Safety Evaluation Report

Related to the SHINE Medical Technologies, Inc. Construction Permit Application for a Medical Isotope Production Facility

Docket No. 50-608

SHINE Medical Technologies, Inc.

U. S. Nuclear Regulatory Commission
Office of Nuclear Regulation
Washington, DC 20555-0001

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ABSTRACT

This safety evaluation report (SER) documents the U.S Nuclear Regulatory Commission (NRC) staff's findings related to the technical review of the construction permit application submitted by SHINE Medical technologies, Inc. (SHINE) for a medical isotope production facility consisting of an Irradiation Facility (IF) and Radioisotope Production Facility (RPF). The IF would consist of eight subcritical operating assemblies (or irradiation units), which would each be licensed as utilization facilities as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) 50.2, "Definitions." The RPF would consist of three hot cell structures, licensed collectively as a production facility, as defined in 10 CFR 50.2. In the staff's evaluation, the IF and RPF are collectively referred to as the SHINE facility. An environmental review was also performed of the SHINE construction permit application and its evaluation and conclusions are documented in an environmental impact statement, published as NUREG-2183, "Final Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility." (Reference X)

By letter dated May 31, 2013 (Reference 1), SHINE submitted the second and final part of its two-part application for a construction permit pursuant to the regulations contained in 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." Part one of SHINE's construction permit application, primarily consisting of SHINE's environmental report, was submitted by letter dated March 26, 2013 (Reference 2). By letter dated September 25, 2013 (Reference 3), SHINE supplemented its construction permit application with a discussion of preliminary plans for coping with emergencies, as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 50.34(a)(10), completing its application for a construction permit.

The preliminary design and analysis of the SHINE IF and RPF were evaluated against the appropriate 10 CFR regulatory requirements primarily using the guidance and acceptance criterial contained in NUREG-1537 Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 4), and NUREG-1537 Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (Reference 5), as well as the "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (Reference 6), 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 (Reference 7).

As appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers [IEEE] standards, American National Standards Institute/American Nuclear Society [ANSI/ANS] standards) has been utilized in the review of SHINE's IU cooling systems. The use of additional guidance is based on the technical judgement 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 Preliminary Safety Analysis Report (PSAR) (Reference 13).

This SER presents the results of the staff's review of the SHINE construction permit application, as supplemented by responses to requests for additional information. In Appendix A to this

SER, the staff has identified certain permit conditions that the staff recommends the Commission impose, should the construction permit be issued to the applicant. Additionally, Appendix A contains a listing of those elements of design, analysis, and administration identified as requiring additional research and development or correction by the applicant through its Issues Management Report System. The staff has determined that while resolution of these items is not necessary to support the issuance of a construction permit, it is the responsibility of the applicant to ensure that these items have been full addressed in the final safety analysis report (FSAR) supporting the issuance of an operating license. The staff is tracking these items as regulatory commitments and will verify their implementation during the review of SHINE's operating license application. Appendix B to this SER provides a listing of references, including regulatory criteria, guidance, and correspondence (e.g., requests of additional information and associated responses) used to develop this SER. Routine correspondence and documentation related to the review of the SHINE construction permit application (e.g., public meeting summaries or proprietary determination reviews), but not directly supporting the development of this SER may be found in the Agencywide Documents Access and Management System (ADAMS) under SHINE's Docket Number, 50-608, or project number, PROJ0792. Appendix C to this SER provides a listing of principal contributors, including areas of technical expertise and chapters of authorship.

The NRC's Advisory Committee on Reactor Safeguards (ACRS) also reviewed the bases for the conclusions in this report. The ACRS independently reviewed those aspects of the application that concern safety and provided the results of its review to the Commission in a report dated October XX, 2015. Appendix D to this SER includes a copy of the report by the ACRS on the SHINE construction permit application, as required by 10 CFR 50.58, "Hearings and Report of the Advisory Committee on Reactor Safeguards."

The staff finds that the preliminary design and analysis of the SHINE IF and RPF, including the principle design criteria; design bases; information relative to materials of construction, general arrangement, and approximate dimensions; and preliminary analysis and evaluation of the design and performance of structures, systems, and components (SSCs) of the facility, as described in the SHINE preliminary safety analysis report, and as supplemented by responses to requests for additional information: (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 ISG Augmenting NUREG-1537.

The staff's evaluation of the preliminary design and analysis of the SHINE IF and RPF does not constitute approval of the safety of any design feature or specification. Such approval will be made following the evaluation of the final design of the SHINE IF and RPF, as described in the FSAR, as part of SHINE's operating license application.

On the basis of these findings as documented in this SER, the staff recommends that the Commission make the following conclusions to support the issuance of a construction permit in accordance with 10 CFR 50.35:

(1) 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.

(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 FSAR.
(3) Safety features or components, if any, which require research and development have been described by SHINE and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.
(4) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) the proposed facility can be constructed at the proposed location without undue risk to the health and safety of the public.

