

1.0 THE FACILITY

This chapter of the safety evaluation report (SER) is a general introduction to the SHINE Medical Technologies, LLC (SHINE, the applicant) medical radioisotope production facility and an overview of the topics covered in detail in other chapters of this SER, including areas of review, regulatory requirements and guidance, review procedures, and summary and conclusions on principal safety considerations.

1.1 Introduction

This SER documents the results of the U.S. Nuclear Regulatory Commission (NRC, the Commission) staff's technical/safety review of the operating license application submitted by SHINE under section 103 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.) (the Act), and Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," for a medical radioisotope production facility in Janesville, Wisconsin. The facility would consist of an irradiation facility (IF) and radioisotope production facility (RPF) for the irradiation and processing of special nuclear material to produce medical radioisotopes, such as molybdenum-99 (Mo-99). In turn, the IF would consist of eight subcritical operating assemblies (or irradiation units (IUs)), which would each be licensed as utilization facilities, as defined in 10 CFR 50.2, "Definitions"; the RPF would consist of hot cell structures and systems, where the irradiated material is processed to separate medical isotopes and where the resulting material is packaged for shipment to customers, licensed collectively as a production facility, as defined in 10 CFR 50.2. In this SER, the IF and RPF are collectively referred to as the SHINE facility. The staff separately performed an environmental review of the SHINE operating license application and its evaluation and conclusions are documented in an environmental impact statement published as NUREG-2183, Supplement 1, "Environmental Impact Statement Related to the Operating License for the SHINE Medical Isotope Production Facility." A record of decision will be published at a future date concerning the proposed issuance of the operating license.

The NRC staff previously issued Construction Permit No. CPMIF-001 for the SHINE facility (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16041A471), in response to a SHINE construction permit application (ML13088A192, ML15259A272, and ML15258A431). The staff's technical/safety and environmental reviews in support of this issuance are NUREG-2189, "Safety Evaluation Report Related to SHINE Medical Technologies, Inc. Construction Permit Application for a Medical Radioisotope Production Facility Docket Number 50-608" (ML16229A140), and NUREG-2183, "Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility" (ML15288A046), respectively. The issuance was also supported by Commission Memorandum and Order CLI-16-04, dated February 25, 2016 (ML16056A094), and a Summary Record of Decision (ML16041A470). The NRC noticed the issuance of the construction permit in the *Federal Register* (FR) on March 4, 2016 (81 FR 11600).

The SHINE operating license application was filed by letter dated July 17, 2019 (ML19211C143), as supplemented by letters dated November 14, 2019 (ML19337A275), March 27, 2020 (ML20105A295), August 28, 2020 (ML20255A027), November 13, 2020 (ML20325A026), December 10, 2020 (ML20357A084), December 15, 2020 (ML21011A264), March 23, 2021 (ML21095A235), May 7, 2021 (ML21127A051), June 3, 2021 (ML21154A303), July 2, 2021 (ML21183A128), August 31, 2021 (ML21243A269), September 28, 2021 (ML21271A076), September 29, 2021 (ML21272A342 and ML21272A344), October 15, 2021

(ML21288A050), October 28, 2021 (ML21301A131), November 3, 2021 (ML21307A306), November 22, 2021 (ML21326A209), December 16, 2021 (ML21350A191), December 30, 2021 (ML21364A055), January 27, 2022 (ML22027A353), January 27, 2022 (ML22027A669), January 27, 2022 (ML22027A664), January 28, 2022 (ML22028A221), February 1, 2022 (ML22032A339), February 28, 2022 (ML22059A017), March 9, 2022 (ML22068A217), March 18, 2022 (ML22077A086), March 25, 2022 (ML22084A030), April 4, 2022 (ML22094A045), April 22, 2022 (ML22112A195), May 23, 2022 (ML22143A814), May 24, 2022 (ML22144A231), June 27, 2022 (ML22178A035), July 7, 2022 (ML22188A194), July 21, 2022 (ML22202A449), July 26, 2022 (ML22207A006), August 21, 2022 (ML22249A125), and September 28, 2022 (ML22271A963). The NRC staff noticed the receipt and availability of the application in the *Federal Register* on September 10, 2019 (84 FR 47557) and noticed the opportunity to request a hearing and petition for leave to intervene on the application in the *Federal Register* on January 10, 2020 (85 FR 1340).

