United States Nuclear Regulatory Commission Official Hearing Exhibit
In the Matter of: SHINE MEDICAL TECHNOLOGIES, INC.
(Medical Radioisotope Production Facility)
Commission Mandatory Hearing
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POLICY ISSUE

(Information)

October 22, 2015 SECY-15-0130

FOR: The Commissioners

FROM: Victor M. McCree
Executive Director for Operations

SUBJECT: STAFF STATEMENT IN SUPPORT OF THE UNCONTESTED HEARING FOR ISSUANCE OF CONSTRUCTION PERMIT FOR THE SHINE MEDICAL TECHNOLOGIES, INC. MEDICAL RADIOISOTOPE PRODUCTION FACILITY

PURPOSE:

The U.S. Nuclear Regulatory Commission (NRC) staff (the staff) has completed its review of the SHINE Medical Technologies, Inc. (SHINE), Medical Radioisotope Production Facility construction permit application. The proposed facility would be located in the City of Janesville, Rock County, Wisconsin. This paper does not address any new commitments or resource implications.

This paper serves as the staff's primary pre-filed testimony for the uncontested (mandatory) hearing for issuance of the SHINE construction permit.[1] This paper, with its references, also provides the information requested to support the Commission's determination that the staff's review has been adequate to support the findings for issuance of a construction permit. These findings are set forth in Title 10 of the *Code of Federal Regulations* (10 CFR) 50.35, "Issuance of construction permits," 10 CFR 50.40, "Common Standards," 10 CFR 50.50, "Issuance of licenses and construction permits," and 10 CFR 51.105, "Public hearings in proceedings for issuance of construction permits or early site permits; limited work authorizations."

CONTACTS: Steven T. Lynch, NRR/DPR
301-415-1524

Michelle R. Moser, NRR/DLR
301-415-6509

[1] In SRM-SECY-15-0088 (Agencywide Documents Access & Management System (ADAMS) Accession No. ML15238B093), the Commission agreed to conduct the mandatory hearings associated with construction permit applications for medical radioisotope production and utilization facilities and directed the NRC staff to follow Chapter IV of the Internal Commission Procedures, "Conduct of Mandatory Hearings on Applications for Combined Licenses," to the extent practical.

In accordance with the internal Commission procedures, this paper focuses on nonroutine matters supporting the findings related to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 51, "Environmental Protections Regulations for Domestic Licensing and Related Regulatory Functions." Nonroutine matters with regard to areas of particular importance are matters that relate to any unique features of the facility or novel issues that arose as part of the review process.

SUMMARY:

This paper follows the issuance of the SHINE safety evaluation report (SER) on October 20, 2015 (ADAMS Accession No. ML15288A076), and the final environmental impact statement (final EIS) on October 16, 2015 (NUREG-2183, ADAMS Accession No. ML15288A046). Drafts of the SHINE construction permit and record of decision are referenced in this paper and are available under ADAMS Accession Nos. ML15272A009 and ML15272A019, respectively.

The staff's review of the SHINE construction permit application is complete. The agency issued a final rule amending the 10 CFR Part 50 definition of utilization facility on October 17, 2014. The rule became effective on December 31, 2014.

This paper addresses the findings in 10 CFR 50.35, 10 CFR 50.40, 10 CFR 50.50, and 10 CFR 51.105 and provides an adequate basis for the Commission to conclude that each of these findings can be made for the SHINE construction permit application. This paper focuses on nonroutine matters that arose as part of the review process, such as unique features of the facility or novel issues. This paper does not address routine aspects of the safety and environmental review process.

BACKGROUND:

I. Application History

Guidance Developed by Staff Based on Pre-Application Discussions with SHINE and Other Potential Applicants

In anticipation of receiving construction permit applications for utilization and production facilities dedicated to the production of molybdenum-99 (Mo-99), the staff developed technology-specific Interim Staff Guidance (ISG) augmenting NUREG-1537 for aqueous homogeneous reactors (AHRs) and production facilities in October 2012. SHINE used the final ISG, as applicable, in preparing its application.

Application, Ownership, and Location

As allowed by an exemption granted March 20, 2013 (78 FR 19537), SHINE submitted the first part of its two-part 10 CFR Part 50 construction permit application to construct a medical radioisotope production facility on March 26, 2013. Part one of SHINE's application consisted primarily of an environmental report, but also included a description and safety assessment of the site and general financial information (ADAMS Accession No. ML13088A192). On May 31, 2013, SHINE submitted the second part of its construction permit application (ADAMS

Accession No. ML13172A361).[2] On September 25, 2013, SHINE supplemented its construction permit application with a discussion of preliminary plans for coping with emergencies, as required by 10 CFR 50.34(a)(10), completing its application for a construction permit (ADAMS Accession No. ML13269A378). SHINE most recently updated its construction permit application on August 27, 2015 (ADAMS Accession No. ML15258A431). As applicable, SHINE used the ISG to develop its preliminary safety analysis report (PSAR).

The publicly available portions of the application are available in ADAMS and on the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. There are portions of the application that contain non-public information and have been withheld in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." The non-public version of the application is available in ADAMS, but is restricted to authorized users.

SHINE identifies itself as a Wisconsin corporation, a private organization that was created for the purpose of designing, constructing, and operating a medical radioisotope production facility which will be located on previously undeveloped agricultural property in Rock County, Wisconsin, within the southern corporate boundaries of the City of Janesville. SHINE would construct, own, and operate the proposed facility.

Additional information about SHINE and ownership is available in "Part One of the SHINE Medical Technologies, Inc. Application for Construction Permit," as provided by letter dated March 26, 2013, and supplemented by letters dated May 15, 2014, and September 16, 2015 (ADAMS Accession Nos. ML13088A192, ML14135A360, and ML15259A272, respectively). Additional information about the site location and characteristics appears in Chapters 1 and 2 of the construction permit application (ADAMS Accession Nos. ML15258A369 and ML15258A370, respectively), as well as in the SHINE Environmental Review, PSAR Section 19.2, "Proposed Action" (ADAMS Accession No. ML15258A413).

Overview of the SHINE Safety Review Approach for the Construction Permit Application

The staff's safety review was tailored to the nature of SHINE's application and was informed by the staff's ISG, NUREG-1537, as well as other relevant guidance cited therein, cited in the application, or used based on the staff's technical judgment. In particular, SHINE's 10 CFR Part 50 application only seeks authorization to construct the proposed SHINE facility. Therefore, the level of detail needed in the application and the staff's corresponding SER is different than for a combined license or operating license. For the purposes of issuing a construction permit, the SHINE facility may be adequately described at a functional or conceptual level in the PSAR. As such, SHINE has deferred providing many design and analysis details until the submission of its final safety analysis report (FSAR) with its operating license application.