CONTENTS

The chapter and section layout of this safety evaluation report (SER) is consistent with the format of (1) NUREG-1537, Parts 1 and 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors;” (2) Interim Staff Guidance Augmenting NUREG-1537, Parts 1 and 2, “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; and (3) the applicant’s preliminary safety analysis report (PSAR).

FIGURES

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TABLES

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APPENDICES

ABBREVIATIONS AND ACRONYMS

[A consolidated list of abbreviations and acronyms from each chapter of this SER will be provided at a later date.]

1.0 THE FACILITY

This chapter of the SHINE construction permit (CP) safety evaluation report (SER) serves as a general introduction to the facility and provides an overview of the topics covered in detail other chapters, including areas of review, regulatory criteria and guidance, review procedures and findings, and conclusions.

1.1 Introduction

This SER documents the U.S Nuclear Regulatory Commission (NRC) staff's findings related to the technical review of the CP application submitted by SHINE Medical Technologies, Inc. (SHINE) for a medical isotope production facility consisting of an Irradiation Facility (IF) and Radioisotope Production Facility (RPF). The IF would consist of eight subcritical operating assemblies (or irradiation units), which would each be licensed as utilization facilities as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) 50.2, "Definitions." The RPF would consist of three hot cell structures, licensed collectively as a production facility, as defined in 10 CFR 50.2. In the staff's evaluation, the IF and RPF are collectively referred to as the SHINE facility. An environmental review was also performed of the SHINE construction permit application and its evaluation and conclusions are documented in an environmental impact statement, published as NUREG-2183, "Final Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility" (Reference X).

By letter dated March 26, 2013 (Reference 2), SHINE submitted part one of a two-part application for a construction permit, which, if granted, would allow SHINE to construct a medical isotope production facility in Janesville, Wisconsin. The NRC staff acknowledged receipt of part one of SHINE's two-part application for a construction permit under 10 CFR Part 50 in the *Federal Register* (78 FR 29390) on May 20, 2013. An exemption from certain requirements of 10 CFR 2.101(a)(5) granted by the Commission on March 20, 2013 (Reference 8), in response to a letter from SHINE dated February 18, 2013 (Reference 9), allowed for SHINE to submit its construction permit application in two parts. Specifically, the exemption allowed SHINE to submit a portion of its application for a construction permit up to 6 months prior to the remainder of the application regardless of whether or not an environmental impact statement or a supplement to an environmental impact statement is prepared during the review of its application. In accordance with 10 CFR 2.101(a)(5), SHINE submitted the following in part one of its construction permit application:

- the description and safety assessment of the site required by 10 CFR 50.34(a)(1)
- the environmental report required by 10 CFR 50.30(f)
- the filing fee information required by 10 CFR 50.30(e) and 10 CFR 170.21
- the general information required by 10 CFR 50.33
- the agreement limiting access to classified information required by 10 CFR 50.37

By letter dated June 25, 2013 (Reference 10), the NRC staff determined that part one of SHINE's application for a CP was complete and acceptable for docketing assigning the application Docket No. 50-608.

By letter dated May 31, 2013 (Reference 1), SHINE submitted the second and final part of its two-part application for a construction permit pursuant to the regulations contained in 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," which contained the remainder of the PSAR required by 10 CFR 50.34(a).

As the staff neared completion of its acceptance review of part two of SHINE's application for a construction permit, it identified an apparent deficiency in the application. Specifically, SHINE did not provide a discussion of preliminary plans for coping with emergencies, as required by 10 CFR 50.34(a)(10). Requirements for this plan are set forth in Appendix E to 10 CFR Part 50, "Emergency Planning and Preparedness for Production and Utilization Facilities." Meeting regulatory requirements, with respect to the information necessary to be submitted to support a construction permit application, as outlined in applicable NRC regulations, is the principal focus of the NRC staff's acceptance review. If required information is not submitted, SHINE's application for a construction permit will be considered incomplete and unacceptable for docketing. Therefore, the NRC staff requested that SHINE provide a preliminary plan for coping with emergencies, as required by 10 CFR 50.34(a)(10), within 30 days of the date of a letter dated August 28, 2013 (Reference 11), otherwise the application would be considered incomplete and unacceptable for docketing.

By letter dated September 25, 2013 (Reference 3), 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.

By letter dated December 2, 2013 (Reference 12), the NRC staff informed SHINE that part two of its CP application, as supplemented, contained the remainder of the preliminary safety analysis report (PSAR) required by 10 CFR 50.34(a), was submitted in accordance with the requirements of 10 CFR 2.101(a)(5), and was placed, in its entirety, under Docket No. 50-608.

