

SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

FOR INDIRECT TRANSFER OF AND CONFORMING AMENDMENT

TO CONSTRUCTION PERMIT NO. CPMIF-001

RESULTING FROM THE ESTABLISHMENT OF ILLUMINATED HOLDINGS, INC.

AND SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL ISOTOPE PRODUCTION FACILITY

DOCKET NO. 50-608

Enclosure 3 contains a public version of this safety evaluation (SE) in which proprietary information is redacted and denoted by blank space enclosed with boldface double brackets, as shown here: **[[ ]]**. Enclosure 4 contains proprietary information withheld from public disclosure pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Section 2.390. This information is indicated by **bold text**.

1.0 INTRODUCTION

By application dated December 11, 2018 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML18347A215), as supplemented by letter dated March 8, 2019 (ADAMS Accession No. ML19071A055), SHINE Medical Technologies, Inc. (SHINE or the applicant) requested that the U.S. Nuclear Regulatory Commission (NRC or the Commission) consent to the indirect transfer of Construction Permit No. CPMIF-001 for the SHINE Medical Isotope Production Facility, currently held by SHINE, pursuant to Section 184, "Inalienability of Licenses," of the Atomic Energy Act of 1954, as amended (AEA), and 10 CFR 50.80, "Transfer of licenses." The indirect transfer would result from the establishment of a holding company, Illuminated Holdings, Inc. (Illuminated).

SHINE also requested, pursuant to 10 CFR 50.90, "Application for amendment of license, construction permit, or early site permit," the issuance of an administrative conforming amendment to the license to reflect the proposed transfer. Specifically, the amendment would revise SHINE's construction permit to reflect SHINE's new name, SHINE Medical Technologies, LLC (SHINE LLC), resulting from its conversion from a corporation into a single-member limited liability company, owned and controlled by Illuminated.

2.0 BACKGROUND

SHINE has proposed to construct and operate a 91,000-square-foot facility in Janesville, Wisconsin for the production of molybdenum-99 (Mo-99) through the irradiation and processing of a uranyl sulfate solution. The proposed facility would comprise an irradiation facility and radioisotope production facility. The irradiation facility would consist of eight subcritical operating assemblies (or irradiation units), which would each be licensed as a utilization facility, as defined in 10 CFR 50.2, "Definitions." The radioisotope production facility would consist of three hot cell structures, licensed collectively as a production facility, as defined in 10 CFR 50.2. The irradiation facility and radioisotope production facility are collectively referred to as the SHINE Medical Isotope Production Facility.

Enclosure 4

The SHINE irradiation units would operate as subcritical operating assemblies in a batch mode. Each irradiation unit would consist of a neutron driver assembly, a subcritical assembly system, a light water pool system, a target solution vessel off-gas system, and other supporting systems. The SHINE radioisotope production facility would also operate in a batch mode, and consist of processes dedicated to the extraction, purification, and packaging of Mo-99 for the end users, as well as the preparation of the target solution for the irradiation units.

In order to produce Mo-99, first, the uranyl sulfate target solution would be prepared from recycled materials and/or raw feed materials in the radioisotope production facility. The target solution would then be transferred to the target solution vessels within the irradiation facility. Once the target solution is in a target solution vessel, the irradiation unit would be operated at full power for approximately 5.5 days, at which time the irradiation unit would be shut down and the irradiated target solution transferred to the radioisotope production facility for radioisotope extraction. Following initial extraction, the Mo-99 would be purified and packaged for shipment to customers. The remaining target solution would then be prepared for further irradiation in the irradiation units.

SHINE submitted a two-part construction permit application for its eight utilization facilities and one production facility in 2013. The NRC issued Construction Permit No. CPMIF-001 to SHINE on February 29, 2016. Excavation and initial pouring of concrete could begin as soon as fiscal year 2019. SHINE expects to submit its operating license application to the NRC in fiscal year 2019.