The objective of the staff's evaluation was to assess the sufficiency of information contained in the PSAR for the issuance of a construction permit in accordance with 10 CFR 50.35(a), 10 CFR 50.40, and 10 CFR 50.50. An in-depth evaluation of the SHINE design will be performed following the staff's receipt of SHINE's FSAR.

[2] Because SHINE's proposed medical radioisotope production facility is not a nuclear power plant, 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," does not apply. See 10 CFR 52.0 (providing scope and applicability of 10 CFR Chapter I provisions).

The staff's safety review was also tailored to the unique and novel technology described in SHINE's construction permit application. SHINE proposes to construct an Irradiation Facility (IF) and a Radioisotope Production Facility (RPF). The proposed IF consists of eight subcritical operating assemblies (or irradiation units [IUs]), each of which would be licensed as a utilization facility as defined in 10 CFR 50.2, "Definitions." The proposed RPF consists of three "supercells" for the separation of Mo-99 from irradiated target solution, plus hot-cell and glove-box structures for the processing of irradiated and un-irradiated low-enriched uranium (LEU) materials, and licensed collectively as a production facility, as defined in 10 CFR 50.2. In the staff's evaluation and in this paper, the IF and RPF are collectively referred to as the SHINE facility.

Given the similarities in SHINE's proposed facility and non-power research reactors, the staff used established guidance documents and the Commission's regulations to determine the acceptance criteria for demonstrating compliance with 10 CFR regulatory requirements. For example, the staff used:

- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (ADAMS Accession No. ML042430055);

- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (ADAMS Accession No. ML042430048);

- "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ADAMS Accession No. ML12156A069); and

- "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ADAMS Accession No. ML12156A075).

In applying these criteria, the staff used its judgement as to which acceptance criteria were relevant to SHINE's proposed facility, as much of this guidance was originally developed for nuclear reactors. The staff evaluated the sufficiency of the SHINE preliminary design, as described in the PSAR, based on SHINE's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases and allow adequate margin for safety. Importantly, the staff's evaluation of SHINE's preliminary design does not constitute approval of any design feature or specification. Such approval would be made following the evaluation of SHINE's final design and analysis, submitted in support of SHINE's operating license application.

The staff has prepared a draft construction permit for the SHINE facility. The draft permit is available to the Commission (ADAMS, Accession No. ML15272A009).

Advisory Committee on Reactor Safeguards

To support the Advisory Committee on Reactor Safeguards (ACRS) in providing an independent review and report to the Commission regarding the SHINE construction permit application, the staff presented the results of its safety evaluation to the Radiation Protection & Nuclear Materials Subcommittee at four meetings on: June 23, 2015, June 24, 2015, August 19, 2015, and September 22, 2015. The staff presented the results of its SHINE construction permit application review to the ACRS full committee on October 8, 2015. The ACRS issued a letter on October 15, 2015 (ADAMS Accession No. ML15286A426), fulfilling the requirement of 10 CFR 50.58, "Hearings and report of the Advisory Committee on Reactor Safeguards," that the ACRS review and report on construction permits for a facility of the type described in 10 CFR 50.22, "Class 103 licenses; for commercial and industrial facilities." The ACRS conclusions and recommendations, as well as the staff's response, are discussed later in this paper.

II. Outreach

Public Meetings

At SHINE's request, the staff hosted public meetings at NRC headquarters prior to docketing the SHINE construction permit application in 2013. These meetings were used to discuss technical and environmental information related to the development of the application, clarify the applicability of relevant guidance, and address public questions on the NRC's review process. Public meetings were also held following the receipt of SHINE's construction permit application to discuss design changes.

On July 17, 2013, the staff held two meetings in Janesville, Wisconsin, to discuss the environmental scoping process and to give members of the public an opportunity to provide comments on environmental issues the NRC should consider during its review of the application. After issuing the draft EIS on May 31, 2015 (ADAMS Accession No. ML15127A241), the staff held two more public meetings in Janesville, Wisconsin, on June 10, 2015, to provide an overview of the draft EIS and to accept public comments on the document.

In total, the staff conducted approximately 15 public meetings and teleconferences prior to and during the review of the application.

Federal Register Notices

The NRC published the following *Federal Register* (FR) notices, as required, for key milestones in the licensing process:

- On April 1, 2013, the NRC published a notice of exemption from 10 CFR 2.101(a)(5), allowing SHINE to submit its application in two parts (78 FR 19537).

- After the NRC received part one of SHINE's two-part application on March 26, 2013, the agency published a notice of receipt and availability on May 20, 2013 (78 FR 29390).

- The NRC docketed part one of the SHINE construction permit application on June 25, 2013, and published a notice of acceptance for docketing on July 1, 2013 (78 FR 39342).

- On July 1, 2013, the NRC published a notice of intent to prepare an EIS and to conduct scoping (78 FR 39343).

- After the NRC received the second and final part of SHINE's two-part application on May 31, 2013, the agency published a notice of receipt and availability on August 23, 2013 (78 FR 52579).

- The NRC docketed the second and final part of the SHINE construction permit application on December 2, 2013, and published a notice of docketing on December 9, 2013 (78 FR 73897). On June 4, 2014, the staff published a notice of correction of the December 9, 2013, notice of docketing of the SHINE application (79 FR 32333).

- On October 17, 2014, 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 SHINE's IUs, so that they could be licensed under 10 CFR Part 50 (79 FR 62329).

- On March 12, 2015, the NRC published a notice of hearing, opportunity to intervene, and order imposing procedures for access to Sensitive Unclassified Non-Safeguards Information (80 FR 13036).

- On May 14, 2015, the NRC published a notice of availability of the draft EIS for public comment and notice of public meetings to present an overview of the draft EIS and to accept public comments on the document (80 FR 27710).

- On October 22, 2015, the NRC published a notice of availability of the final EIS (80 FR 64025).

Consultations

In accordance with Section 657 of the Energy Policy Act of 2005, the NRC consulted with the U.S. Department of Homeland Security concerning the potential vulnerabilities of the location of the proposed irradiation facility to terrorist attack. As part of its environmental review, in accordance with the National Environmental Policy Act (NEPA) and other applicable statutes, including the Endangered Species Act, the National Historic Preservation Act,and the American Medical Isotopes Production Act of 2012, the staff consulted with and obtained input from appropriate Federal, State, and local agencies, as well as Tribal organizations.

Adjudicatory Actions

On March 12, 2015, the NRC published in the *Federal Register* (80 FR 13036) a notice of hearing, opportunity to petition for leave to intervene, and order imposing procedures for access

to Sensitive Unclassified Non-Safeguards Information. No petitions for leave to intervene were filed following publication of this notice.

