review

Q30. Please discuss whether the form and content of the CP Application for the SHINE Facility conforms to NRC's regulatory guidance.

A30. SHINE prepared the CP Application to be generally consistent with NRC guidance in NUREG-1537, Parts 1 and 2 (ML042430055 and ML042430048, respectively) and the Interim Staff Guidance (ISG) that augments NUREG-1537, Parts 1 and 2 (ML12156A069 and ML12156A075, respectively).

E. NRC Review of the CP Application for the SHINE Facility

Q31. Did the NRC staff document its safety and environmental reviews of the CP Application for the SHINE Facility?

A31. Yes. The NRC documented its safety review in the Safety Evaluation Report (SER) (ML15288A076), issued on October 20, 2015, and documented its environmental review in the final EIS (FEIS) (NUREG-2183, ML15288A046), issued on October 16, 2015.

Q32. What were the conclusions of the NRC staff?

A32. In the SER, the staff concluded that the information provided by the applicant and documented in the SER (1) provides reasonable assurance that the final design will

conform to the design basis; (2) includes an adequate margin of safety; (3) SSCs adequately provide for the prevention of accidents and the mitigation of consequences of accidents; and (4) meets applicable regulatory requirements as well as NRC guidance. Therefore, the staff recommended that the Commission make the necessary safety findings to issue the CP. In the FEIS, the staff concluded that a weighing of the environmental, economic, technical, and other benefits against environmental and other costs, and considering reasonable alternatives, supports issuance of the CP.

Q33. Has the Advisory Committee on Reactor Safeguards (ACRS) conducted a review of the CP for the SHINE Facility?

A33. Yes. The ACRS Subcommittee on Radiation Protection and Nuclear Materials reviewed the PSAR and draft SER during meetings on June 23-24, August 19, and September 22, 2015. The Subcommittee had the benefit of discussions with SHINE and the NRC staff and review of referenced documents. The full ACRS considered the SHINE Facility during its 628th meeting on October 7-10, 2015.

Q34. What were the conclusions of the ACRS?

A34. The ACRS issued a letter report dated October 15, 2015 (ML15286A426) supporting issuance of the CP. The ACRS recommended: "The Construction Permit for the SHINE medical isotope production facility should be approved." The ACRS also concluded: "The staff demonstrated an ability to develop a practical licensing approach for a unique facility."

The ACRS also identified topics to be further addressed in the application for an Operating License, including criticality control and margin, adequacy of confinement, systems that provide support to safety-related systems, partial losses of electrical power,

hydrogen generation and control, underwater maintenance issues, and possible "red oil" and acetohydroxamic acid reactions. These topics were addressed to the ACRS's satisfaction for issuance of the CP.

Q35. Have you reviewed 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," dated October 22, 2015, that was submitted by the NRC staff to support the mandatory hearing for the SHINE Facility?

A35. Yes.

Q36. Do you agree with the staff's conclusions in SECY-15-0130 regarding the staff safety review, ACRS Report, exemptions, and the safety matters the staff considers to be "Nonroutine Unique Facility Features or Novel Issues"?

A36. Yes.

Q37. Does SECY-15-0130 address the safety and environmental findings that must be made to issue the CP for the SHINE Facility?

A37. Yes.

Q38. What are the staff's conclusions in SECY-15-0130 regarding those findings?

A38. The staff concludes that there is sufficient information in the record to support the required findings to issue the CP. I discuss each of the findings in more detail in subsequent sections of my testimony.

Q39. Do you agree with the overall conclusions reached in SECY-15-0130?

A39. Yes.

F. Litigation on the Application

Q40. Were any petitions to intervene submitted on the CP Application for the SHINE Facility?

A40. No.

III. SAFETY FINDINGS

Q41. Please describe the regulatory requirements applicable to the safety review of the CP Application for the SHINE Facility.

A41. The regulatory requirements applicable to the safety review of the CP Application are contained in 10 CFR Part 50. Specifically:

- Section 50.30 identifies certain filing requirements for applications for licenses, including the provision of an Environmental Report.
- Section 50.33 identifies general information requirements for applications.
- Section 50.34 includes requirements for the content of the PSAR.

Q42. Please summarize the NRC staff's safety review of the CP Application for the SHINE Facility.

A42. The NRC staff's review is summarized in SECY-15-0130. In addition, I would note that the staff issued and we responded to approximately 370 questions in requests for additional information (RAIs), which indicates the depth of the staff's review of the CP for the SHINE Facility.

Q43. What safety findings must the Commission make under 10 CFR Part 50 in order to issue the CP for the SHINE Facility?

A43. The findings necessary to issue a CP are found in 10 CFR §§ 50.35(a), 50.40, and 50.50.

Section 50.35(a) identifies the following findings:

- (1) 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 the major features or components incorporated therein for the protection of the health and safety of the public;
- (2) such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report;
- (3) safety features or components, if any, which require research and development have been described by the applicant and the applicant has identified, and there will be conducted, a research and development program reasonably designed to resolve any safety questions associated with such features or components; and
- (4) on the basis of the foregoing, there is reasonable assurance that, (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in part 100 of this chapter, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

Section 50.40 identifies the following findings:

- (a) Except for an early site permit or manufacturing license, the processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other technical specifications, or the proposals, in regard to any of the

foregoing collectively provide reasonable assurance that the applicant will comply with the regulations in this chapter, including the regulations in part 20 of this chapter, and that the health and safety of the public will not be endangered.