1.1.1 Areas of Review

For its technical/safety review of the SHINE operating license application, the NRC staff reviewed the final safety analysis report (FSAR) included in the application against applicable regulatory requirements and using appropriate regulatory guidance and standards, as discussed below. The staff evaluated the sufficiency of the SHINE facility description and of the design bases, the limits on facility operation, and the safety analysis of the structures, systems, and components (SSCs) and of the facility as a whole presented in the FSAR. The staff also reviewed the kinds and quantities of radioactive materials expected to be produced in the operation of the facility and the means for controlling and limiting radioactive effluents and radiation exposures within the limits in 10 CFR Part 20, "Standards for Protection Against Radiation." In addition, the staff reviewed the proposed technical specifications for the facility, the description and plans for implementation of an operator requalification program, the technical qualifications of SHINE to engage in the proposed activities, and the physical security plan. The staff also reviewed the final analysis and evaluation of the design and performance of SSCs with the objective of assessing the risk to public health and safety resulting from operation of the facility.

For its environmental review of the SHINE operating license application, in accordance with section 102(2) of the National Environmental Policy Act of 1969, as amended (42 U.S.C. § 4332(2)), the NRC staff prepared an environmental impact statement (EIS) based on its independent assessment of the information provided by SHINE and information developed independently by the staff. Specifically, in accordance 10 CFR 51.95, "Postconstruction environmental impact statements," paragraph (b), the staff prepared a supplement to the EIS prepared in connection with the issuance of the construction permit for the SHINE facility, NUREG-2183, updating the prior EIS and only covering matters that differ from those or that reflect significant new information relative to that discussed in NUREG-2183. Upon acceptance of the SHINE operating license application, the staff commenced its environmental review process by publishing in the *Federal Register* (84 FR 65424; November 27, 2019) a notice of intent to prepare a supplement to NUREG-2183 and to conduct a scoping process. In preparing this supplement, the staff conducted a public scoping meeting in Janesville, Wisconsin, conducted a site audit, reviewed the SHINE operating license application, including SHINE's supplemental environmental report, consulted with Federal, State, Tribal, and local agencies, conducted a systematic, interdisciplinary review of the potential impacts of the proposed action on the human environment and reasonable alternatives to SHINE's proposal, and considered the public comments received during scoping and on the draft of the supplement, which was published for public comment (87 FR 40868; July 8, 2022).

The staff's review did not identify any information that presented a seriously different picture of the environmental consequences of constructing, operating, and decommissioning the SHINE facility than those presented in the original EIS. The final EIS, published as NUREG-2183, Supplement 1, meets the requirements of 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions."

1.1.2 Regulatory Requirements and Guidance

The NRC staff reviewed the SHINE FSAR against the following regulatory requirements, as applicable:

- 10 CFR 50.2, "Definitions"
- 10 CFR 50.22, "Class 103 licenses; for commercial and industrial facilities"
- 10 CFR 50.33, "Contents of applications; general information"
- 10 CFR 50.34, "Contents of applications; technical information"
- 10 CFR 50.36, "Technical specifications"
- 10 CFR 50.40, "Common standards"
- 10 CFR 50.50, "Issuance of licenses and construction permits"
- 10 CFR 50.54, "Conditions of licenses"
- 10 CFR 50.57, "Issuance of operating license"
- 10 CFR 50.58, "Hearings and report of the Advisory Committee on Reactor Safeguards"
- 10 CFR Part 50, Appendix E, "Emergency Planning and Preparedness for Production and Utilization Facilities"
- 10 CFR 20.1201, "Occupational dose limits for adults"
- 10 CFR 20.1301, "Dose limits for individual members of the public"

In determining the regulatory guidance and standards to apply, the NRC staff used its technical judgment, as the available guidance and acceptance criteria were typically developed for nuclear reactors. Given the similarities between the SHINE facility and non-power research reactors, the staff determined to use the following regulatory guidance and acceptance criteria:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996.
- 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.

- “Final Interim Staff Guidance 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.
- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘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.

As stated in the interim staff guidance (ISG) augmenting NUREG-1537, the NRC staff determined that certain guidance originally developed for heterogeneous non-power research and test reactors is applicable to aqueous homogeneous facilities and production facilities. SHINE used this guidance to inform the design of its facility and to prepare its FSAR. The staff’s use of reactor-based guidance in its evaluation of the SHINE FSAR is consistent with the ISG augmenting NUREG-1537.