As described in the license transfer application, the indirect transfer of the construction permit would result from the establishment of a parent holding company, Illuminated, a Delaware corporation, which would be owned by the current SHINE owners. The administrative, conforming amendment would revise SHINE's construction permit to reflect SHINE's new name, SHINE Medical Technologies, LLC, resulting from its conversion from a corporation into a single-member limited liability company, owned and controlled by Illuminated. No physical changes to the SHINE Medical Isotope Production Facility or operational changes are proposed in the application.

### 3.0 REGULATORY EVALUATION

The applicant's request for approval of the indirect transfer of control of SHINE Construction Permit No. CPMIF-001, as discussed in this SE, is made under 10 CFR 50.80. The Commission's regulation at 10 CFR 50.80(a) states, in part, that "No license for a production or utilization facility ... or any right thereunder, shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission gives its consent in writing."

In addition, the regulations at 10 CFR 50.80(b) and (c) apply. Pursuant to 10 CFR 50.80(b), an application for a license transfer shall include as much of the information described in 10 CFR 50.33, "Contents of applications; general information," and 10 CFR 50.34, "Contents of applications; technical information," with respect to the identity and technical and financial qualifications of the proposed transferee as would be required by those sections if the application were for an initial license. The regulation at 10 CFR 50.80(c) states, in part, that:

... [T]he Commission will approve an application for the transfer of a license, if the Commission determines: (1) That the proposed transferee is qualified to be the holder of the license; and (2) That transfer of the license is otherwise

consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto.

Additionally, consistent with the regulations in 10 CFR 50.40, “Common standards,” paragraph (b), the proposed indirect transfer must not affect the technical and financial qualifications of the licensee to hold the license.

With respect to financial qualifications, 10 CFR 50.33(f) requires, in part, that each application state:

Except for an electric utility applicant for a license to operate a utilization facility of the type described in § 50.21(b) or § 50.22, information sufficient to demonstrate to the Commission the financial qualification of the applicant to carry out, in accordance with the regulations in this chapter, the activities for which the permit or license is sought.

For an application for a construction permit, 10 CFR 50.33(f)(1) states that this information shall:

[D]emonstrate[] that the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated construction costs and related fuel cycle costs. The applicant shall submit estimates of the total construction costs of the facility and related fuel cycle costs, and shall indicate the source(s) of funds to cover these costs.

As for the level of assurance that the Commission requires for an applicant’s ability to meet its financial obligations, the Commission determined in CLI-99-06 (ADAMS Accession No. ML16195A533) that it is not within the NRC’s purview to manage the finances of its licensees. Thus, the Commission does not require absolute certainty in the financial area and recognizes that some speculation is unavoidable when the issue at stake concerns predictive judgments about an applicant’s future financial capabilities. However, the applicant still bears the burden to show, by a preponderance of the evidence, that it meets the Commission’s financial qualifications rules. This means that the applicant’s cost-and-revenue projections must not rely on assumptions seriously at odds with governing realities and must not involve uncertainties significantly greater than those that usually cloud business outlooks.

Finally, pursuant to 10 CFR 50.33(f)(5), the Commission may request that an applicant “submit additional or more detailed information respecting its financial arrangements and status of funds if the Commission considers this information appropriate. This may include information regarding a licensee’s ability to continue the conduct of the activities authorized by the license....” As such, the NRC staff finds that it is appropriate to request that an applicant for an indirect transfer of control of a construction permit provide the applicable information required for initial construction permit applicants, including newly formed entities, in Appendix C, “A Guide for the Financial Data and Related Information Required To Establish Financial Qualifications for Construction Permits and Combined Licenses,” to 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities.”

In addition to the regulations in 10 CFR Part 50, the NRC staff applies the following guidance to evaluate whether the proposed transferee is qualified to construct the facility:

- 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 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)

The NRC staff’s financial qualifications review for a construction permit is limited to estimates of construction costs, estimates of related fuel cycle costs, and sources of funds to cover these costs. If, at the time of issuance of the construction permit, the licensee has not requested to possess special nuclear material (SNM), the NRC staff will defer evaluation of information related to nuclear insurance and indemnity to such a time when the licensee applies for either an operating license or a license under 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material,” to possess SNM. By extension, the scope of the NRC staff’s financial qualifications review of an application for indirect license transfer and conforming amendment of a construction permit is limited to estimates of construction costs, estimates of fuel cycle costs, and sources of funds to cover these costs.