1.1.1 Areas of Review

The staff reviewed the SHINE PSAR against applicable regulatory requirements using appropriate regulatory guidance and standards, as discussed below, to assess the sufficiency of the preliminary design of the SHINE IF an RPF. As part of this review, the staff evaluated descriptions and discussions of SHINE's SSCs, with special attention to design and operating characteristics, unusual or novel design features, and principal safety considerations. The preliminary design of the SHINE IF and RPF was evaluated to ensure the sufficiency of principle design criteria, design bases, and information relative to materials of construction, general arrangement, and approximate dimensions, sufficient to provide reasonable assurance that the final design will conform to the design bases. In addition, the staff reviewed SHINE's identification and justification for the selection of those variables, conditions, or other items that are determined to be probable subjects of technical specifications for the facility, with special attention given to those items that may significantly influence the final design. Structures, systems, and components (SSCs) were also evaluated to ensure that they would adequately provide for the prevention of accidents and the mitigation of consequences of accidents. The staff considered the preliminary 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.

1.1.2 Regulatory Basis and Acceptance Criteria

The staff reviewed the SHINE PSAR against applicable regulatory requirements, using appropriate regulatory guidance and standards, to assess the sufficiency of the preliminary facility design and analysis in support of the issuance of a construction permit. In accordance with paragraph (a) of 10 CFR 50.35, "Issuance of Construction Permits," a construction permit

authorizing SHINE to proceed with construction may be issued once the following findings have been made:

(1) 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.
(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 FSAR.
(3) Safety features or components, if any, which require research and development have been described by SHINE and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.
(4) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) the proposed facility can be constructed at the proposed location without undue risk to the health and safety of the public.

The staff's evaluation of the preliminary design and analysis of the SHINE facility does not constitute approval of the safety of any design feature or specification. Such approval will be made following the evaluation of the final design of the SHINE facility, as described in the FSAR as part of SHINE's operating license application.

While the SHINE construction permit application is evaluated against all applicable regulatory requirements, the primary evaluation of SHINE's preliminary design and analysis was based upon the following 10 CFR requirements:

- 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," paragraph (f)
- 10 CFR 50.34, "Contents of applications; technical information," paragraph (a), "Preliminary safety analysis report"
- 10 CFR 50.35, "Issuance of construction permits"
- 10 CFR 50.55, "Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses"
- 10 CFR 50.58, "Hearings and report of the Advisory Committee on Reactor Safeguards"
- 10 CFR Part 50, Appendix C, "A Guide for the Financial Data and Related Information Required To Establish Financial Qualifications for Construction Permits and Combined Licenses"

- 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"

Note: As required by 10 CFR 50.34(a)(3)(i), SHINE must describe the principle design criteria for its facility in the PSAR; however, SHINE is not required to follow 10 CFR Part 50, Appendix A, "General Design Criteria [GDCs] for Nuclear Power Plants," as this appendix only applies to nuclear power reactors. Nonetheless, SHINE has applied several of the GDCs to the preliminary design of some of its SSCs. As such, the staff based its review, in part, on SHINE's scaled application of the following GDCs, as appropriate:

- GDC 2, "Design Bases for Protection Against Natural Phenomena"
- GDC 4, "Environmental and Dynamic Effects Design Bases"
- GDC 5, "Sharing of Structures, Systems, and Components"
- GDC 10, "Reactor Design"
- GDC 12, "Suppression of Reactor Power Oscillations"
- GDC 13, "Instrumentation and Control"
- GDC 15, "Reactor Coolant System Design"
- GDC 16, "Containment Design"
- GDC 17, "Electric Power Systems"
- GDC 19, "Control Room"
- GDC 20, "Protection System Functions"
- GDC 21, "Protection System Reliability and Testability"
- GDC 22, "Protection System Independence"
- GDC 23, "Protection System Failure Modes"
- GDC 24, "Separation of Protection and Control Systems"
- GDC 25, "Protection System Requirements for Reactivity Control Malfunctions"
- GDC 26, "Reactivity Control System Redundancy and Capability"
- GDC 27, "Combined Reactivity Control Systems Capability"
- GDC 28, "Reactivity Limits"
- GDC 29, "Protection Against Anticipated Operational Occurrences"

The NRC staff evaluated SHINE's preliminary facility design and analysis against the applicable regulatory requirements listed above, primarily using the guidance and acceptance criteria contained in NUREG-1537 Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (Reference 4), and NUREG-1537 Part 2, "Guidelines for Preparing and Reviewing Applications for the

Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (Reference 5), as well as the "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (Reference 6), and "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 (Reference 7).

For the evaluation of the RPF, NRC staff has determined that the use of Integrated Safety Analysis (ISA) methodologies as described in 10 CFR Part 70 and NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR 70.61, and establishment of management measures are an acceptable way of demonstrating adequate safety for the radioisotopes production facility. Applicants are free to propose alternate accident analysis methodologies, to propose alternate radiological and chemical consequence and likelihood criteria, to propose alternate safety features, and to propose alternate methods of assuring the availability and reliability of the safety features.

As used in Section 13b and elsewhere in this SER, the term "performance requirements" is not intended to suggest that Part 50 licensees are required to comply with the performance requirements found in 10 CFR 70.61, only that their use as accident consequence and likelihood criteria for the SHINE RPF would be found acceptable by NRC staff. Alternate accident consequence and likelihood criteria may be found acceptable if the applicant demonstrates that the proposed equipment and facilities to prevent or mitigate accidents are adequate to protect health and minimize danger to life or property, and that proposed procedures to prevent or mitigate accidents are adequate to protect health and to minimize danger to life or property.