As appropriate, the NRC staff used additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers standards, American National Standards Institute/American Nuclear Society standards) in the review of the SHINE FSAR. The additional guidance was used based on the technical judgment of the reviewer, as well as references in NUREG-1537, Parts 1 and 2; the ISG augmenting NUREG-1537, Parts 1 and 2; and the SHINE FSAR. Additional guidance documents used to evaluate the SHINE FSAR are provided as references in appendix B, “References,” of this SER.

1.1.3 Review Procedures

The NRC staff’s review was tailored to the nature of the SHINE operating license application and was informed by NUREG-1537 and the ISG augmenting NUREG-1537, as well as other relevant guidance cited therein, cited in the application, or used based on the staff’s technical judgment. The staff considered the final analysis and evaluation of the design and performance of the SSCs of the SHINE facility, including those SSCs shared by both the IF and RPF, with the objective of assessing the risk to public health and safety resulting from operation of the facility.

The NRC staff’s review was also tailored to the unique and novel technology described in the SHINE operating license application. SHINE proposes to operate an IF and an RPF housed within a single building. The IF consists of eight subcritical operating assemblies, each of which would be licensed as a utilization facility, as defined in 10 CFR 50.2. The RPF consists of structures and systems for the separation of Mo-99 from irradiated target solution, plus hot-cell and glove-box structures for processing of irradiated and un-irradiated low-enriched uranium (LEU) materials, licensed collectively as a production facility, as defined in 10 CFR 50.2.

By letter dated February 26, 2021 (ML21057A340), SHINE stated that it intends to pursue a phased approach to startup of the SHINE facility. SHINE stated that this approach consists of four phases of process equipment installation and operation and described the phases. To incorporate its phased approach to startup, SHINE supplemented its operating license application by letter dated January 27, 2022 (ML22027A354 and ML22027A356), as supplemented by letters dated May 23, 2022 (ML22143A814), August 31, 2022 (ML22249A125 and ML22249A143), September 19, 2020 (ML22263A027), and

September 20, 2022 (ML22263A344) (hereafter, the SHINE Supplement). The SHINE Supplement describes new or different information from the facility descriptions and analyses provided in the SHINE FSAR resulting from the phased approach to startup. The NRC staff's evaluation of the SHINE Supplement and SHINE's phased approach to startup is discussed separately in appendix A, "Evaluation of the SHINE Medical Technologies, LLC Phased Approach to Startup," to this SER.

1.1.4 Application Availability

Publicly available documents related to the SHINE operating license application may be obtained online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to PDR.Resource@nrc.gov.

The current version of the SHINE FSAR, submitted by letter dated August 31, 2022, is publicly available in ADAMS under ML22249A148. Other public documents and correspondence related to the SHINE operating license application may be obtained by searching in ADAMS for the SHINE Docket Number, 50-608, or project number, PROJ0792. Portions of the application or related correspondence containing sensitive information (e.g., proprietary information) are withheld from public disclosure pursuant to 10 CFR 2.390, "Public inspections, exemptions, requests for withholding."

1.1.5 NRC Staff Contact Information

The project manager for this SER was Michael Balazik, Project Manager, Office of Nuclear Reactor Regulation, Division of Advanced Reactors and Non-Power Production and Utilization Facilities, Non-Power Production and Utilization Licensing Branch of the U.S. Nuclear Regulatory Commission. Mr. Balazik may be contacted regarding this SER at 301-415-2856 or by email to Michael.Balazik@nrc.gov. Appendix C, "Principal Contributors," to this SER provides a listing of principal contributors, including areas of technical expertise and chapters of authorship.

1.2 Summary and Conclusions on Principal Safety Considerations

The NRC staff reviewed the SHINE FSAR, as supplemented, against the applicable regulatory requirements and using appropriate regulatory guidance and acceptance criteria. The staff determined, among other things, the sufficiency of the following information in the FSAR:

- (1) the general description of the facility;
- (2) the design bases, the limits on facility operation, and the safety analysis of the SSCs and of the facility as a whole;
- (3) the kinds and quantities of radioactive materials expected to be produced in the operation of the facility and the means for controlling and limiting radioactive effluents and radiation exposures within the limits in 10 CFR Part 20 and as low as is reasonably achievable;
- (4) the proposed technical specifications for the facility;

- (5) the description and plans for implementation of an operator requalification program;
- (6) the technical qualifications of SHINE to engage in the proposed activities;
- (7) the physical security plan for the facility;
- (8) the final analysis and evaluation of the design and performance of SSCs with respect to assessing the risk to public health and safety resulting from operation of the facility;
- (9) the financial qualifications of SHINE to engage in the proposed activities;
- (10) the emergency plan for the facility;
- (11) the relationship of specific facility design features to the major processes that will be ongoing at the facility, including the building locations of major process components, drawings illustrating the layout of the buildings, and structures within the controlled area boundary; and
- (12) the major chemical or mechanical processes involving licensable quantities of radioactive material based, in part, on integrated safety analysis methodology, including the building locations of major process components and brief accounts of the process steps.