- (b) The applicant for a construction permit . . . is technically and financially qualified to engage in the proposed activities in accordance with the regulations in this chapter.
- (c) The issuance of a construction permit . . . will not, in the opinion of the Commission, be inimical to the common defense and security or to the health and safety of the public.
- (d) Any applicable requirements of subpart A of 10 CFR part 51 have been satisfied.

Section 50.50 identifies the following findings:

- Upon determination that an application for a license meets the standards and requirements of the act and regulations, and that notifications, if any, to other agencies or bodies have been duly made, the Commission will issue a license, or if appropriate a construction permit, in such form and containing such conditions and limitations including technical specifications, as it deems appropriate and necessary.

Q44. What is the staff's conclusion in the SER regarding the SHINE Facility?

A44. The SER concludes that:

> Based upon the review documented in the SER, the staff finds that the preliminary design and analysis of the SHINE IF and RPF, including the principal design criteria; design bases; information relative to materials of construction, general arrangement, and approximate dimensions; and preliminary analysis and evaluation of the design and performance of structures, systems, and

components (SSCs) of the facility, as described in the SHINE preliminary safety analysis report, and as supplemented by responses to RAIs: (1) provides reasonable assurance that the final design will conform to the design basis; (2) includes an adequate margin of safety; (3) SSCs adequately provide for the prevention of accidents and the mitigation of consequences of accidents; and (4) meets applicable regulatory requirements as well as NRC guidance. Therefore, the staff recommends that the Commission make the necessary findings with respect to the safety of the construction permit in accordance with 10 CFR 50.35, "Issuance of construction permits"; 50.40, "Common standards"; and 50.50, "Issuance of licenses and construction permits."

Q45. Are the necessary findings in 10 CFR Part 50 met for the SHINE Facility?

A45. Yes. Based upon the staff's conclusions discussed in my previous answer, and as summarized on pages 17-21 of SECY-15-0130, each of the relevant findings in 10 CFR Part 50 have been met. I address each of these findings in more detail below.

A. 10 CFR § 50.35(a)(1) ("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 the major features or components incorporated therein for the protection of the health and safety of the public")

Q46. Please discuss whether SHINE has described the proposed design of the facility.

A46. SHINE described the proposed design of the facility throughout the PSAR. Some of the relevant portions of the PSAR include Chapter 1 (The Facility), Chapter 3 (Design of Structures, Systems, and Components), Chapter 4 (Irradiation Unit and Radioisotope Production Facility Description), Chapter 5 (Cooling Systems), Chapter 6 (Engineered Safety Features), Chapter 7 (Instrument and Control Systems), Chapter 8 (Electrical Power Systems), and Chapter 9 (Auxiliary Systems). The PSAR includes principal architectural and engineering criteria for the design, and major features or components incorporated therein for the protection of the health and safety of the public.

Q47. Has the NRC staff reached a conclusion on this finding?

A47. Yes. The staff discusses this finding on pages 17-18 of SECY-15-0130 and concludes that "SHINE 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 the major features or components incorporated therein for the protection of the health and safety of the public."

Q48. Do you agree with the NRC staff's conclusion?

A48. Yes.

B. <u>10 CFR § 50.35(a)(2) ("such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report")</u>

Q49. Has the applicant identified technical or design information that is required to complete the safety analysis and will be provided in the future Final Safety Analysis Report (FSAR)?

A49. Yes. SHINE recognizes that additional technical and design information for the SHINE Facility needs to be provided to support operation of the Facility. SHINE identified throughout the PSAR and in responses to RAIs the areas in which further information would be provided in the FSAR to complete the safety analysis. SHINE is tracking these issues as part of its Corrective Action Program to ensure that these issues are addressed in the FSAR. Additionally, Appendix A.2 and Appendix A.4 of the SER identify the issues that must be addressed as part of an Operating License Application.

Q50. Has the NRC staff reached a conclusion on this finding?

A50. Yes. The staff discusses this finding on pages 18-19 of SECY-15-0130 and concludes that "SHINE has provided reasonable assurance that further technical or design

information, which can reasonably be left for later consideration, will be supplied in the FSAR."

Q51. Do you agree with the NRC staff's conclusion?

A51. Yes.

C. <u>10 CFR § 50.35(a)(3) ("safety features or components, if any, which require research and development have been described by the applicant and the applicant has identified, and there will be conducted, a research and development program reasonably designed to resolve any safety questions associated with such features or components")</u>

Q52. Did SHINE identify safety features or components which require research and development?

A52. Yes. In accordance with 10 CFR § 50.34(a), PSAR Section 1.3.9, supplemented by SHINE's Response to RAI G-1 (ML14296A192), includes identification of those SSCs of the Facility 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 SSCs; 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.

As described in Appendix A.5 of the SER, SHINE has identified two ongoing research and development activities:

- Irradiation and corrosion testing at Oak Ridge National Laboratory to study mechanical performance of materials.
- Precipitation studies at Argonne National Laboratory to ensure precipitation of uranyl peroxide in the target solution will not occur.

Q53. Has the NRC staff reached a conclusion on this finding?

A53. Yes. The staff discusses this finding on pages 19-20 of SECY-15-0130 and concludes that "SHINE has described safety features and components that require research and development" and will conduct the corresponding research and development program.

Q54. Do you agree with the NRC staff's conclusion?

A54. Yes.