III. Review Process/ Methodology

The staff used the processes and methodologies, as applicable, described in the following documents to ensure quality, consistency, and completeness in preparation of the SER and final EIS:

1. **NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content" (ADAMS Accession No. ML042430055).** The principal purpose of the format and content guide is to suggest a uniform format for presenting information in non-power reactor applications, help ensure completeness of information provided, assist the staff and others in locating information, and aid in increasing the efficiency of the review process. While this guide presents a format for applications that is acceptable to the staff, conformance is not required.

2. **NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria" (ADAMS Accession No. ML042430048).** The principal purpose of the standard review plan (SRP) is to ensure the quality and uniformity of staff safety reviews. It is also a vehicle for disseminating information on regulatory matters concerning non-power reactors and clarifying the staff review process for applicants, licensees, and the public. Each section of the SRP outlines areas of review, acceptance criteria, review procedures, and evaluation findings to guide the staff's review. The SRP is the most definitive basis available for evaluating whether an application meets the set of regulations established by the Commission.

3. **Interim Staff Guidance.** For areas in which the existing SRP does not contain review guidance, the staff prepared and used ISGs documents. The ISGs clarify technical review approaches and address questions related to regulatory processes and licensing activities. The staff used the following ISGs in the SHINE construction permit application review:

    - "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 (ADAMS Accession No. ML12156A069).

    - "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 (ADAMS Accession No. ML12156A075).

4. **NUREG-0849, "Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors" (ADAMS Accession No. ML062190191).** This SRP assures that complete and uniform reviews are made of research and test reactor radiological emergency plans. As applicable and described in the ISG Augmenting NUREG-1537, this standard review plan was used to evaluate the SHINE preliminary emergency plan submitted in accordance with Appendix E, "Emergency Planning and Preparedness for Production and Utilization Facilities," to 10 CFR Part 50.

5. **Regulatory Guides.** Regulatory guides (RGs) provide guidance to licensees and applicants on implementing specific parts of the NRC's regulations, techniques used by the staff in evaluating specific problems and scenarios, and information needed by the staff in its review of applications for permits or licenses. Consistent with the ISG Augmenting NUREG-1537, RGs from Division 2, "Research and Test Reactors," were generally found to be applicable to SHINE. SHINE's PSAR identifies RGs relevant to the construction permit application and whether the SHINE conformed to or departed from each RG. As appropriate, regulatory guides endorse American National Standards Institute/American Nuclear Society standards for use in the staff's reviews.

6. **Office Instructions.** In its review, the staff followed administrative guidance contained in a number of office instructions. These internal documents address a range of procedural matters, including the staff's process for issuing a request for additional information (RAI), handling audits, ensuring the qualification and training of technical staff and managers, ensuring consistency between staff offices, and overseeing interactions with applicants, intervenors, and the public.

IV. Advisory Committee on Reactor Safeguards Review

The ACRS review of the SHINE construction permit culminated with a letter to the Commission dated October 15, 2015, recommending that the SHINE construction permit should be approved (ADAMS Accession No. ML15286A426).

The ACRS letter identified two safety concerns that could impact the operation of the SHINE facility, if not sufficiently addressed during construction: (1) the facility's layup capability, and (2) the facility's ability to withstand potential aircraft impact. The ACRS noted that "nuclear chemical processing facilities need to have built-in capability to support layup following unexpected process interruptions. It must be possible to stop the process, safely remove materials within the system, clean the system, and place it in a safe condition for an extended period in a way that does not challenge the facility piping systems and chemical reactors." SHINE and the NRC staff: (1) provided information addressing the provisions made to address facility layup, and (2) clarified the analysis of the SHINE facility's ability to withstand aircraft impacts. Additionally, SHINE clarified the relationship between safety-related structures, systems, and components (SSCs) and safety-related activities by defining safety-related activities.

SHINE has committed to providing procedures for facility layup and an updated quality assurance program description that includes its definition of safety-related activities in its FSAR. The staff is tracking these commitments in Appendix A of its SER.

Based on discussions during the subcommittee and full committee meetings, the ACRS determined that SHINE and the NRC staff provided sufficient information to address facility layup and potential aircraft impact, such that it could recommend the issuance of a construction permit. The ACRS letter closed by acknowledging that the NRC staff demonstrated an ability to develop a practical licensing approach for a unique facility.

DISCUSSION:

I. Excluded Matters

Excluded from consideration in this uncontested hearing are issues resolved by the direct final rule associated with SHINE's IUs. A full discussion of this rulemaking can be found in the final rule (79 FR 62329) published October 17, 2014. As explained in the statements of consideration for this direct final rule of particular applicability, the Commission determined by rule that each of SHINE's IUs is a utilization facility subject to 10 CFR Part 50. Therefore, this uncontested hearing does not involve consideration of whether 10 CFR Part 50 is the appropriate regulatory framework for licensing SHINE's IUs as that has been resolved by rule.

The NRC's rule amending the definition of utilization facility became effective December 31, 2014, and states, in relevant part, that:

> *Utilization facility* means:
>
> (2) An accelerator-driven subcritical operating assembly used for the irradiation of materials containing special nuclear material and described in the application assigned Docket Number 50–608.

II. Exemption

Exemption from NRC Regulations

Prior to the submission of SHINE's construction permit application, SHINE sought and was granted an exemption from the stipulation of 10 CFR 2.101(a)(5) that applications for a construction permit under 10 CFR Part 50 must be of the type requiring an EIS or a supplement to an EIS as described in 10 CFR 51.20(b) (ADAMS Accession No. ML13051A007) in order to submit such an application in two parts. Since SHINE's application is not of the type requiring an EIS or supplement to an EIS in 10 CFR 51.20(b), the application could not be submitted in two parts. Therefore, the exemption allowed SHINE to submit part one of its construction permit up to 6 months prior to the submittal of the remainder of the application regardless of whether or not an EIS or a supplement to an EIS would be prepared for its construction permit application. SHINE submitted the following in part one of its construction permit application:

- The environmental report required by 10 CFR 50.30(f);
- The description and safety assessment of the site required by 10 CFR 50.34(a)(1);
- The filing fee required by 10 CFR 50.30(e) and 10 CFR 170.21;

- The general information required by 10 CFR 50.33; and

- The agreement limiting access to Classified Information required by 10 CFR 50.37.

Part two of SHINE's construction permit application contained the remainder of the PSAR required by 10 CFR 50.34(a).

In its exemption request, SHINE noted that the underlying purpose of the regulation was to remove unnecessary obstacles to the timely and efficient licensing and construction of nuclear facilities that are of national interest. SHINE's exemption request argued that the nation's demand for medical radioisotopes is a significant public health and safety concern, similar to the concerns over energy sources and supply for which the initial rule was created to address. SHINE stated that an exemption would facilitate the completion of the environmental review and ultimate issuance of the construction permit, eliminating delays in construction of the SHINE facility.