Therefore, the applicable regulatory requirements and appropriate regulatory guidance and acceptance criteria are met and the NRC staff makes the following findings:

- (1) the facility will operate in conformity with the application, as amended, the provisions of the Act, and the rules and regulations of the Commission;
- (2) there is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public and (ii) that such activities will be conducted in compliance with the Commission's regulations;
- (3) the applicant is technically and financially qualified to engage in the activities authorized by the operating license in accordance with the Commission's regulations;
- (4) the applicable provisions of 10 CFR Part 140, "Financial Protection Requirements and Indemnity Agreements," have been satisfied;
- (5) the issuance of the operating license will not be inimical to the common defense and security or to the health and safety of the public; and
- (6) required notifications to other agencies or bodies have been duly made.

1.3 General Description

The NRC staff evaluated the sufficiency of the general description of the SHINE facility, as presented in SHINE FSAR section 1.3, "General Description of the Facility," in part, by reviewing the geographical location of the facility; principal characteristics of the site; principal design criteria, operating characteristics, and safety systems; engineered safety features; instrumentation and control and electrical systems; coolant and other auxiliary systems; radioactive waste management provisions; radiation protection; the general arrangement of major structures and equipment; research and development; and novel facility design considerations using the guidance and acceptance criteria from section 1.3, "General Description of the Facility," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

The SHINE facility is located on previously undeveloped agricultural property in Rock County, Wisconsin, in the City of Janesville. SHINE developed a new method for producing Mo-99 using accelerator-driven neutron sources to induce fission in LEU within IUs, creating Mo-99 as a byproduct. The IUs would operate in a batch mode with an approximate week-long operating cycle. Each IU consists of a neutron driver assembly, a subcritical assembly system, a light water pool system, a target solution vessel (TSV) off-gas system, and other supporting systems. The RPF would also operate in a batch mode, and consists of the following processes dedicated to the extraction, purification, and packaging of Mo-99 for end users, as well as preparing the target solution for the IUs:

- Target solution preparation system (TSPS)
- Molybdenum extraction and purification system (MEPS)
- Iodine and xenon purification and packaging (IXP)
- Target solution staging system (TSSS)
- Uranium receipt and storage system (URSS)
- Process vessel vent system (PVVS)
- Radioactive liquid waste storage (RLWS)
- Radioactive liquid waste immobilization (RLWI)
- Vacuum transfer system (VTS)
- Molybdenum isotope product packaging system (MIPS)
- Radioactive drain system (RDS)

In order to produce Mo-99, first, the uranyl sulfate target solution is prepared from recycled materials and/or from raw feed materials in the RPF. The target solution is then transferred to the TSVs within the IF. Once the target solution is in a TSV, the subcritical assembly is operated at full power for approximately 5.5 days, at which time the IU is shut down and the irradiated target solution is transferred to the RPF for radioisotope extraction. Following initial extraction,

the Mo-99 is purified and packaged for shipment to customers. The remaining target solution is then prepared for further irradiation in the IUs.

As described in greater detail in subsequent chapters of this SER, the design of the SHINE facility includes engineered safety features to mitigate design basis events or accidents; control and protection systems; an uninterruptable electrical power supply; primary cooling; ventilation; equipment and processes related to handling and storage of target solution, byproduct material, and special nuclear material; a tritium purification system; and fire protection systems. SHINE has a radioactive waste management program and a radiation protection program.

1.4 Shared Facilities and Equipment

The NRC staff evaluated the sufficiency of the evaluation of shared facilities and equipment, as presented in SHINE FSAR section 1.4, "Shared Facilities and Equipment," using the guidance and acceptance criteria from section 1.4, "Shared Facilities and Equipment," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of NUREG-1537, Part 2, section 1.4, the NRC staff confirmed that all facilities or equipment shared by the SHINE facility are discussed in the FSAR. The staff verified that the applicant discussed in the FSAR how the normal operating use and malfunctions of the facility could affect the other facilities. The staff also assessed the discussion in the FSAR of the effect of the shared facilities on the safety of the facility.