D. <u>10 CFR § 50.35(a)(4) ("there is reasonable assurance that, (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in part 100 of this chapter, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public")</u>

Q55. Explain why there is reasonable assurance that safety questions will be satisfactorily resolved at or before the latest date for completion of construction.

A55. SHINE has informed the NRC that the latest date for completion of construction of the SHINE Facility is expected to be December 31, 2022. As described in Appendix A.5 of the SER, SHINE has identified two ongoing research and development activities. There is ample time between the scheduled completion of these research and development activities and the latest date for completion of construction to satisfactorily resolve any related safety questions.

Q56. Explain why there is reasonable assurance that the SHINE Facility can be constructed and operated at the proposed location, taking into consideration the site criteria contained in 10 CFR Part 100, without undue risk to the health and safety of the public.

A56. Because the SHINE Facility is not a reactor, the requirements of 10 CFR Part 100 do not directly apply. Nonetheless, SHINE considered relevant siting criteria in Part 100, as directed by NRC guidance in NUREG-1537 and related ISGs. For example, Chapter 2 of the CP Application considers site characteristics, such as geography and demography; nearby industrial, transportation, and military facilities; meteorology; hydrology; and geology, seismology, and geotechnical engineering. Other relevant portions of the CP Application include the Radiation Protection Program in Chapter 11, operations plans in Chapter 12, and the accident analysis in Chapter 13. This information and other portions of the Application provide reasonable assurance that the SHINE Facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

Q57. What actions did the NRC staff take to satisfy itself that the SHINE Facility could be constructed and operated safely?

A57. In addition to reviewing the CP Application material provided by SHINE, the NRC staff issued numerous RAIs. The RAIs sought additional information or clarifications in order to develop sufficient information for the NRC staff to make a reasonable assurance finding. The NRC staff also conducted audits and inspections of SHINE's records and documentation and performed confirmatory calculations in order to confirm conclusions made by SHINE.

Q58. Has the NRC staff reached a conclusion on this finding?

A58. Yes. The staff discusses this finding on pages 20-21 of SECY-15-0130 and concludes that (1) "there is reasonable assurance that SHINE's research and development activities will be satisfactorily completed at or before the latest date for the completion of

construction of the SHINE facility"; and (2) "there is reasonable assurance that the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public."

Q59. Do you agree with the NRC staff's conclusion?

A59. Yes.

E. <u>10 CFR § 50.40(a) ("the processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other technical specifications, or the proposals, in regard to any of the foregoing collectively provide reasonable assurance that the applicant will comply with the regulations in this chapter, including the regulations in part 20 of this chapter, and that the health and safety of the public will not be endangered")</u>

Q60. Please discuss how the applicant and the SHINE Facility will comply with the NRC regulations, including those in 10 CFR Part 20, and that the health and safety of the public will not be endangered.

A60. The CP Application was based on NRC regulations and applicable portions of NRC guidance, such as ISGs and NUREGs. The NRC staff reviewed the CP Application and evaluated it against the applicable regulations in 10 CFR Part 50 and 10 CFR Part 20. The NRC staff considered applicable portions of its guidance. Based on the CP Application and the NRC staff's review, documented in the SER and the FEIS, SHINE concludes that, for the purpose of issuing the CP for the SHINE Facility, the applicable standards and requirements of the Commission's regulations have been met. Compliance with these regulations ensures that the health and safety of the public will not be endangered.

Q61. Did the NRC staff reach a conclusion on whether the applicable Commission regulations have been met by the CP Application for the SHINE Facility?

A61. Yes. As discussed on page 24 of SECY-15-0130, the staff has concluded that the applicable standards and requirements of the Commission's regulations have been met.

Q62. Do you agree with the NRC staff's conclusion?

A62. Yes.

F. 10 CFR § 50.40(b) ("The applicant for a construction permit . . . is technically and financially qualified to engage in the proposed activities in accordance with the regulations in this chapter")

Q63. Please discuss why the applicant is technically qualified to engage in the activities to be authorized by the CP for the SHINE Facility.

A63. SHINE has developed a new method for the manufacture of medical isotopes and was created specifically for the purpose of designing, constructing, and operating the SHINE Facility. SHINE has engaged contractors experienced with the design and construction of nuclear process facilities to assist with the preliminary design and development of the PSAR. SHINE will continue to use qualified contractors to complete the detailed design and to help manage the construction of the facility. Experienced and qualified SHINE engineering and management staff provided oversight and detailed review of the preliminary design. SHINE staff and management, supplemented by experienced contractors and consultants, will continue to review and oversee the detailed design and construction. The SHINE Quality Assurance Program will guide the activities authorized by the CP to ensure the completed facility meets the applicable regulations and the design criteria described in the PSAR.

Q64. Did the NRC staff conclude that the applicant is technically qualified to engage in the activities authorized by the CP?

A64. Yes. On page 23 of SECY-15-130, the staff concluded: "SHINE is technically qualified to engage in the construction of its proposed facility in accordance with the Commission's regulations."

Q65. Do you agree with the NRC staff's conclusion?

A65. Yes.

Q66. Please discuss why SHINE is financially qualified to engage in the activities proposed for the SHINE Facility.

A66. As demonstrated in PSAR Chapter 15, SHINE is financially qualified to own, construct, operate, and decommission the SHINE Facility. Some of this information in Chapter 15 was unnecessary to support issuance of a CP, and will be further considered at the Operating License stage.