As appropriate, additional guidance (e.g., NRC regulatory guides, Institute of Electrical and Electronics Engineers [IEEE] standards, American National Standards Institute/American Nuclear Society [ANSI/ANS] standards) has been utilized in the review of SHINE's IU cooling systems. The use of additional guidance is based on the technical judgement 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 PSAR.

Specific acceptance criteria are provided in the section-by-section technical evaluations of this SER. Additional guidance documents used to evaluate SHINE's preliminary design and analysis are provided as references in Appendix B.

1.1.3 Review Procedures

The staff performed a thorough and complete section-by-section evaluation of the technical information presented in the SHINE PSAR, as supplemented by the applicant's responses to RAIs, to assess the sufficiency of the preliminary design and performance of SHINE's SSCs in support of the issuance of a construction permit, in accordance with 10 CFR 50.35(a). The sufficiency of the preliminary design and performance of SHINE's SSCs is demonstrated by compliance with applicable regulatory requirements, guidance, and acceptance criteria, as discussed in each section of this SER. This review was performed in accordance with applicable review procedures in support of making necessary section-by-section findings.

For the purposes of reviewing SHINE's preliminary facility design, as described in its PSAR, the staff evaluated the sufficiency of the preliminary design of the SHINE systems based on the applicant'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 will 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.

For the purposes of issuing a CP, the preliminary design and analysis of the SHINE facility may be adequately described at a functional or conceptual level. In some cases, this has resulted in the availability of limited information on certain topics in the PSAR. In these cases, the scope and level of documentation of the evaluations performed by the NRC staff appropriately reflects an understanding that a more detailed evaluation will be performed during the staff's review of SHINE's FSAR, submitted in support of an operating license application.

1.1.4 Resolving Technical Deficiencies

For those technical areas that require additional information supported by research and development (i.e., a maturation of facility design), the staff has several options:

1) The staff may determine that such technical issues must be resolved prior to the issuance of a construction permit,

2) The staff may determine that such information may be left until the submission of the FSAR, or

3) The staff may require that such technical issues be resolved prior to the completion of construction, but after the issuance of the construction permit.

Technical issues that fall within the scope of the first option should require that additional information be provided in order to establish principal design criteria and/or design bases so that the staff may have confidence that the final facility design will conform to the design basis. The staff resolves such technical issues through requests for additional information.

In the second and third options, the staff may or may not issue requests for additional information to resolve identified technical issues. These types of technical issues are those that require a more mature or final design beyond what is necessary to issue a construction permit. While determining what constitutes a preliminary vs. a final design may be somewhat subjective, a preliminary design, according to 10 CFR 50.34, must only include principal design criteria, the design bases, general facility arrangement, and approximate dimensions. The preliminary design does not necessary need to conform to the proposed design bases, but the staff should, in its engineering judgement, have confidence that the applicant has applied appropriate methodology in the development of its preliminary design to conform to its design basis in the final design. In these situations, the staff may issue requests for additional information if it determines that it is necessary for the applicant to acknowledge certain technical deficiencies that could impact final design and commit to resolving these deficiencies either in the FSAR or before the completion of construction. In either of these two cases, the staff may also include provisions in the construction permit requiring the applicant to furnish periodic

reports of the progress and results of research and development programs designed to resolve safety questions.

In the course of reviewing SHINE's application, the NRC staff determined that additional information was required to complete the review of SHINE's PSAR in order to prepare this SER. Therefore, the staff prepared and issued requests for additional information dated September 19, 2014, January 6, 2015, March 25, 2015, April 15, 2015, and September xx, 2015. (Reference 14, Reference 15, Reference 16, Reference 17, and Reference 18, respectively).

As of September 2015, SHINE had adequately responded to all of the NRC's requests for additional information in support of developing an SER.

Appendix A to this SER identifies certain permit conditions that the staff recommends the Commission impose, should the construction permit be issued to the applicant. Additionally, Appendix A contains a listing of those elements of design, analysis, and administration identified as requiring additional research and development or correction by the applicant through its Issues Management Report System. The staff has determined that while resolution of these items is not necessary to support the issuance of a construction permit, it is the responsibility of the applicant to ensure that these items have been fully addressed in the final safety analysis report supporting the issuance of an operating license. The staff is tracking these items as regulatory commitments and will verify their implementation during the review of SHINE's operating license application.

1.1.5 Application Availability

Publicly-available documents related to the SHINE construction permit application may be obtained online in the ADAMS Public Documents collection at http://www.nrc.gov/reading-rm/adams.html. To begin the search, select "ADAMS Public Documents" and then 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, at 301-415-4737, or by e-mail to pdr.resource@nrc.gov.

The current version of SHINE's construction permit application, submitted June 16, 2015, is publicly available in ADAMS, Accession No. ML15175A274 (Reference 19). Other documents and correspondence related to this application may be found by searching SHINE's Docket Number, 50-608, or project number PROJ0792 in ADAMS.