As stated, in part, in SHINE FSAR section 1.4, "[t]he SHINE facility does not share any systems or equipment with facilities not covered by this report." However, the SHINE facility building includes both the IF and RPF, which, while functionally separate, share some common systems.

The NRC staff finds that all facilities or equipment that will be shared by the SHINE facility represent new construction on previously undeveloped agricultural property. The interface between the IF and RPF, including common systems shared between these facilities, has been adequately analyzed in other chapters in the FSAR.

On the basis of its review, the NRC staff has determined that the level of detail provided on shared facilities and equipment satisfies the applicable acceptance criteria of NUREG-1537, Part 2, section 1.4, allowing the staff to make the following relevant findings:

- (1) There are no facilities, systems, or equipment shared by the SHINE facility that are not covered in the SHINE FSAR.
- (2) While the SHINE IF and RPF share a common building and several common systems (e.g., cooling and electrical systems), the applicant has shown that a malfunction or a loss of function of either of these facilities would not affect the operation of the other. Neither facility would be damaged as a result of a malfunction or a loss of function of the other and both facilities would maintain the capability to be safely shut down or maintained in a safe condition.
- (3) Neither normal operation nor a loss of function of the IF or RPF would lead to uncontrolled release of radioactive material from the licensed facility to unrestricted areas, or in the event of release, the exposures are analyzed in SER chapter 13, "Accident Analyses," and are found to be acceptable.

Therefore, the NRC staff finds that the evaluation of shared facilities and equipment, as described in SHINE FSAR section 1.4, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of an operating license.

1.5 Comparison with Similar Facilities

The NRC staff evaluated the sufficiency of the comparison of the SHINE facility with other similar facilities, as presented in SHINE FSAR section 1.5, "Comparison with Similar Facilities," using the guidance and acceptance criteria from section 1.5, "Comparison with Similar Facilities," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of NUREG-1537, Part 2, section 1.5, the NRC staff confirmed that the characteristics of any facilities compared with the SHINE facility were similar and relevant. The staff also verified that the operating history of licensed facilities cited by the applicant demonstrates consistently safe operation, use, and protection of the public.

As stated, in part, in SHINE FSAR section 1.5.1, "the SHINE facility uses new technology for the manufacture of medical isotopes. The [IU], consisting of the neutron driver, subcritical assembly, light water pool, [TSV] off-gas system (TOGS), and other supporting systems, represents new technology. As such, there are no similar facilities that compare to the IUs."

One basis of the SHINE facility design is that the IUs will not be operated such that their effective neutron multiplication factor (k_{eff}) is greater than or equal to 1.0, the range for which nuclear reactors are designed, analyzed, and licensed to operate safely. Instead, the IUs will only operate in a subcritical range of k_{eff} that is below 1.0. To maintain this margin of subcriticality, the IUs are designed with several features similar to a nuclear reactor except that, by design, the TSVs have insufficient reactivity to sustain a chain reaction (i.e., to reach a k_{eff} of 1.0 or greater).

While the NRC staff agrees that an IU represents new technology, its accelerator and neutron multiplier add sufficient external neutrons to the TSV such that, although the k_{eff} is below 1.0, a fission rate is achieved with a thermal power level comparable to that of non-power reactors typically licensed under 10 CFR Part 50 as utilization facilities.¹ Given this thermal power, IUs also have many safety considerations similar to those of non-power reactors, including the following:

- Provisions for removal of fission heat during operation
- Consideration of decay heat generation after shutdown
- Reactivity feedback mechanisms similar to non-power reactors

¹ The thermal power levels of non-power reactors currently licensed to operate by the NRC range from 5 watts to 20 megawatts. In the past, the NRC has licensed 12 aqueous homogeneous reactors (AHRs) with thermal power levels ranging from 5 watts to 50 kilowatts. An AHR is similar to the SHINE target solution vessel in that both contain fissile material in an aqueous solution; the difference is that the SHINE target solution vessel has insufficient fissile material for a sustained chain reaction (i.e., to reach a k_{eff} of 1.0 or greater).