PSAR Section 15.1 describes SHINE's financial ability to construct the SHINE Facility. In accordance with NRC regulatory requirements, SHINE provided information to demonstrate that it possesses or has reasonable assurance of obtaining the necessary funds to cover estimated construction costs and related fuel cycle costs. That included budget estimates, sources of financing, and financing plans.

Additionally, PSAR Section 15.4 demonstrates that SHINE is not owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government. In particular, SHINE is a private corporation; all of the current shareholders holding 1 percent or more of SHINE's stock are U.S. citizens or entities owned or controlled by U.S. citizens; all of the current employees holding stock options are U.S. citizens; and all directors are U.S. citizens, except for one Canadian citizen with U.S. permanent resident status.

Q67. Did the NRC staff conclude that the applicant is financially qualified to engage in the activities authorized by the CP?

A67. Yes. On page 24 of SECY-15-0130, the staff concluded: "SHINE is financially qualified to engage in the construction of its proposed facility in accordance with the Commission's regulations."

Q68. Do you agree with the NRC staff's conclusion?

A68. Yes.

G. 10 CFR § 50.40(c) ("The issuance of a construction permit . . . will not, in the opinion of the Commission, be inimical to the common defense and security or to the health and safety of the public")

Q69. Please discuss whether the issuance of the CP will be inimical to the common defense and security or to the health and safety of the public.

A69. SHINE provided information, analysis, and conclusions regarding site-specific conditions, including geography and demography of the site; nearby industrial, transportation, and military facilities; site meteorology; site hydrology; and site geology, seismology, and geotechnical engineering to ensure that issuance of the CP will not be inimical to public health and safety. In addition to a review of that information, SHINE also evaluated the design of structures, systems, and components to ensure safe operation, performance, and shutdown when subject to events, such as extreme weather, floods, seismic events, and missiles (including aircraft impact). This and other information in the CP Application demonstrates that issuance of the CP will not be inimical to the common defense and security or to the health and safety of the public. SHINE's Security Plan will be provided with the Operating License Application.

Q70. Did the NRC staff make an overall inimicality finding?

A70. Yes. As discussed on page 24 of SECY-15-0130, the staff concluded: "The issuance of a permit for the construction of the facility would not be inimical to the common defense and security or to the health and safety of the public."

Q71. Do you agree with the NRC staff's conclusion?

A71. Yes.

H. 10 CFR § 50.40(d) ("Any applicable requirements of subpart A of 10 CFR part 51 have been satisfied")

Q72. Please discuss whether the NRC staff's review has been adequate to support the findings set forth in 10 CFR § 51.105(a).

A72. As discussed in the sections below, the NRC staff's environmental review has been adequate to support the findings set forth in 10 CFR § 51.105(a).

I. 10 CFR § 50.50 ("application for a license meets the standards and requirements of the act and regulations, and that notifications, if any, to other agencies or bodies have been duly made")

Q73. Please discuss why the applicable standards and requirements of the Atomic Energy Act of 1954, as amended (Act) and the Commission's regulations have been met by the CP Application for the SHINE Facility.

A73. As discussed above, the CP Application was based on NRC regulations and applicable portions of NRC guidance, such as ISGs and NUREGs. The NRC staff reviewed the CP Application and evaluated it against the applicable regulations in 10 CFR Part 50. The NRC staff considered applicable portions of its guidance. Based on the CP Application and the NRC staff's review, documented in the SER and the FEIS, SHINE concludes

that, for the purpose of issuing the CP for the SHINE Facility, the applicable standards and requirements of the Act and the Commission's regulations have been met.

Q74. Has the staff identified any proposed permit conditions for the CP for the SHINE Facility?

A74. Yes. As discussed in Appendix A.1 of the SER, the staff determined that additional information is needed to address certain matters related to nuclear criticality safety and radiation protection in the RPF. Therefore, the staff recommends that any CP include five permit conditions that would require SHINE to provide periodic reports and information related to these topics to the NRC prior to completing construction.

Q75. Did the NRC staff reach a conclusion on whether the applicable standards and requirements of the Act and the Commission's regulations have been met by the CP Application for the SHINE Facility, and whether the required notifications to other agencies or bodies have been made?

A75. Yes. As discussed on page 24 of SECY-15-0130, the staff has concluded that the applicable standards and requirements of the Act and the Commission's regulations have been met. It also concluded that any required notifications have been made to other agencies or bodies.

Q76. Do you agree with the NRC staff's conclusion?

A76. Yes.

IV. ENVIRONMENTAL FINDINGS

Q77. Please describe the regulatory requirements applicable to the environmental review for the SHINE Facility.

A77. 10 CFR § 50.30(f) (Environmental report) states that "[a]n application for a construction permit . . . for a . . . production or utilization facility whose construction or operation may be determined by the Commission to have a significant impact in the environment, shall be accompanied by an Environmental Report required under subpart A of part 51 of this chapter." SHINE provided its Environmental Report (ER) in PSAR Chapter 19. The format and content of the ER follows the guidance in the ISG for NUREG-1537, Part 1, Chapter 19. In summary, the regulations in 10 CFR Part 51 as described in the guidance require an ER to include a description of: the proposed action and its purposes; regulatory provisions, permits, and required consultations; the environment affected and the impact of the proposed action on the environment; alternatives to the proposed action; unavoidable adverse environmental impacts of the proposed action; the relationship between short-term uses of the environment and the maintenance and enhancement of long-term productivity; any irreversible and irretrievable commitments of resources; and the benefits and costs of the proposed action and its alternatives.