The staff evaluated the exemption request and determined that such an exemption was authorized by law, would not present an undue risk to public health or safety, and was consistent with the common defense and security, and that special circumstances were present as described in 10 CFR 50.12(a)(2)(ii). The staff determined that the underlying purpose of 10 CFR 2.101(a)(5), as discussed above, is to facilitate the application submittal process for construction permit applicants when it is in the interest of the public to remove unnecessary obstacles to meet the needs of the nation. Recognizing that SHINE's proposed medical radioisotope production facility would contribute towards meeting the nation's domestic demands for Mo-99 and its decay product (technetium-99m) in nuclear medicine procedures, the staff determined that the underlying purpose of the rule was achieved and special circumstances were present. The staff's evaluation and issuance of the exemption request appeared in the *Federal Register* on April 1, 2013 (78 FR 19537). A summary of this evaluation appears in Section 1.1 of the SER.

III. Nonroutine Unique Facility Features and Novel Issue

Safety Matters

a. Licensing Considerations

The proposed SHINE facility presents novel and unique licensing considerations for the staff, requiring unique application of statutory and regulatory provisions, issuance of a direct final rule, and development of technology-specific guidance.

Applicability of Atomic Energy Act Section 103

Past non-power utilization facilities licensed under 10 CFR Part 50 have been nuclear reactors useful in the conduct of research and development activities and/or used in medical therapy, also known as "research and test reactors." All such facilities have been licensed pursuant to Section 104 of the Atomic Energy Act (AEA). However, neither the RPF nor the IUs within the IF is a reactor. Neither is useful in the conduct of research or medical therapy. Instead, SHINE's proposed facility is intended to be primarily for commercial purposes (i.e., the

production of materials or products for sale or commercial distribution). Therefore, the staff determined that SHINE's proposed facility should be licensed under Section 103 of the AEA. As a Section 103 facility, SHINE's proposed facility is subject to review by the ACRS and a mandatory hearing, pursuant to 10 CFR 50.58.

Applicability of 10 CFR Part 50 Regulations

SHINE's proposed RPF and the IUs presented unique licensing considerations under 10 CFR Part 50,[3] since SHINE is not proposing to construct and operate nuclear reactors. SHINE's facility includes new technology to produce medical radioisotopes. For example, the IU consists of a neutron driver, subcritical assembly, light water pool, target solution vessel off-gas system, and other supporting systems. The SHINE IUs will not be operated such that the effective neutron multiplication factor (k_{eff}) is greater than or equal to 1.0, a range for which nuclear reactors are designed, analyzed, and licensed to operate safely. Instead, the irradiation units will operate in a minimally subcritical range of k_{eff}.

While the individual components of the irradiation units are familiar to the staff, the compilation of these components into the SHINE IUs represents largely new technology. In particular, the accelerator and neutron multiplier achieve a fission rate with a thermal power level comparable to that of non-power reactors licensed as utilization facilities under 10 CFR Part 50. Because of their thermal power levels, the IUs share similar safety considerations with other non-power reactors (e.g., AHRs), including the following:

- Provisions for removal of fission heat during operation;
- Passive decay heat generation after shutdown;
- Inherent negative reactivity feedback;
- Fission gas release during operation and gas management engineering safety features;
- Radiolytic decomposition of water into oxygen and hydrogen;
- Fission products; and
- Accident scenarios, such as loss of coolant, reactivity addition, and fission product release.

Given these safety considerations and the functional similarities of the IUs to non-power reactors, the NRC staff used its technical judgment in determining applicable acceptance criteria for SHINE's construction permit application and the applicable regulations.

[3] The RPF meets the definition of production facility in 10 CFR 50.2. The IUs were designated by rule to be utilization facilities in the direct final rule effective December 31, 2014. See 79 FR 62329.

Licensing Production Facilities

Another unique aspect of licensing SHINE's proposed facility is that the SHINE RPF represents the first production facility licensed by the NRC since West Valley, which ceased operations in 1972. The SHINE RPF consists of hot cells used to process irradiated target solution for Mo-99 separation and purification. According to the SHINE PSAR Section 1.5.1, "[t]he hot cell design is conventional and is similar to the design used in many other facilities." The primary chemical processes occurring in the hot cells are molybdenum extraction, molybdenum purification, uranyl nitrate conversion, uranium extraction, evaporation and thermal denitration, waste evaporation and solidification, and tritium purification. The staff determined that the SHINE RPF meets the third definition of "production facility" in 10 CFR 50.2, which defines a production facility as any facility designed or used for the processing of irradiated materials containing special nuclear material.

While the NRC has historically licensed production facilities, no such facilities are currently operating. Only two previously-licensed NRC facilities have conducted activities similar to the SHINE RPF (Cintichem and West Valley), and both ceased operations at least 25 years ago. Cintichem, which operated until 1990, employed a molybdenum purification process similar to SHINE's purification process. The primary difference between the two processes is a slight change in chemistry to accommodate the change in chemical and isotopic composition caused by the switch from highly-enriched uranium to LEU. Similar to Cintichem, shielding and confinement will serve as the principal engineered safety features in reducing worker doses at the SHINE facility. However, in contrast to SHINE, the Cintichem purification processing was licensed under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

The staff also considered whether the RPF was a fuel reprocessing facility. The SHINE uranium extraction (UREX) process is a modification of the widely-used plutonium and uranium extraction (PUREX) process in which irradiated fuel goes through dissolution, fission product and waste separation, and uranyl and plutonium nitrate purification. The PUREX process was developed in the late 1940s and uses tributyl phosphate to selectively remove uranium and plutonium from a nitric acid solution typically containing a host of fission product and other actinide contaminants. The only NRC-licensed facility to use the UREX process was West Valley, a fuel reprocessing facility that ceased operations in 1972.

There is currently neither a statutory nor regulatory definition for what does and does not constitute a fuel reprocessing facility. While fuel reprocessing plants are considered production facilities under 10 CFR Part 50, more specific definitions and interpretations have varied over the years, as evidenced in *Federal Register* notices, staff-generated SECY Papers, and Nuclear Energy Institute white papers (see: http://www.nrc.gov/materials/reprocessing.html, "Additional Documents," and 39 FR 26293).