- Control of fission gas release during operation and subsequent gas management engineering safety features
- Control of radiolytic decomposition of water and generated oxygen and hydrogen gases
- Control of fission product inventory buildup
- Accident scenarios similar to non-power reactors, such as loss of coolant, reactivity additions, and release of fission products

As such, given that the SHINE IUs have similarities to non-power reactors, which are licensed as utilization facilities under 10 CFR Part 50, the NRC determined that it would be appropriate to license the SHINE IUs as utilization facilities under 10 CFR Part 50. Accordingly, on October 17, 2014 (79 FR 62329), the NRC issued a direct final rule, which became effective December 31, 2014, amending the definition of utilization facility in 10 CFR 50.2 to include the SHINE IUs, so that they could be licensed under 10 CFR Part 50. Therefore, this rulemaking allowed the NRC staff to conduct its licensing review of the SHINE IUs following regulations designed for technologies with similar radiological, health, and safety considerations.

The SHINE RPF consists of hot cells used to process irradiated target solution for Mo-99 separation and purification. According to SHINE FSAR section 1.5.1, “[t]he hot cell design is conventional and is similar to the design used in many other facilities.”

Regarding Mo-99 extraction, there are currently no NRC-licensed or U.S. Department of Energy facilities that use SHINE’s specific process. However, SHINE cites the Site Ion Exchange Effluent Plant (SIXEP) in the United Kingdom, which uses clinoptilolite to remove cesium and strontium from aqueous process streams, as an example of a facility performing a similar process to SHINE’s Mo-99 extraction. SIXEP has been in operation since 1985.

With respect to the Mo-99 purification process, SHINE states that its process is similar to the Cintichem process developed in the 1950s and 1960s by Union Carbide. Cintichem, licensed by the NRC, operated until 1990 as a means to purify Mo-99 for use as a medical radioisotope. The primary difference between SHINE’s Mo-99 purification process and that of Cintichem is a slight change in process chemistry to accommodate the change in chemical and isotopic composition due to SHINE’s use of LEU instead of the highly enriched uranium used by Cintichem.

SHINE likens its tritium purification system to similar processes conducted at the Savannah River Site and Laboratory for Laser Energetics. However, in FSAR section 1.5.2.3, “Tritium Purification System,” SHINE states, in part, that “[d]ue to the sensitive and confidential nature of information relating to tritium production and purification, the design and operational details of these systems are not published. A comparison of the SHINE system with existing facilities is therefore not possible.”

On the basis of its review, the NRC staff has determined that the level of detail provided on comparisons with similar facilities satisfies the applicable acceptance criteria of NUREG-1537, Part 2, section 1.5, allowing the staff to make the following relevant findings:

- (1) SHINE has compared the design bases and safety considerations with similar facilities, as practicable. The history of these facilities demonstrates consistently safe operation that is acceptable to the NRC staff.
- (2) Aspects of SHINE's design that are similar to features in other facilities, which have been found acceptable to the NRC, should be expected to perform in a similar manner when constructed to that design.
- (3) SHINE is using test data and operational experience in designing components and SHINE cited the actual facilities with similar components, as practicable.

Therefore, the NRC staff finds that the comparisons with similar facilities, as described in SHINE FSAR section 1.5, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of an operating license.

1.6 Summary of Operations

The NRC staff evaluated the sufficiency of the SHINE summary of operations, as presented in SHINE FSAR section 1.6, "Summary of Operations," using the guidance and acceptance criteria from section 1.6, "Summary of Operations," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

Consistent with the review procedures of NUREG-1537, Part 2, section 1.6, the NRC staff verified that proposed operations of the SHINE facility had been summarized.

In FSAR section 1.6, SHINE listed the major operations to be performed in the SHINE facility as follows:

- Target solution preparation from raw feed material (uranium metal)
- Irradiation of target solution
- Mo-99 extraction from irradiated target solution
- Mo-99 purification
- Target solution adjustments
- Solidification of radioactive liquid waste

As described in SHINE FSAR section 1.6, the uranyl sulfate target solution is prepared from raw feed materials. The target solution is then transferred to the target solution hold tank and then the TSVs within the IF. Once the target solution is in a TSV, the associated neutron driver is energized and the IU is operated at power for approximately 5.5 days, at which time the IU is shut down and the irradiated target solution is allowed to decay. The target solution is then transferred to the RPF for processing. Following initial extraction, the Mo-99 is purified and packaged for shipment.