1.1.6 NRC Staff Contact Information

This SER was prepared by Steven Lynch, Project Manager, Division of Policy and Rulemaking, U.S. Nuclear Regulatory Commission. Mr. Lynch may be contacted regarding this SER by telephone at 301-415-1524 or e-mail at Steven.Lynch@nrc.gov. Appendix C 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 staff evaluated descriptions and discussions of SHINE's IF and RPF, including probable subjects of technical specifications, as described in the SHINE PSAR and supplemented by the applicant's responses to RAIs, and, on the basis of its review, makes the following findings:

1) Applicable standards and requirements of the Atomic Energy Act and Commission regulations have been met, including acceptance criteria in or referenced in NUREG-1537 or the ISG Augmenting NUREG-1537
2) Required notifications to other agencies or bodies related to this licensing action have been duly made.
3) The design of the facility includes adequate margins of safety and there is reasonable assurance that the final design will conform to the design basis.
4) There is reasonable assurance that the facility can be constructed in conformity with the permit, the provisions of the Atomic Energy Act, and the Commission's regulations.
5) The applicant has considered the expected consequences of several postulated accidents. The staff has performed conservative analyses of the most serious, hypothetically credible and non-credible accidents and determined that the calculated potential radiation doses outside the facility site are not likely to exceed the guidelines of 10 CFR Part 20. Furthermore, SSCs have been designed to provide for the prevention of accidents and the mitigation of consequences of accidents.
6) Releases of radioactive materials and wastes from the facility are not expected to result in concentrations outside the limits specified by 10 CFR 20, Subpart D, and are as low as is reasonably achievable (ALARA).
7) The financial data demonstrate that the applicant has reasonable access to sufficient revenues to cover construction.
8) Issuance of the license will not be inimical to the common defense and security or to the health and safety of the public.
9) The preliminary emergency plan provides reasonable assurance that the applicant will be prepared to assess and respond to emergency events.
10) The application presents information at a level of detail that is appropriate for general familiarization and understanding of the proposed radioisotope production facility.
11) The application describes the relationship of specific facility features to the major processes that will be ongoing at the facility. This description includes the building locations of major process components; drawings illustrating the layout of the buildings and structures within the controlled area boundary are used to support the description.
12) The application describes the major chemical or mechanical processes involving licensable quantities of radioactive material based, in part, on ISA methodology. This description includes the building locations of major process components and brief accounts of the process steps.

Therefore, the staff finds that the preliminary design and analysis of the SHINE IF and RPF, as described in the SHINE PSAR, is sufficient and meets the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with

10 CFR 50.35. The staff will confirm that the final design conforms to this established design basis during the evaluation of SHINE's FSAR.

Further technical or design information required to complete the safety analysis may reasonably be left for later consideration. Appendix A to this SER identifies certain permit conditions that the staff recommends the Commission impose, should the construction permit be issued to the applicant. Additionally, Appendix A contains a listing of those elements of design, analysis, and administration identified as requiring additional research and development or correction by the applicant through its Issues Management Report System. The staff has determined that while resolution of these items is not necessary to support the issuance of a construction permit, it is the responsibility of the applicant to ensure that these items have been full addressed in the final safety analysis report supporting the issuance of an operating license. The staff is tracking these items as regulatory commitments and will verify their implementation during the review of SHINE's operating license application.

On the basis of these findings as documented in this SER, the staff recommends that the Commission make the following conclusions to support the issuance of a construction permit in accordance with 10 CFR 50.35:

(1) 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.
(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 FSAR.
(3) Safety features or components, if any, which require research and development have been described by SHINE and a research and development program will be conducted that is reasonably designed to resolve any safety questions associated with such features or components.
(4) On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) the proposed facility can be constructed at the proposed location without undue risk to the health and safety of the public.

1.3 General Description

The staff evaluated the sufficiency of the general description of the SHINE facility, as presented in SHINE PSAR 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; thermal power level; engineered safety features; instrumentation control, and electrical systems; coolant and other auxiliary systems; radioactive waste management provisions; radiation protection; the general arrangement of major structures and equipment; safety features of special interest; and novel facility design considerations using the guidance and acceptance criteria from Section 1.3, "General Description," of NUREG-1537, Parts 1 and 2.

SHINE identifies itself as a Wisconsin corporation, a private organization that was created for the purpose of designing, constructing, and operating a medical isotope production facility which will be located on previously undeveloped agricultural property in Rock County, Wisconsin, approximately 1 mile south of the corporate boundaries the City of Janesville. SHINE

developed a new method for producing molybdenum-99 (Mo-99) using accelerator-driven neutron sources to induce fission in low-enriched uranium (LEU) within a subcritical operating assembly, creating Mo-99 as a byproduct.