In 2006, the Commission directed the Advisory Committee on Nuclear Waste and Materials (the Committee) to define the issues most important to the NRC concerning fuel reprocessing facilities. As a result, the Committee published NUREG-1909, "Background, Status, and Issues Related to the Regulation of Advanced Spent Nuclear Fuel Recycle Facilities," in June 2008, which describes "reprocessing" as the separation of spent nuclear fuel into its constituent components (ADAMS Accession No. ML082100043). As defined in 10 CFR 72.3, spent nuclear fuel or spent fuel means "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…". Based on these definitions of fuel reprocessing and spent nuclear fuel, the staff concluded that only fuel from a nuclear power reactor is considered spent nuclear fuel, and therefore, only fuel from a nuclear power reactor may be reprocessed. Since the SHINE RPF will only process the LEU target solution previously irradiated in the IF and will not be processing spent nuclear fuel, as defined in 10 CFR 72.3, the processing of SHINE's irradiated LEU target solution does not constitute fuel reprocessing. Therefore, the staff concluded that SHINE's production facility is not a fuel reprocessing facility.

b. Accident Analysis Methodology

Accident analyses for 10 CFR Part 50 facilities need to show that the health and safety of both the public and workers are protected; potential radiological and non-radiological consequences have been considered in the event of malfunctions; and the 10 CFR Part 50 facility is capable of accommodating disturbances in the functioning of SSCs. Additionally, accident analyses need to demonstrate that design features, safety limits, limiting safety system settings, and limiting conditions for operation ensure that no credible accident could lead to unacceptable radiological consequences to people or the environment.

For the SHINE facility, two accident analysis methodologies were applied to analyze accident scenarios based on the guidance contained in NUREG-1537 and the ISG Augmenting NUREG-1537. Accident analyses at the SHINE facility were evaluated against the radiological exposure limits prescribed in 10 CFR Parts 20 and 50. Radiological events at the IF and RPF were evaluated using the maximum hypothetical accident methodology typically used at non-power reactors licensed under 10 CFR Part 50. For the RPF accident analysis, the staff determined that use of Integrated Safety Analysis methodologies as described in 10 CFR Part 70 and incorporated into the ISG augmenting NUREG-1537 is an acceptable way of demonstrating safety given the RPF's similarity to existing fuel cycle facilities licensed under 10 CFR Part 70, which is unique for a facility licensed under 10 CFR Part 50.

In addition to radiological exposure considerations, per the guidance in the ISG augmenting NUREG-1537, the RPF accident analyses used consequence and likelihood criteria for potential accidents resulting in chemical exposure to workers or members of the public. Additionally, consistent with the guidance in the ISG augmenting NUREG-1537, the chemical performance requirements in 10 CFR 70.61(b)(4) and (c)(4) were used as criteria for chemical-related accident sequences.

Radiological Accidents

For radiological accidents within the IF and RPF, analyzed scenarios ranged from anticipated events (e.g., a loss of normal electrical power) to a postulated fission-product release with radiological consequences exceeding those of any accident considered to be credible. The latter of these two scenarios is referred to as the maximum hypothetical accident (MHA), as described in NUREG-1537. Because the MHA is not expected to occur, the scenario need not be entirely credible. The initiating event and the scenario details need not be analyzed, but the potential consequences are analyzed and evaluated.

SHINE postulated MHAs for both the IF and RPF and determined that the bounding scenario for the facility occurred in the RPF. This bounding scenario (i.e., the MHA) involves a release of radiological material from the Noble Gas Removal System tanks that results in the maximum doses to workers and individual members of the public. For the MHA, a total effective dose equivalent (TEDE) of 3.59 roentgen equivalent man (rem) was calculated for the workers at the facility, which is less than the 5 rem regulatory limit specified in 10 CFR 20.1201. A TEDE of 0.0820 rem was calculated for a member of the public at the site boundary, and a TEDE of 0.0115 rem was calculated at the nearest residence. The off-site doses are less than the 0.1 rem regulatory limit specified in 10 CFR 20.1301. Thus, the dose consequences of the MHA were all within the regulatory limits of 10 CFR Part 20.

Non-radiological Accidents

The staff also conducted a chemical process safety review for the SHINE RPF. This review covered chemical safety-related accidents, chemical safety controls, and the corresponding surveillance requirements. The scope included equipment and facilities that protect against releases of and chemical exposures to licensed material or hazardous chemicals produced from licensed material. The staff also looked at chemical risks of plant conditions that affect the safety of licensed material. As described in the ISG augmenting NUREG-1537, Part 2, this review is conducted as part of the 1988 "Memorandum of Understanding Between the NRC and the Occupational Safety and Health Administration" (53 FR 43950). The staff determined that SHINE's preliminary facility design, proposed operations, and anticipated safety controls for chemical safety provide reasonable assurance that they will function as intended and, thus, that they will be adequate to protect public health and safety and the environment.

Environmental Matters

a. Determination to Prepare an Environmental Impact Statement and to Make Findings In 10 CFR 51.105

One novel consideration for the environmental review of the SHINE construction permit application was determining the appropriate methodology and level of detail for the staff's environmental findings. Environmental reviews for licensing actions, such as construction permits, operating licenses, or license amendments, fall into one of three categories: those identified as categorical exclusions, those requiring the preparation of an Environmental Assessment (EA), and those requiring the preparation of an EIS. The regulations in 10 CFR 51.20, "Criteria for and identification of licensing and regulatory actions requiring environmental impact statements," describe several types of actions that would require an EIS. Construction permits and operating licenses for medical radioisotope facilities are not specifically included in 10 CFR 51.20. Such activities may require an EA or an EIS, depending on the action's potential for significant impacts that may affect the quality of the human environment.

An EA is used to determine if the impacts from the proposed action may be significant and whether a finding of no significant impact can be made. If an EA concludes that the proposed action could result in significant impacts to the human environment, then an EIS will be prepared. In some cases, the NRC may decide to prepare an EIS, rather than an EA, if there is

the potential for significant impacts to the human environment or the proposed action involves a matter that the Commission, by discretion, has determined should be covered by an EIS.

After reviewing the environmental report and the nature of the application, the NRC staff determined, as a matter of discretion, that an EIS was appropriate to assess the environmental impacts of the proposed action. This determination was made because of the potential for significant environmental impacts and the considerations of a first-of-a-kind application for a medical radioisotope production facility with a unique application of technologies. The EIS process also allowed for maximum public involvement, such as a comment period during the scoping period to develop the draft EIS, a comment period after publication of the draft EIS, and public meetings in Janesville, Wisconsin, during each of the two comment periods.

Another unique aspect of the SHINE construction permit review is that the staff had to use its technical judgment to determine the appropriate environmental findings to make in support of issuance of a construction permit, as required by 10 CFR 50.40 and 10 CFR Part 51. After reviewing the application and the Commission's 10 CFR Part 51 regulations implementing NEPA, the staff determined that 10 CFR 51.105(a) provided the applicable findings given that the proposed action is the issuance of a construction permit, and the generic NEPA findings in that regulation are required to license similar facilities.[4]

b. Department of Energy as a Cooperating Agency

Another nonroutine aspect of the SHINE construction permit environmental review is that two Federal agencies are obligated to conduct environmental reviews under the NEPA, as amended (42 U.S.C. 4321 et seq.). NRC is required to conduct an environmental review under NEPA to decide whether to grant SHINE a construction permit. The U.S. Department of Energy (DOE) is required to conduct an environmental review under NEPA to engage in cost-sharing activities to accelerate domestic endeavors to demonstrate and produce a reliable supply of Mo-99 using a technology that does not rely on the use of highly-enriched uranium.