As described in Section 15.1, “Financial Ability to Construct a Non-Power Reactor,” of NUREG-1537, construction cost estimates may be obtained from facility designers, construction bids from contractors, or from costs, adjusted for inflation, for similar completed projects. Fuel cycle cost estimates may be obtained from analysis of proposed facility operations or proposals from vendors and providers of other services needed for the fuel cycle. Applicants may also quote recent costs of operating similar facilities. With respect to the sources of funds to cover estimated costs, if a funding source is not committed, the applicant should discuss the probability of acquiring the funds and the potential source(s) of the funds. Applicants should also discuss the options available to secure funding that is not committed through the completion of the project. Supporting documentation should be provided for funding that is committed.

With respect to the issue of foreign ownership, control, or domination (FOCD) Section 103, “Commercial Licenses,” paragraph d. of the AEA provides, in relevant part, that no license may be issued to “any corporation or other entity if the Commission knows or has reason to believe it is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government.”

The NRC’s regulation in 10 CFR 50.38, “Ineligibility of certain applicants,” is the regulatory provision that implements this statutory provision. The NRC staff evaluates license transfer applications in a manner that is consistent with the guidance provided in the NRC Standard Review Plan (SRP) on FOCD, published in the *Federal Register* (FR) on September 28, 1999, to determine whether the proposed transferee is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government (64 FR 52355).

With respect to the requested administrative, conforming license amendment, 10 CFR 50.90 states, in part, whenever a holder of a license, including a construction permit, desires to amend the license or permit, application for an amendment must be filed with the Commission fully describing the changes desired and following, as far as applicable, the form prescribed for original applications. Pursuant to 10 CFR 2.1315, "Generic determination regarding license amendments to reflect transfers," where administrative license amendments are necessary to reflect an approved license transfer, such amendments will be included in the order that approves the license transfer and any challenge to the administrative license amendment is limited to the question of whether the license amendment accurately reflects the approved transfer.

#### 4.0 FINANCIAL QUALIFICATIONS

SHINE holds Construction Permit No. CPMIF-001 for a Medical Isotope Production Facility licensed under AEA Section 103 and 10 CFR 50.22, "Class 103 licenses; for commercial and industrial facilities." The construction permit authorizes the construction of eight utilization facilities and one production facility for the commercial production of medical radioisotopes, such as Mo-99. The NRC staff finds that, as a construction permit holder for a facility dedicated to medical radioisotope production, SHINE does not qualify as an electric utility as defined in 10 CFR 50.2 because it is not an entity that would generate or distribute electricity. In accordance with 10 CFR 50.33(f), a non-electric utility applicant must provide information sufficient to demonstrate its financial qualifications to carry out the activities for which the permit is being sought. For construction permits, the information must show that the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated construction costs and related fuel cycle costs. In making this showing, the applicant must submit estimates of the total construction costs of the facility and related fuel cycle costs, and indicate the source(s) of funds to cover these costs. For an indirect transfer of a license, the information must demonstrate that the transfer will not affect the qualifications of the licensee to hold the license.

In accordance with 10 CFR 50.33(f) and consistent with CLI-99-06 and the guidance in Section 15.1 of NUREG-1537, the NRC staff reviewed the financial qualifications information submitted by SHINE for the reasonableness of the estimated construction costs and related fuel cycle costs, including the assumptions underlying these estimates, to determine whether SHINE, as SHINE LLC, would possess or have reasonable assurance of obtaining the funds necessary to cover estimated construction costs and related fuel cycle costs.