Q78. Please describe the content of the ER for the SHINE Facility.

A78. The ER in PSAR Chapter 19 contains the following six sections:

- Section 19.1 – Introduction of the Environmental Report
  - 19.1.1 – Purpose and Need for the Proposed Action
  - 19.1.2 – Regulatory Provisions, Permits, and Required Consultations

- Section 19.2 – Proposed Action
  - 19.2.1 – Site Location and Layout
  - 19.2.2 – Radioisotope Facility Description
  - 19.2.3 – Water Consumption and Treatment
  - 19.2.4 – Cooling and Heating Dissipation Systems
  - 19.2.5 – Waste Systems
  - 19.2.6 – Storage, Treatment, and Transportation of Radioactive and Nonradioactive Materials, Including LEU, Waste, Radioisotopes, and Any Other Materials

- Section 19.3 – Description of the Affected Environment
  - 19.3.1 – Land Use and Visual Resources
  - 19.3.2 – Air Quality and Noise
  - 19.3.3 – Geologic Environment
  - 19.3.4 – Water Resources
  - 19.3.5 – Ecological Resources
  - 19.3.6 – Historic and Cultural Resources
  - 19.3.7 – Socioeconomics
  - 19.3.8 – Human Health

- Section 19.4 – Impacts of Proposed Construction, Operations, and Decommissioning
  - 19.4.1 – Land Use and Visual Resources
  - 19.4.2 – Air Quality and Noise
  - 19.4.3 – Geologic Environment
  - 19.4.4 – Water Resources
  - 19.4.5 – Ecological Resources
  - 19.4.6 – Historic and Cultural Resources
  - 19.4.7 – Socioeconomics
  - 19.4.8 – Human Health
  - 19.4.9 – Waste Management
  - 19.4.10 – Transportation
  - 19.4.11 – Postulated Accidents
  - 19.4.12 – Environmental Justice
  - 19.4.13 – Cumulative Effects

- Section 19.5 – Alternatives
  - 19.5.1 – No-Action Alternative
  - 19.5.2 – Reasonable Alternatives
  - 19.5.3 – Cost-Benefit of the Alternatives
  - 19.5.4 – Comparison of the Potential Environmental Impacts

- Section 19.6 – Conclusions
  - 19.6.1 – Unavoidable Adverse Environmental Impacts
  - 19.6.2 – Relationship Between Short-Term Uses and Long-Term Productivity of the Environment
  - 19.6.3 – Irreversible and Irretrievable Commitments of Resources

Q79. Does the ER for the SHINE Facility satisfy the requirements of 10 CFR Part 51 and the National Environmental Policy Act (NEPA)?

A79. Yes. The ER for the SHINE Facility satisfies the requirements of 10 CFR Part 51 and NEPA.

Q80. What conclusions does the ER for the SHINE Facility make regarding unavoidable adverse environmental impacts?

A80. Tables 19.6.1-1 and 19.6.1-2 in the ER indicate that all of the adverse environmental impacts associated with construction and operation of the SHINE Facility are SMALL and are further reduced through the application of mitigation and control measures. Most of the impacts from construction and operation are SMALL due to design features that result in lower levels of impacts, best management practices that control and mitigate emissions and discharges to air and water, use of agricultural/cultivated crop lands that were previously altered or disturbed, and applicable federal and state permitting requirements designed to protect humans and biota. These SMALL impacts generally have no detectable adverse impacts or only minor adverse impacts.

Q81. What conclusions does the ER for the SHINE Facility make regarding alternatives to the project?

A81. Section 19.5 of the ER evaluates the following types of alternatives:

- No-Action Alternative
- Alternative Sites
- Alternative Technologies

The ER makes the following conclusions:

- In light of the benefits of the proposed project (*e.g.*, socioeconomic; health benefit from supply of Tc-99m; support for U.S. government policy to encourage domestic production of medical isotopes; nonproliferation), the No-Action alternative is not preferable to the construction and operation of the SHINE Facility. Although the No-Action Alternative would avoid the environmental

impacts associated with construction and operation, these impacts are SMALL for the SHINE technology, and avoiding these impacts is not significant.

- The ER considered two alternatives sites (Chippewa Falls and Stevens Point); however, neither of the alternative sites would reduce or avoid adverse effects as compared with the SHINE project site.
    - Table 19.5.4-1 summarizes the expected environmental impacts of project construction at the SHINE project site and each of the alternative sites. Construction impacts at the SHINE project site are SMALL for every resource category. Both of the alternative sites have MODERATE construction impacts in several resource categories. Chippewa Falls and Stevens Point both have a MODERATE construction impact in Visual Resources, Noise, and Socioeconomic Transportation. In addition, Stevens Point has a MODERATE construction impact in Land Use and Ground Water Resources.
    - Table 19.5.4-2 summarizes the expected environmental impacts of project operation at the SHINE project site and each of the alternative sites. Operation impacts at the SHINE project site and both of the alternative sites are SMALL for every resource category.
- A linear accelerator-based technology and a LEU aqueous homogenous reactor are considered reasonable alternatives to the SHINE technology for the Janesville site. However, none of the alternative technologies would reduce or avoid adverse effects as compared with the SHINE technology.

Q82. What conclusions does the ER for the SHINE Facility make regarding irreversible and irretrievable commitments of resources?