The SHINE medical isotope production facility consists of an Irradiation Facility (IF) and Radioisotope Production Facility (RPF). The IF would consist of eight subcritical operating assemblies (or irradiation units), which would each be licensed as utilization facilities as defined in 10 CFR Section 50.2, "Definitions." The RPF would consist of three hot cell structures, licensed collectively as a production facility, as defined in 10 CFR 50.2. In the staff's evaluation, the IF and RPF are collectively referred to as the SHINE facility.

The irradiation units operate as subcritical operating assemblies in a batch mode with an approximate week-long operating cycle. Each irradiation unit consists of a neutron driver assembly, a subcritical assembly system, a light water pool system, target solution vessel (TSV) off-gas system, and other supporting systems. The RPF also operates in a batch mode, and consists of the following processes dedicated to the extraction, purification, and packaging of Mo-99 for the end users, as well as preparing the target solution for the IU:

- Target solution preparation system (TSPS),
- Molybdenum extraction and purification system (MEPS),
- Uranyl nitrate conversion system (UNCS),
- Noble gas removal system (NGRS),
- Process vessel vent system (PVVS),
- Radioactive liquid waste evaporation and immobilization (RLWE),
- Aqueous radioactive liquid waste storage (RLWS),
- Organic liquid waste storage and export (OLWS),
- Molybdenum isotope product packaging system (MIPS),
- Radioactive drain system (RDS).

In order to produce Mo-99, first, the uranyl sulfate 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 the 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 molybdenum-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, the design of the SHINE facility includes engineered safety features to mitigate design basis events or accidents; control and protection systems; a Class 1E 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; fire protection systems; a radioactive waste management program; and radiation protection program.

1.4 Shared Facilities and Equipment

The staff evaluated the sufficiency of the evaluation of shared facilities and equipment, as presented in SHINE PSAR 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.

In accordance with the review procedures of NUREG-1537, Part 2, Section 1.4, the staff confirmed whether there were any facilities or equipment shared by the SHINE facility.

As stated, in part, in SHINE's PSAR 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 agrees that there are no facilities or equipment that will be shared by the SHINE facility, as this facility represents 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 PSAR.

On the basis of its review, the staff finds 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 PSAR.

(2) While the SHINE IF and RPF share a common building and several common 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) Either normal operation or a loss of function of the IF or RPF would not 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 Chapter 13, "Accident Analyses," and are found to be acceptable.

Therefore, the staff finds that the evaluation of shared facilities and equipment, as described in SHINE PSAR Section 1.4, is sufficient and meets the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis may reasonably be left for later consideration. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

1.5 Comparison with Similar Facilities

The staff evaluated the sufficiency of the comparison of the SHINE facility with other similar facilities, as presented in SHINE PSAR 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.

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

As stated, in part, in SHINE PSAR Section 1.5.1, "Comparison of Physical Plant Equipment," "the SHINE facility uses new technology for the manufacture of medical isotopes. The IU, consisting of the neutron driver, subcritical assembly, light water pool, TOGS [target solution vessel off-gas system], and other supporting systems represent the new technology. As such, there are no similar facilities that compare to the IUs."

The premise of the SHINE technology is that the irradiation units 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 only operate in a minimally subcritical range of k_{eff}. To operate safely within this margin of subcriticality, the irradiation units are designed with several features of a nuclear reactor except that, by design, the target solution vessels have insufficient reactivity to sustain a chain reaction.

While the NRC staff agrees that the IUs represent new technology, the accelerator and neutron multiplier add sufficient external neutrons to the target solution vessel to achieve a fission rate with a thermal power level comparable to non-power reactors typically licensed under 10 CFR Part 50 as utilization facilities.[1] Given this fission power, the irradiation units 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.
- 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 SHINE's proposed irradiation units closely resemble non-power reactors, which are licensed as utilization facilities under 10 CFR Part 50, the NRC staff determined that it would be most appropriate to license SHINE's IUs as utilization facilities under 10 CFR Part 50. However, at the time of SHINE's initial application submission, the irradiation units could not be licensed as utilization facilities because they are not nuclear reactors. Therefore, while 10 CFR Part 50 would have been appropriate to apply from a technical and licensing review

[1] Non-power reactors currently licensed to operate by the NRC range in thermal power 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 target solution vessel has insufficient fissile material to support a sustained chain reaction.

process standpoint, the irradiation units could not be licensed as utilization facilities under the current regulations.

The NRC staff also considered whether it should review SHINE's irradiation units under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," which regulates the issuance of licenses to receive title to, own, acquire, deliver, receive, possess, use, and transfer special nuclear material (SNM). From a regulatory perspective, 10 CFR Part 70 could have been applied because SHINE will acquire, receive, possess, use, and transfer SNM. The requirements of 10 CFR Part 70, subpart H, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material," could also be applied because SHINE will possess a critical mass of SNM, and will engage in an activity that could significantly affect public health and safety.