NEPA provisions lay the groundwork for coordination between two (or more) agencies that may both have jurisdiction by law or special expertise on an environmental issue. One agency is considered the lead agency and has the primary role in preparing an EIS, while the other Federal agency, referred to as a "cooperating agency," is responsible for assisting the lead agency in the development of the EIS. The cooperating agency provides technical input to the environmental analysis and provides staff support, as needed, to the lead agency.
In addition to the NRC's and DOE's obligations under NEPA, the National Defense Authorization Act for fiscal year 2013, Title XXXI, Subtitle F, known as the American Medical Isotopes Production Act of 2012 (42 U.S.C. 2065 et seq.), directs the NRC and DOE to ensure, to the maximum extent practicable, that environmental reviews for facilities to produce medical radioisotopes are complementary and not duplicative.

Based on NEPA groundwork for coordinating environmental review efforts and the need to coordinate environmental reviews as described in the American Medical Isotopes Production Act, the NRC and DOE decided to enter into a cooperative agreement to make the most

[4] See, e.g., 10 CFR 51.107, "Public hearings in proceedings for issuance of combined licenses; limited work authorizations," and 51.109, "Public hearings in proceedings for issuance of materials license with respect to a geologic repository."

effective and efficient use of Federal resources in reviewing SHINE's construction permit application. On December 1, 2014, and February 3, 2015, the NRC and DOE signed a Memorandum of Agreement (MOA) on the review of the SHINE application (ADAMS Accession No. ML13304B666). The goal of this agreement is to develop one EIS that serves the NRC licensing process and the DOE funding process. The MOA designates the NRC as the lead Federal agency and DOE as a cooperating agency in developing an EIS for the proposed SHINE facility. The MOA also provides that DOE, as a cooperating agency, will commence the process to adopt the final EIS after it is completed.

c. Range of Reasonable Alternatives

Chapter 5 of the EIS describes alternatives to granting a construction permit for the proposed SHINE facility and the environmental impacts of those alternatives. The need to compare the proposed action with alternatives arises from the requirement in Section 102(2)(C)(iii) of NEPA. NEPA states that an EIS shall include an analysis of alternatives to the proposed action. The NRC implements this requirement through regulations in 10 CFR Part 51 and its ISG augmenting NUREG–1537, which state that the EIS will include an analysis that considers and weighs the environmental effects of the proposed action, the environmental impacts of alternatives to the proposed action, and alternatives available for reducing or avoiding adverse environmental effects.

As part of the EIS, the NRC staff considered alternative technologies to produce Mo-99. This analysis was novel for the SHINE review because several entities have proposed new technologies to produce Mo-99 and the proposed new technologies are at various stages of development. When a large number of potential alternatives exist, NEPA requires that an agency analyze a reasonable number of examples, covering the full spectrum of alternatives, in the EIS (46 FR 18026). For the alternative technologies analysis, the NRC staff initially narrowed down the broad range of potential alternatives by considering three alternative technologies that received cooperative agreements from DOE-National Nuclear Security Administration (NNSA) and appeared to be technologically reasonable. In awarding these cooperative agreements, DOE-NNSA based its decision, in part, on an evaluation of the technical feasibility. The three alternative technologies included:

(1) Neutron capture technology,

(2) Aqueous homogenous reactor technology, and

(3) Linear-accelerator-based technology.

The NRC staff then considered whether sufficient environmental data existed to conduct a meaningful alternatives analysis for each of the three technologies. For the neutron capture and aqueous homogenous reactor technology, the NRC staff determined that due to the lack of environmental data regarding the potential impacts from construction, operations, and decommissioning, insufficient environmental information existed to meaningfully analyze the environmental impacts of these two alternatives. The NRC staff determined that sufficient environmental data existed for the linear-accelerator-based alternative, whereby Mo-99 would be produced by utilizing an accelerator to irradiate natural molybdenum that has been enriched in the radioisotope Mo-100. The NRC staff analyzed this alternative in depth and evaluated the

environmental impacts of construction, operations, and decommissioning a hypothetical linear-accelerator-based facility to produce Mo-99. The NRC staff determined that the impacts from construction, operations, and decommissioning would be SMALL for all resource areas, with the exception of transportation. The impacts to transportation would be SMALL to MODERATE because of the noticeable increase in average daily traffic flow. During construction and decommissioning, traffic would increase due to the removal of excavated materials, shipment of construction materials or dismantled buildings to or from the site, transport of worker personnel, and movement of heavy equipment for onsite construction or decommissioning activities. During operations, traffic would increase due to transport of worker personnel, shipments of hazardous and radioactive waste to treatment and disposal facilities; receipt of processing materials (e.g., acids and other chemicals); receipt of target materials; shipment of the Mo-99 and other medical radioisotopes; and, potentially, the return of technetium-99m generators.

IV. Findings

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.

The principal architectural and engineering criteria incorporated into the proposed design of the SHINE facility to protect the health and safety of the public are presented in the SHINE PSAR. Principal design criteria, design bases, administrative controls, passive safety features, and active safety features are found in the following PSAR chapters:

Chapter 1	The Facility
Chapter 2	Site Characteristics
Chapter 3	Design of Structures, Systems, and Components
Chapter 4	Reactor and Isotope Production Facility Design
Chapter 5	Coolant Systems
Chapter 6	Engineered Safety Features
Chapter 7	Instrumentation and Control Systems
Chapter 8	Electrical Power Systems
Chapter 9	Auxiliary Systems
Chapter 13	Accident Analysis
Chapter 14	Technical Specifications

The staff evaluated SHINE's preliminary design to ensure the sufficiency of principal design criteria; design bases; and information relative to materials of construction, general arrangement, and approximate dimensions. Special attention was given to design and operating characteristics, unusual or novel design features, and principal safety considerations. Based on its evaluation, the staff concludes that SHINE's preliminary facility design is sufficient to provide reasonable assurance that the final design will conform to the design basis. In addition, the staff reviewed SHINE's identification and justification for the selection of variables,

conditions, or other items that are probable subjects of technical specifications for the SHINE facility.

In areas where the staff found that the information submitted initially was incomplete or insufficient to allow the staff to reach a conclusion, the staff issued RAIs to SHINE. The staff reviewed SHINE's RAI responses to ensure that the additional information provided was sufficient to support the staff's conclusion. Where necessary, SHINE provided supplemental RAI responses. The staff also conducted audits of SHINE's records and calculations and performed its own confirmatory calculations.