A82. The ER makes the following conclusions regarding irreversible and irretrievable commitments of resources:

- The land used for the SHINE facility is not irreversibly committed because once SHINE ceases operations and the facility is decommissioned in accordance with NRC requirements, the land supporting the facilities could be returned to other industrial or nonindustrial uses. Approximately 26 acres of prime farmland or farmland of statewide importance on the SHINE site could be irreversibly converted to developed land or experience surface soil damage during temporary use such that the soil properties responsible for the prime farmland designation would be irreversibly damaged.
- There are no direct impacts to water quality or hydrology from the SHINE Facility; therefore, there will be no irreversible impacts.
- Long-term irreversible losses of terrestrial biota are not anticipated. Subsequent to the completion of construction, floral and faunal resources are expected to recover in areas that are not affected by on-going operations. There are no operational impacts associated with impingement or entrainment of aquatic biota. The SHINE Facility avoids any impacts associated with pollutant or thermal discharges to aquatic resources.
- No irreversible commitments will be made to socioeconomic resources because they are reallocated for other purposes once the facility is decommissioned.

- No known historic or cultural resources are irreversibly altered due to the SHINE Facility.
- Mitigation measures will minimize impacts from dust and other emissions during construction. Emissions during operations are in compliance with applicable Federal and State regulations, minimizing their impact on public health and the environment.
- Irretrievable commitments of resources during new plant construction are generally similar to that of any small-scale medical facility construction project. During operations, the main resource that is irreversibly and irretrievably committed is the uranium used as the source for the molybdenum isotope. While a given quantity of material consumed during new facility construction and operation at the SHINE site is irretrievable, except for materials recycled during decommissioning, the impact on their availability is SMALL.

Q83. What conclusions does the ER for the SHINE Facility make regarding the relationship between short-term uses and long-term productivity of the human environment?

A83. The impacts resulting from the SHINE Facility construction and operation result in both adverse and beneficial short-term impacts. The principal short-term adverse impacts are SMALL residual impacts (after mitigation measures are implemented) to land use, terrestrial ecology, local traffic, and air quality. There are no long-term impacts to the environment. The principal short-term benefits are the creation of additional jobs, additional tax revenues, and improvements to local infrastructure. The principal long-term benefit is the continued availability of the improved infrastructure and potential

benefits from increased tax revenues after facility decommissioning. The short-term impacts and benefits and long-term benefits do not affect long-term productive use of the SHINE site.

Q84. What is the overall conclusion in the ER for the SHINE Facility regarding the benefits and costs of the proposed project?

A84. The costs and benefits of the project are summarized in ER Tables 19.5.4-1 to 19.5.4-4 and discussed in Section 19.5.3.1.1. The primary benefits are jobs (approximately 450 construction jobs during the peak construction activities and 150 permanent operational jobs), tax payments (expected to be approximately $635,000 per year during construction and approximately $660,000 per year during operation), health benefit from reliable source of diagnostic isotopes (expected to satisfy approximately half of the annual demand for Tc-99m in the United States), production of commercial products (Mo-99, I-131, Xe-133), and other programmatic benefits. The costs from construction and operation of the SHINE Facility are economic and some environmental impacts to air quality, water quality, biotic resources, aesthetic resources, socioeconomics, and land use, but all of the environmental impacts are SMALL. Based upon these tables, SHINE concludes that the benefits of the project outweigh the costs.

Q85. What environmental findings must the Commission make under 10 CFR Part 51 in order to issue the CP for the SHINE Facility?

A85. Under 10 CFR § 51.105(a), the Commission must do the following:

- Determine whether the requirements of Sections 102(2) (A), (C), and (E) of NEPA and the regulations in Subpart A of 10 CFR Part 51 have been met;

- Independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken;
- Determine, after weighing the environmental, economic, technical, and other benefits against environmental and other costs, and considering reasonable alternatives, whether the CP should be issued, denied, or appropriately conditioned to protect environmental values; and
- Determine whether the NEPA review conducted by the NRC staff has been adequate.

Q86. Are the findings in 10 CFR § 51.105(a) met for the SHINE Facility?

A86. Yes, as discussed in more detail below.

A. 10 CFR § 51.105(a)(1) ("Determine whether the requirements of Sections 102(2) (A), (C), and (E) of NEPA and the regulations in this subpart have been met")

Q87. Please describe the NRC staff's environmental review process for the CP and whether it utilized a systematic, interdisciplinary approach.

A87. The staff prepared the FEIS for the SHINE Facility based on its independent assessment of the information in the ER and other information provided by the applicant. The staff also developed some of the information in the FEIS independently, such as through visiting the site and consultation with other agencies. The staff's technical analysis used a systematic, interdisciplinary approach to integrate information from many fields, including use of individuals experienced in the fields of water resources, land use, human health, waste management, accidents, historic and cultural resources, socioeconomic impacts, and Environmental Justice, as listed in Chapter 7 to the FEIS.

Q88. Please discuss whether the FEIS for the SHINE Facility discusses the environmental impacts of the project, any adverse environmental effects that cannot be avoided, alternatives, the relationship between local short term uses of man's environments and the maintenance of long-term productivity, and any irreversible and irretrievable commitments of resources.