However, the facilities conducting the types of activities typically regulated under 10 CFR Part 70, generally referred to as fuel cycle facilities, have a common objective of avoiding criticality by maintaining a significant margin from criticality under normal operating and accident conditions. Specifically, 10 CFR 70.61(d) calls for "… use of an approved margin of subcriticality for safety." SHINE's irradiation units have a proposed routine operating margin of subcriticality of less than what has been previously approved for other 10 CFR Part 70 licensees. This operating state more closely resembles the effective neutron multiplication factor of nuclear reactors than fuel cycle facilities. Because SHINE proposes to operate each irradiation unit in a manner similar to a nuclear reactor, the NRC staff determined that it would be most appropriate to use the regulations contained in 10 CFR Part 50 to perform its technical review of the irradiation units.

Therefore, 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 SHINE's IUs, so that they could be licensed under 10 CFR Part 50:

> *Utilization facility* means:
>
> (1) Any nuclear reactor other than one designed or used primarily for the formation of plutonium or U–233; or
>
> (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.

The rulemaking allowed the NRC staff to conduct its licensing review of the proposed SHINE irradiation units following regulations designed for technologies with similar radiological, health, and safety considerations. Additionally, the rule does not affect the ability of the public to comment and request a hearing on the application; and the inclusion of SHINE's Docket Number as well as a description of the SHINE irradiation unit technology limits the applicability of the rule to SHINE's proposed irradiation units, ensuring no impact to other existing or future facilities. If, in the future, any applicant proposes a technology similar to SHINE's irradiation units,[2] the Commission would consider that application on a case-by-case basis, and assign a distinct Docket Number to each application. Should SHINE propose a technology other than the

[2] At this time, the NRC staff does not anticipate receiving any other applications for medical radioisotope production facilities that would propose a technology similar to SHINE's irradiation units.

irradiation units currently described in its PSAR, the rule would no longer apply to SHINE, and the NRC staff would pursue an alternative licensing approach.

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.

Regarding molybdenum extraction, there are currently no U.S. NRC or U.S. Department of Energy (DOE) 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 SHINE's proposed molybdenum extraction.

According to a paper prepared by Aker Kvaerner Engineering Services, titled "Radio Active Waste Plants – Back to the Future," SIXEP has been in operation since 1985 and "represents an early generation of Radwaste plant for the treatment of site magnox sourced liquid effluents, designed in the late 1970's, and based on the use of filtration and ion exchange."

With respect to the molybdenum 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 means to purify Mo-99 for used as a medical radioisotope. The primary difference between SHINE's molybdenum purification process and that of Cintichem is a slight change in process chemistry to accommodate the change in chemical and isotopic composition due to the switch from highly-enriched uranium to low enriched uranium. Similar to Cintichem, shielding and confinement will serve as the principal engineered safety features designed to reduce worker doses associated with this activity at the SHINE facility.

As stated, in part, in SHINE PSAR Section 1.5.2.3, "Uranyl Nitrate Converstion," "[t]he conversion of uranyl sulfate to uranyl nitrate is necessary to enable fission products to be removed from the uranium, in order to recycle the uranium within the target solution loop. The conversion step for the uranyl sulfate is not currently used in any NRC or DOE facilities." However, the NRC staff notes that Argonne National Laboratory is conducting research in support of the SHINE project on the conversion of uranyl sulfate solution to uranyl nitrate solution for processing in UREX, as presented at the Mo-99 Topical Meeting, hosted by Argonne National Laboratory in Washington, DC from June 24-27, 2014.

The SHINE uranium extraction (UREX) process is a modification of a widely-used uranium and plutonium separation and purification process known as plutonium and uranium extraction (PUREX). The PUREX process was developed in the late 1940s and uses tributyl phosphate (TBP) to selectively remove uranium and plutonium from a nitric acid solution typically containing a host of fission product and other actinide contaminants. SHINE lists the principal locations that either currently or have historically used the PUREX Process:

a. Hanford, Washington.
b. Savannah River Site, South Carolina.
c. Idaho National Laboratory, Idaho.
d. West Valley, New York.

e. Radiochemical Engineering Development Center, Oak Ridge National Laboratory, Tennessee.
f. Sellafield, United Kingdom.
g. Mayak, Russia.
h. AREVA La Hague site, France.
i. Rokkasho, Japan.

The staff notes that the PUREX process has traditionally been employed by fuel reprocessing facilities (i.e., Hanford, Savanna River and West Valley), in which irradiated fuel goes through dissolution, fission product and waste separation, and uranyl and plutonium nitrate purification. Despite similarities in process, the staff does not consider the SHINE RPF a fuel reprocessing facility. While the SHINE UREX process is similar to these facilities, unlike the traditional fuel reprocessing facilities, the UREX process used by SHINE will not be separating plutonium from its irradiated target solution.

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 of fuel reprocessing facilities 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 become knowledgeable in the area of spent nuclear fuel reprocessing and define the issues most important to the NRC concerning fuel reprocessing facilities. As a result, the Committee published a white paper, NUREG-1909, "Background, Status, and Issues Related to the Regulation of Spent Nuclear Fuel Recycle Facilities," in June 2008, representing the only current regulatory guidance on this issue. In this white paper, the Committee describes "reprocessing" as the separation of spent nuclear fuel into its constituent components (pages xv and 152) [3].