The staff finds that the preliminary design and analysis of the SHINE IF and RPF: (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 all applicable regulatory requirements and acceptance criteria in or referenced in NUREG-1537 and the ISG augmenting NUREG-1537. Furthermore, the staff's review confirmed that radiological releases and human doses during both normal operation and accident scenarios will remain within the regulatory limits of 10 CFR Part 20. This supports the staff's conclusion that issuance of the permit will not be inimical to the common defense and security or to the health and safety of the public. As discussed in Chapter 1 of the SHINE SER, the staff made its inimicality finding after determining that SHINE met all applicable regulations and acceptance criteria.

The staff 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. SHINE meets the applicable standards and requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations.

(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.

The staff evaluated the sufficiency of the preliminary design of the SHINE facility based on SHINE's design methodology and ability to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety. As such, the staff's evaluation of SHINE's preliminary design does not constitute approval of the safety of any design feature or specification. Such approval would be made following the evaluation of SHINE's final design and analysis, as described in the FSAR submitted as part of SHINE's operating license application.

Throughout the PSAR, and in responses to RAIs, SHINE clearly indicated areas in which further technical or design information would be provided in the FSAR to complete the safety analysis. For those areas identified in responses to RAIs, SHINE has generated Issues Management Reports (IMRs) as a means of internally tracking unresolved issues requiring follow-up in the FSAR. The staff is independently tracking SHINE's IMRs as regulatory commitments, enumerated as Appendix A of the SHINE construction permit SER.

Based on its review of the application and RAIs, the staff has determined 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. Thus, the staff concludes that SHINE has met the applicable standards and requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations.

(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.

As described in SHINE PSAR Section 1.3.9, "Research and Development," and in response to RAI G-1, SHINE has identified two ongoing research and development activities:

- Irradiation and corrosion testing at Oak Ridge National Laboratory to study mechanical performance of materials, as described in the PSAR; and

- Precipitation studies at Argonne National Laboratory to ensure precipitation of uranyl peroxide in the target solution will not occur, as described in response to RAI G-1.

In support of these activities, SHINE has provided descriptions of affected SSCs, the remaining work to be performed, and anticipated schedules for completion.

However, the staff has determined that additional information is needed to address certain matters related to nuclear criticality safety and radiation protection in the RPF. Accordingly, the construction permit is conditioned upon SHINE providing information related to nuclear criticality safety and radiation protection. The draft construction permit lists these conditions. The conditions of the construction permit are confirmatory in nature and must be satisfied prior to the completion of construction. Additional details on the basis for each condition appear in the technical evaluations of the SHINE construction permit SER, Chapters 6 and 11, "Radiation Protection Program and Waste Management."

On the basis of the staff's review of the SHINE construction permit application, the staff concludes that SHINE has described safety features and components that require research and development. Furthermore, SHINE will conduct a research and development program reasonably designed to resolve any safety questions associated with mechanical performance of materials and uranyl peroxide precipitation. Such further matters associated with nuclear criticality safety and radiation protection that require additional information are addressed by conditions of the permit. Thus, the staff concludes that SHINE meets the applicable standards and requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations.

(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

By letter dated September 29, 2015 (ADAMS Accession No. ML15272A395), SHINE has stated that the latest date for completion of construction is expected to be December 31, 2022. Based on the schedules provided in response to RAI G-1, SHINE's two research and development activities would be resolved in advance of the estimated completion of construction. As described in Chapters 6 and 11 of the staff's SER, the conditions of SHINE's permit must also be satisfied prior to the completion of construction.

On the basis of the staff's review of the SHINE construction permit application, the staff concludes that 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. Thus, the staff concludes that the applicable standards and requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations have been met.

(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.

The staff reviewed the application to assure that issuance of the permit will not be inimical to the common defense and security or to the health and safety of the public. While the site criteria contained in 10 CFR Part 100 are applicable to nuclear power reactors, and not the SHINE facility, the staff considered site-specific conditions similar to those in 10 CFR Part 100 in Chapter 2 of its SER. Using the guidance in NUREG-1537, the staff evaluated SHINE's analysis of site-specific conditions, including the 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 permit will not be inimical to the common defense and security or to the health and safety of the public in Chapter 2 of the staff's SER. The review also evaluated SSCs and equipment designed to ensure safe operation, performance, and shutdown when subjected to extreme weather, floods, seismic events, missiles (including aircraft impacts), chemical and radiological releases, and loss of offsite power.

As discussed in Chapters 11 and 13 of the staff's SER, the review confirmed that radiological releases and doses during both normal operation and accident scenarios will remain within the regulatory limits of 10 CFR Part 20. Thus, the staff concludes that the issuance of the construction permit will not be inimical to the common defense and security or to the health and safety of the public.

The staff's review of SHINE's preliminary emergency planning information concluded that the preliminary emergency plan contains the information required in Appendix E, to 10 CFR Part 50. Therefore, as discussed in Chapter 12 of the staff's SER, the plan is acceptable and supports the staff's conclusion that issuance of the permit will not be inimical to the common defense and security or to the health and safety of the public.

On the basis of the staff's review of the application, as discussed in this paper and the referenced documents, the staff concludes that 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. The staff also concludes that the provisions of the Atomic Energy Act of 1954, as amended, and the Commission's regulations have been met. In some

cases, the staff's "reasonable assurance" finding required the inclusion of conditions in the permit. The draft construction permit lists these conditions.

10 CFR 51.105(a):

(i) 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.

Although not expressly applicable to a construction permit application for SHINE's proposed facility, the staff reviewed the application and the Commission's regulations in 10 CFR Part 51 and determined that 10 CFR 51.105(a) provided the applicable environmental findings. The staff performed this evaluation using applicable portions of the environmental standard review plan (NUREG-1537) and the ISG augmenting NUREG-1537.

In accordance with NEPA Section 102(2)(A) (42 U.S.C. § 4332(2)(A)), the staff prepared the final EIS (NUREG-2183) based on its independent assessment of the information provided by SHINE and information developed independently by the staff, including through consultation with other agencies. The staff's technical analysis used a systematic, interdisciplinary approach to integrate information from many fields, including the natural and social sciences as well as the environmental design arts. Consequently, the staff concludes that its review comports with the NRC's requirements in Appendix A, "Format for Presentation of Material in Environmental Impact Statements," to 10 CFR Part 51. The staff concludes that environmental findings in the final EIS constitute the "hard look" required by NEPA and have reasonable support in logic and fact.

In accordance with NEPA Sections 102(2)(C)(i–v) (42 USC § 4332(2)(C)(i–v), the final EIS for the SHINE construction permit addresses: (1) the environmental impact of the proposed action, (2) any unavoidable adverse environmental effects, (3) alternatives to the proposed action, (4) the relationship between local short-term uses of the environment and the maintenance and enhancement of long-term productivity, and (5) any irreversible and irretrievable commitments of resources that would be involved in the proposed action should it be implemented.