A88. The FEIS for the SHINE Facility addressed (1) the environmental impacts of the proposed action (Chapter 4 of the FEIS); (2) unavoidable adverse environmental effects (Section 6.3.1 of the FEIS): (3) alternatives to the proposed action (Chapter 5 of the FEIS): (4) the relationship between local short-term uses of the environment and the maintenance and enhancement of long-term productivity (Section 6.3.2 of the FEIS); and (5) irreversible and irretrievable commitments of resources that would be involved in the proposed action should it be implemented (Section 6.3.3 of the FEIS).

Q89. Did the NRC staff consult with other agencies in preparing the FEIS for the SHINE Facility?

A89. The U.S. Department of Energy (DOE) participated as a cooperating agency in preparing the FEIS for the SHINE Facility. This collaboration was defined under a Memorandum of Agreement between the NRC and DOE. The staff also consulted with and received comments from other Federal, State, regional, local, and tribal agencies such as the U.S. Fish and Wildlife Service, the Wisconsin Department of Natural Resources, and the Citizen Potawatomi Nation. FEIS Chapter 9 provides a list of those who received a copy of this EIS. FEIS Appendix C contains a chronological list of all correspondence sent and received during the environmental review.

Q90. Please discuss whether the requirements of Sections 102(2) (A), (C), and (E) of NEPA and the regulations in Subpart A of 10 CFR Part 51 have been met with respect to the CP for the SHINE Facility.

A90. Based upon my answers to the previous three questions, I conclude that the requirements of Sections 102(2) (A), (C), and (E) of NEPA and the regulations in Part 51 have been met with respect to the CP for the SHINE Facility.

B. 10 CFR § 51.105(a)(2) ("Independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken")

Q91. Please discuss whether the NRC staff has independently considered the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken with respect to the SHINE Facility.

A91. In FEIS Section 5.4, the NRC staff provides its summary for the cost-benefit balancing for the SHINE Facility. The staff concluded that the overall benefits of constructing, operating, and decommissioning the proposed SHINE Facility at the Janesville site outweigh the disadvantages and costs.

Q92. Do you agree with the conclusions of the NRC staff on this factor?

A92. Yes. SHINE concludes that the benefits of the project outweigh the costs.

C. 10 CFR § 51.105(a)(3) ("Determine, after weighing the environmental, economic, technical, and other benefits against environmental and other costs, and considering reasonable alternatives, whether the construction permit . . . should be issued, denied, or appropriately conditioned to protect environmental values")

Q93. Please discuss whether the NRC staff has weighed the environmental, economic, technical, and other benefits against environmental and other costs with respect to the SHINE Facility.

A93. Based on the assessments summarized in FEIS Section 5.4, the NRC staff concluded that the accrued benefits would outweigh the costs of construction and operation of the SHINE Facility.

Q94. Please discuss whether the NRC staff has considered reasonable alternatives with respect to the SHINE Facility.

A94. The alternatives considered in FEIS Chapter 5 include the no-action alternative, alternative sites, and alternative technologies. The FEIS demonstrates that the NRC staff adequately considered alternatives to the proposed action, consistent with the requirements of NEPA.

Q95. Please discuss whether the NRC staff has determined whether the CP should be issued, after weighing the environmental, economic, technical, and other benefits against environmental and other costs, and considering reasonable alternatives.

A95. As discussed in FEIS Section 6.4, the NRC staff's recommendation to the Commission related to the environmental aspects of the proposed action is that the CP should be issued. The staff's recommendation is based on (1) the ER submitted by SHINE; (2) consultation with Federal, State, and local agencies; (3) the NRC's own independent environmental review; and (4) the staff's consideration of public comments.

Q96. Do you agree with the conclusions of the NRC staff on this factor?

A96. Yes.

D. 10 CFR § 51.105(a)(4) ("Determine, in an uncontested proceeding, whether the NEPA review conducted by the NRC staff has been adequate")

Q97. Please discuss whether the NRC staff's NEPA review has been adequate with respect to the SHINE Facility.

A97. The NRC staff conducted an independent evaluation of the CP Application that consumed over two and a half years and issued approximately 70 questions in environmental RAIs. The NRC staff developed independent, reliable information and conducted a systematic, interdisciplinary review of the potential impacts of the proposed action on the environment and reasonable alternatives to the proposed action. The NRC staff considered the purpose of and need for the proposed action, the environment that could be affected by the action and the consequences of the proposed action, including mitigation that could reduce impacts. The FEIS considered whether there is a need for the SHINE Facility. The FEIS compared the alternatives to the proposed action. The NRC staff considered the adverse environmental effects that could not be avoided should the proposed action be implemented, the relationship between short-term uses of the human environment and the maintenance and enhancement of long-term productivity, and irreversible or irretrievable commitments of resources that would be involved in the proposed project.

Q98. Please discuss whether the NRC staff's environmental review for the SHINE Facility followed NRC regulations and guidance.

A98. As discussed throughout the FEIS for the SHINE Facility, the NRC staff used the guidance in NUREG-1537 and the ISG for NUREG-1537, as well as other guidance, for conducting its environmental review. The ISG for NUREG-1537 provides guidance for the relevant regulations in Part 51 for environmental reviews for medical isotope facilities.

Q99. Did the NRC staff's review satisfy NEPA?

A99. Yes. As I have discussed in my previous answers, the staff's review satisfied Sections 102(2) (A), (C), and (E) of NEPA. Additionally, by implementing the detailed procedures in the regulations in 10 CFR Part 51, the NRC staff's review ensured compliance with NEPA. The FEIS is more than 400 pages long, and takes the requisite "hard look" at the SHINE Facility.