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 is constituent elements by reprocessing…"

Based on the definitions of spent nuclear fuel and reprocessing discussed above, it can be inferred that only fuel from a nuclear power reactor is considered spent nuclear fuel, and therefore, only fuel from a nuclear power reactor may undergo reprocessing. 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 70.4, the staff has concluded that the processing of SHINE's irradiated LEU target solution does not constitute fuel reprocessing. Therefore, the SHINE production facility is not a fuel reprocessing facility.

[3] This definition is also generally consistent with the description of reprocessing on the NRC's public webpage: "Reprocessing refers generally to the processes necessary to separate spent nuclear reactor fuel into material that may be recycled for use in new fuel and material that would be discarded as waste." (http://www.nrc.gov/materials/reprocessing.html)

Regarding evaporation and thermal denitration, while there are no NRC-licensed uranyl nitrate evaporation and dentration facilities in operation, SHINE has identified fluidized bed thermal denitration performed at the previously identified PUREX facilities as a similar process.

SHINE cites the DOE Hanford site with submerged tube forced recirculation evaporator operational experience, as used at the SHINE facility. Construction of the Hanford site was completed in 1977, and the evaporator is anticipated to operate into at least the 2040s.

SHINE likens its tritium purification system with similar processes conducted at the Savannah River Site and Laboratory for Laser Energetics. However, in PSAR Section 1.5.2.7, "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 staff finds 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) The applicant 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 staff.

(2) Aspects of the applicant's design that are similar to features in other similar facilities have been found acceptable to the staff, and should be expected to perform in a similar manner when constructed to that design

(3) The applicant is using test data and operational experience in designing components. The applicant cited the actual facilities with similar components, as practicable.

Therefore, the staff finds that the comparisons with similar facilities, as described in SHINE PSAR Section 1.5 is sufficient and meets the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis may reasonably be left for later consideration. The staff will confirm that the final design conforms to this design basis during the evaluation of SHINE's FSAR.

1.6 Summary of Operations

The staff evaluated the sufficiency of the comparison of the SHINE Summary of Operations, as presented in SHINE PSAR 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.

In accordance with the review procedures of NUREG-1537, Part 2, Section 1.6, the staff verified that proposed operations of the SHINE facility had been summarized.

The SHINE facility is capable of producing up to 8200 6-day curies of Mo-99 per week. SHINE listed the major operations to be performed in the SHINE facility in support of this Mo-99 production as follows:

- Target solution preparation from raw feed material (uranium metal).
- Target solution preparation from irradiated and processed target solution.
- Irradiation of target solution.
- Mo extraction from irradiated target solution.
- Mo purification.
- Target solution processing (cleanup).

As described above in SER Section 1.3, "General Description," the uranyl sulfate 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 the 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 molybdenum-99 is purified and packaged for shipment to customers. The remaining target solution is then prepared for further irradiation in the IUs.

On the basis of its review, the staff finds that the level of detail provided on comparisons with similar facilities satisfies the applicable acceptance criteria of NUREG-1537, Part 2, Section 1.6, allowing the staff to make the following relevant finding:

(1) The proposed operating conditions and schedules are consistent with the design features of the facility and have been found acceptable to the staff. The proposed operations are consistent with the relevant assumptions in later chapters of the PSAR, in which any safety implications of the proposed operations are evaluated.

Therefore, the staff finds that the summary of operations, as described in SHINE PSAR Section 1.6 is sufficient and meets the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with 10 CFR 50.35. Further technical or design information required to complete the safety analysis may reasonably be left for later consideration.

1.7 Compliance with the Nuclear Waste Policy Act of 1982

The staff evaluated the sufficiency of SHINE's compliance with the Nuclear Waste Policy Act of 1982 (Reference 33), as presented in SHINE PSAR Section 1.7, "Compliance with the Nuclear Waste Policy Act," 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.

As stated in SHINE PSAR Section 1.7, the 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 Chapter 11, "Radiation Protection Program and Waste Management," SHINE has identified commercial disposition pathways for all of its radioactive waste.

The staff has verified that the SHINE facility does not produce high-level nuclear wastes or spent nuclear fuel and that the Nuclear Waste Policy Act of 1982 is not applicable to this facility.

Therefore, the staff finds that compliance with the Nuclear Waste Policy Act of 1982, as described in SHINE PSAR Section 1.7 is sufficient and meets the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with 10 CFR 50.35.

1.8 Facility Modifications and History

The staff evaluated the sufficiency of SHINE's descriptions of facility modifications and history, as presented in SHINE PSAR 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.

As stated in SHINE PSAR Section 1.8, "[t]his report is an application for construction of the SHINE facility. As 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 staff has verified that there are no existing facilities, there have been no modifications, and there is no history to report on the SHINE facility. Therefore, this section is not applicable to this facility.

Therefore, the staff finds SHINE description of facility modifications and history, as described in SHINE PSAR Section 1.8 is sufficient and meets the applicable regulatory requirements and guidance to support the issuance of a construction permit in accordance with 10 CFR 50.35.