As supported by correspondence presented in Appendices C and D to the final EIS, the staff concludes that it fulfilled the requirement of NEPA Section 102(2)(C) by consulting with and obtaining comments from other Federal, State, and local agencies with jurisdiction by law or special expertise (see 42 USC § 4332(2)(C)). The DOE fully participated with the NRC in preparing this EIS as a cooperating agency and participated collaboratively on the review team under the NRC's memorandum of agreement with the DOE. The staff also filed the final EIS with the U.S. Environmental Protection Agency (EPA), furnished it to commenting agencies, and made the final EIS available to the public.

The staff concludes that the final EIS demonstrates that the staff adequately considered alternatives to the proposed action to the extent that it involves unresolved conflicts concerning alternative uses of available resources, consistent with the requirements of NEPA Section 102(2)(E) (42 USC § 4332(2)(E)). The alternatives considered in the final EIS include the no-action alternative, alternative sites, and alternative technologies.

(ii) 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.

Section 5.4 of the final EIS provides the staff's cost-benefit balancing. The staff concluded that in weighing the costs and benefits, the overall benefits of constructing, operating, and decommissioning the proposed SHINE facility at the Janesville site outweigh the disadvantages and costs based upon the following considerations:

- U.S. policy is to ensure a reliable supply of medical radioisotopes while minimizing the use of highly enriched uranium for civilian purposes;
- The small environmental impact, including radiological impacts and risk to human health, which would be caused by constructing, operating, and decommissioning the proposed SHINE facility at the Janesville site;
- The economic benefit of constructing and operating the proposed SHINE facility to communities located near the Janesville site; and
- The increased availability of medical radioisotopes for U.S. public health needs.

(iii) 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.

As noted above, in its final EIS, the NRC staff considered the cost-benefit balancing as well as reasonable alternatives. Based on that analysis, the staff recommends that the construction permit be issued. The NRC staff based its recommendation on: (1) the SHINE environmental report submitted as part of its construction permit application; (2) consultation with Federal, State, and local agencies and Tribes; (3) the NRC staff's own independent review; (4) the NRC staff's consideration of public scoping comments related to the environmental review; (5) the NRC staff's consideration of public comments on the draft EIS; and (6) the assessments summarized in the EIS, including the potential mitigation measures identified in the environmental report and in the EIS. In addition, in making its recommendation, the staff determined that none of the alternative sites are environmentally preferable to the proposed Janesville site.

(iv) Determine, in an uncontested proceeding, whether the NEPA review conducted by the NRC staff has been adequate.

The staff conducted an independent evaluation of the application; developed independent, reliable information; and conducted a systematic, interdisciplinary review of the potential impacts of the proposed action on the human environment and reasonable alternatives to SHINE's proposal. Before development of the draft EIS, the staff issued a notice of intent and invited the public to provide any information relevant to the environmental review. The staff also provided opportunities for governmental and general public participation during the public meeting on the draft EIS and used publicly available guidance in the development of its final

EIS. The contents of the final EIS are in conformance with the requirements of Appendix A to 10 CFR Part 51.

The 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 final EIS considered the no-action alternative, alternative sites, and alternative technologies. The final EIS compared the alternatives to the proposed action. The staff considered any 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 any irreversible or irretrievable commitments of resources that would be involved in the proposed project.

The NRC filed the draft EIS with the EPA for its review consistent with its requirements of Section 309 of the Clean Air Act (see 42 U.S.C. § 7609). The staff considered all comments received on the draft EIS and, in Appendix A to the final EIS, described the manner in which each comment was dispositioned.

On these bases, the staff concludes that, for the purpose of issuing the construction permit, it conducted a thorough and complete environmental review that was sufficient to meet the requirements of NEPA and adequate to inform the Commission's action on the construction permit request.

CONCLUSION:

Based on the findings of its review in accordance with 10 CFR 50.35(a) and 10 CFR 51.105, the staff concludes that there is sufficient information for the Commission to issue the subject construction permit to SHINE, as guided by the following considerations described in 10 CFR 50.40 and 10 CFR 50.50, and described in Chapter 1, "The Facility," of the staff's SER:

- There is reasonable assurance: (i) that the construction of the SHINE facility will not endanger the health and safety of the public, and (ii) that construction activities can be conducted in compliance with the Commission's regulations;

- SHINE is technically qualified to engage in the construction of its proposed facility in accordance with the Commission's regulations;

- SHINE is financially qualified to engage in the construction of its proposed facility in accordance with the Commission's regulations;

- 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;

- After weighing the environmental, economic, technical and other benefits of the facility against environmental and other costs and considering reasonable available alternatives, the issuance of this construction permit, subject to the conditions for protection of the environment set forth herein, is in accordance with Subpart A of

10 CFR Part 51 of the Commission's regulations and all applicable requirements have been satisfied; and

- The application meets the standards and requirements of the AEA and the Commission's regulations, and that notifications, if any, to other agencies or bodies have been duly made.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection.

/RA/

Victor M. McCree
Executive Director
for Operations

- SHINE is financially qualified to engage in the construction of its proposed facility in accordance with the Commission's regulations;

- 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;

- After weighing the environmental, economic, technical and other benefits of the facility against environmental and other costs and considering reasonable available alternatives, the issuance of this construction permit, subject to the conditions for protection of the environment set forth herein, is in accordance with Subpart A of 10 CFR Part 51 of the Commission's regulations and all applicable requirements have been satisfied; and

- The application meets the standards and requirements of the AEA and the Commission's regulations, and that notifications, if any, to other agencies or bodies have been duly made.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection.

/RA/
Victor M. McCree
Executive Director
for Operations

ADAMS Accession No.: ML15272A004 ***via e-mail** **SECY-012**

OFFICE	NRR/DPR/PRLB/PM	NRR/DPR/PRLB/LA*	NRR/DLR/RERB/PM*	NMSS/FCSE/ECB/PM*	RES/DSA/ RSAB/PM*
NAME	SLynch	NParker	MMoser	MAdams	TZaki
DATE	09/28/15	9/29/15	10/01/15	9/29/15	9/28/15
OFFICE	Tech Editor*	NRR/DLR/RERB/BC*	NMSS/FCSE/ECB/BC	RES/DSA/RSAB/BC*	NRR/DPR/ PLRB/BC
NAME	CHsu	DWrona	TGrice	SElkins	AAdams
DATE	09/30/15	10/01/15	9/29/15	9/28/15	10/02/15
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NAME	JMarshall	CErlanger	MGavrilas	MCase	EWilliamson
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NAME	CHaney (SMoore for)*	BSheron (SWest for)	LKokajko	WDean	VMcCree
DATE	10/09/15	10/13/15	10/02/15	10/07/15	10/22/15

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