Q100. Was the public permitted to participate in the environmental review process for the SHINE Facility?

A100. Yes. At the start of the environmental review, the NRC staff issued a notice of intent to prepare an EIS and invited the public to provide any information relevant to the environmental review, including holding a public scoping meeting on July 17, 2013. The NRC also provided opportunities for governmental and general public participation during the public meeting on the draft EIS (DEIS) and sought, received, and responded to the comments on the DEIS from the public. Those responses are documented in Appendix A of the FEIS.

Q101. What are your overall conclusions regarding the NRC staff's environmental review for the SHINE Facility?

A101. The NRC staff conducted a thorough and complete environmental review for the CP for the SHINE Facility. That review has been sufficient to meet the requirements of NEPA.

V. CONCLUSIONS

Q102. What are your overall safety conclusions regarding issuance of the CP?

A102. The CP Application contains sufficient information to demonstrate compliance with the applicable standards and requirements in the Act and the Commission's regulations. SHINE has sufficiently described the proposed design of the Facility. Further technical or design information will be supplied in the FSAR. Appendix A.2 and Appendix A.4 of the SER identify the issues that must be addressed as part of an Operating License Application, and those are being tracked by SHINE. There is reasonable assurance that safety questions will be satisfactorily resolved before the latest date stated for completion of construction of the Facility and the proposed Facility can be constructed at the proposed location without undue risk to the health and safety of the public. Issuance of the CP for the SHINE Facility will not be inimical to the common defense and security or the health and safety of the public. Furthermore, the review of the CP Application by the NRC staff has been adequate to support these conclusions.

Q103. What are your overall environmental conclusions regarding issuance of the CP?

A103. The environmental review conducted by the NRC staff pursuant to 10 CFR Part 51 has been adequate; the requirements of Sections 102(2) (A), (C), and (E) of NEPA have been satisfied; an independent weighing and balancing of the environmental, technical, and other costs and benefits of the SHINE Facility support issuance of the CP; and the requested CP should be issued.

Q104. Do the CP Application for the SHINE Facility and the NRC staff's review of the Application satisfy the requirements for issuance of the CP?

A104. Yes.

Q105. Does this conclude your testimony?

A105. Yes.

Attachment 1

Acronym/Abbreviation	Definition
ACRS	Advisory Committee on Reactor Safeguards
Act	Atomic Energy Act of 1954, as amended
ALARA	as low as reasonably achievable
CAAS	criticality accident and alarm system
CAMS	continuous air monitoring system
CP	Construction Permit
DEIS	draft EIS
DOE	U.S. Department of Energy
EIS	Environmental Impact Statement
ER	Environmental Report
ESF	engineered safety feature
ESFAS	engineered safety feature actuation system
FEIS	final EIS
FSAR	Final Safety Analysis Report
IF	irradiation facility
ISG	Interim Staff Guidance
IU	irradiation unit
LEU	low enriched uranium
LWPS	light water pool system
MEPS	molybdenum extraction and purification system
MIPS	molybdenum isotope product packaging system

Mo-99	Molybdenum-99
MUPS	light water pool and primary closed loop cooling make-up system
NDAS	neutron driver assembly system
NEPA	National Environmental Policy Act
NGRS	noble gas removal system
NRC	U.S. Nuclear Regulatory Commission
PCLS	primary closed loop cooling system
PSAR	Preliminary Safety Analysis Report
PSB	primary system boundary
PVVS	process vessel vent system
RAI	request for additional information
RAMS	radiation area monitoring system
RCA	radiologically controlled area
RICS	radiological integrated control system
RLWE	radioactive liquid waste evaporation and immobilization system
RLWS	radioactive liquid waste storage system
RPCS	radioisotope process facility cooling system
RPF	radioisotope production facility
RV	RCA ventilation system
SASS	subcritical assembly support structure
SCAS	subcritical assembly system
SER	Safety Evaluation Report
SHINE	SHINE Medical Technologies, Inc.

SHINE Facility	SHINE's Medical Radioisotope Production Facility
SRWP	solid radioactive waste packaging system
SSCs	structures, systems, and components
Tc-99m	Technetium-99m
TOGS	TSV off-gas system
TPCS	TSV process control system
TPS	tritium purification system
TRPS	TSV reactivity protection system
TSPS	target solution preparation system
TSV	target solution vessel
UNCS	uranyl nitrate conversion system
UPSS	uninterruptible electrical power supply system

CERTIFICATION AND DECLARATION OF WITNESS

I certify that this testimony was prepared by me or under my direction; that the written testimony is true and correct to the best of my information, knowledge, and belief; and that I adopt this testimony as my sworn testimony in this proceeding.

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

Executed on November 24, 2015.

Executed in Accord with 10 CFR § 2.304(d)

/s/ James Costedio
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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE COMMISSION

In the Matter of	)	Docket No. 50-608-CP
SHINE MEDICAL TECHNOLOGIES, INC.	)	
(Medical Radioisotope Production Facility)	)	November 24, 2015

CERTIFICATE OF SERVICE

I hereby certify that on this date a copy of the "Applicants' Pre-Filed Testimony of James Costedio for the Mandatory Hearing on Uncontested Issues for the SHINE Medical Technologies, Inc.'s Medical Radioisotope Production Facility" was submitted through the NRC's E-filing system.

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