On the basis of its review, the NRC staff has determined that the level of detail provided for the summary of operations satisfies the applicable acceptance criteria of NUREG-1537, Part 2,

section 1.6. The staff also determined that the proposed operating conditions and schedules are consistent with the design features of the SHINE facility and have been found acceptable as described in chapters 4, 5, 6, 7 and 12 of this SER. The proposed operations are also consistent with the relevant assumptions in later chapters of the SHINE FSAR, in which any safety implications of the proposed operations are evaluated. In addition, the proposed operating power levels and schedules are in accordance with the proposed license conditions.

Therefore, the NRC staff finds that the summary of operations, as described in SHINE FSAR section 1.6, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of an operating license.

1.7 Compliance with the Nuclear Waste Policy Act of 1982

The Nuclear Waste Policy Act of 1982 provides that the U.S. government is responsible for the permanent disposal of high-level radioactive waste and spent nuclear fuel, but that the cost of disposal should be the responsibility of the generators and owners of such waste and spent fuel. The NRC staff evaluated the sufficiency of SHINE's compliance with the Nuclear Waste Policy Act of 1982, as presented in SHINE FSAR section 1.7, "Compliance with the Nuclear Waste Policy Act of 1982," using the guidance and acceptance criteria from section 1.7, "Compliance with the Nuclear Waste Policy Act of 1982," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 1.7 states that "[t]he SHINE facility does not produce either high-level nuclear wastes or spent nuclear fuel. Therefore, the Nuclear Waste Policy Act of 1982 is not applicable to this facility." As described in FSAR chapter 11, "Radiation Protection Program and Waste Management," SHINE has identified disposition pathways for all of its identified waste streams.

As defined in 10 CFR 72.3, "Definitions," "Spent nuclear fuel or Spent fuel" means, in part, "fuel that has been withdrawn from a nuclear reactor following irradiation, has undergone at least one year's decay since being used as a source of energy in a power reactor, and has not been chemically separated into its constituent elements by reprocessing." Since SHINE will only be removing its target solution from subcritical assemblies, and will not be constructing and operating a nuclear power reactor from which fuel will be removed, the NRC staff determined that the SHINE facility will not produce spent nuclear fuel. Therefore, since SHINE will not be producing spent nuclear fuel or high-level radioactive waste, the Nuclear Waste Policy Act of 1982 is not applicable to the SHINE facility.

As described in the American Medical Isotopes Production Act of 2012 (42 U.S.C. § 2065(f)), radioactive material resulting from the production of medical radioisotopes that has been permanently removed from a reactor or subcritical assembly, and for which there is no further use, is deemed to be low-level radioactive waste if it is acceptable under federal requirements for disposal as low-level radioactive waste. SHINE will be removing radioactive material resulting from the production of medical radioisotopes in a subcritical assembly. As discussed in chapter 11, "Radiation Protection Program and Waste Management," of this SER, SHINE has committed to following applicable federal, state, and local regulations for managing radioactive wastes. Additionally, SHINE has identified licensed waste disposal sites that can take receipt and dispose of the facility's radioactive waste. For these reasons, the NRC staff determined that the SHINE facility will produce low-level radioactive waste and will not produce high-level radioactive waste. Further, based on SHINE's commitments discussed in chapter 11 of

this SER, the staff finds that SHINE's plans for handling radioactive waste demonstrate appropriate consideration of regulatory requirements for the types of waste at the facility.

Therefore, the NRC staff finds that SHINE's description of the applicability of the Nuclear Waste Policy Act of 1982 in section 1.7 of the SHINE FSAR is sufficient and meets the applicable regulatory requirements and guidance for the issuance of an operating license.

1.8 Facility Modifications and History

The NRC staff evaluated the sufficiency of SHINE's descriptions of facility modifications and history, as presented in SHINE FSAR section 1.8, "Facility Modifications and History," using the guidance and acceptance criteria from section 1.8, "Facility Modifications and History," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

SHINE FSAR section 1.8 states that "[t]he SHINE facility described in this report is new construction. There are no existing facilities, there have been no modifications, and there is no history to report. Therefore, this section is not applicable to the SHINE facility."

The NRC staff determined that there are no existing facilities, there have been no modifications, and there is no history to report on the SHINE facility. Accordingly, this section is not applicable to this facility.

Therefore, the NRC staff finds that SHINE's description of facility modifications and history, as described in SHINE FSAR section 1.8, is sufficient and meets the applicable regulatory requirements and guidance for the issuance of an operating license.