In order to satisfy the financial qualifications requirements of 10 CFR 50.33(f)(1), SHINE provided estimates for the total costs of construction and related fuel cycle costs, including estimates for the total production plant costs, plant equipment, and uranium inventory cost for the first year of operation:

SHINE Medical Technologies, Inc.  
Estimates of the  
Costs of Construction and Related Fuel Cycle Costs  
*(Whole Dollars)*

|  |    |    |
|--|----|----|
| Total production plant costs (including support facilities): | [[ | ]] |
| Plant equipment:   | [[ | ]] |
| Uranium inventory cost for first year of operation:          | [[ | ]] |
| Total estimated cost:  | [[ | ]] |

Since the issuance of Construction Permit No. CPMIF-001, SHINE has updated the bases for its estimated costs of construction and related fuel cycle costs, as described in its March 8, 2019, request for additional information (RAI) response (ADAMS Accession No. ML19071A056).

SHINE's estimate for the total production plant costs is comprised of the estimated costs for two elements: (1) the facility structure; support facilities; and mechanical, electrical, plumbing, and piping systems and (2) process-oriented systems. Using drawings and specifications provided by SHINE, as well as input from potential subcontractors and vendors, SHINE's prime construction contractor, Baker Concrete Construction, Inc. (Baker), prepared a cost estimate for the first element of SHINE's total production plant costs described above. The cost estimates for process-oriented systems are based on equipment vendor quotes derived from SHINE's preliminary equipment specifications.

SHINE's cost estimate for plant equipment is based on a binding contract with Phoenix, LLC for the purchase of the neutron driver assembly systems.

SHINE's estimated uranium inventory cost for the first year of operation is based on information provided by the U.S. Department of Energy (DOE), National Nuclear Security Administration (NNSA) Production Office and Y-12 National Security Complex. SHINE's estimate reflects the costs for the total amount of uranium required for the initial target solution batches and spare material to afford operational flexibility.

Additionally, in accordance with 10 CFR 50.33(f)(1), SHINE submitted information to demonstrate that SHINE LLC would possess the funds necessary to cover estimated construction and related fuel cycle costs, including the source(s) of the funds to cover these costs. This information included a summary of SHINE's financing commitments remaining for use in the project:

SHINE Medical Technologies, Inc.  
Current Financing Commitments  
(Whole Dollars)

|  |                  |
|--|------------------|
| Existing cash-on-hand:   | [[            ]] |
| Deerfield Management Company, L.P. financing commitment:       | \$150,000,000    |
| City of Janesville loan packages/guarantees:                   | \$7,000,000      |
| 90 acres of land for the building site provided by Janesville: | \$2,000,000      |

As described in its March 8, 2019, RAI response, SHINE intends to dedicate approximately [[            ]] of the [[            ]] in currently committed financing toward the estimated [[            ]] in total estimated construction costs. This represents approximately [[    ]] of the financing necessary to fully fund the costs of construction and related fuel cycle costs.

Pursuant to the requirements in Appendix C to 10 CFR Part 50, Section II, "Applicants Which Are Newly Formed Entities," SHINE also provided information on its legal and financial relationships associated with each of its sources of funding. As stated in its March 8, 2019, RAI response, SHINE has full control of its existing cash-on-hand. This financing is not subject to any restrictions. The Deerfield Management Company, L.P. (Deerfield) financing commitment is a binding commitment, under which Deerfield is obligated to provide SHINE with incremental financing amounts upon achievement of certain business and construction milestones. The City of Janesville loan packages/guarantees and the 90 acres of land for the building site are also binding obligations related to SHINE's completion of agreed upon milestones.

In addition to the currently available financing commitments, SHINE (1) has been selected to enter into negotiations to receive an additional cooperative agreement award worth up to \$15,000,000 from DOE/NNSA and (2) [ ]

]].

Consistent with the requirements for newly formed entities in 10 CFR 50.33(f)(4) and Section II of Appendix C to 10 CFR Part 50, SHINE described the relationship between SHINE LLC and Illuminated and, as part of its March 8, 2019, RAI response, provided a 2018 year end statement of assets, liabilities, and capital structure as of the date of the application. This year end statement updates information that SHINE had previously provided as part of its 2017 annual financial report submitted in accordance with the requirements of 10 CFR 50.71, "Maintenance of records, making of reports," paragraph (b) (ADAMS Accession No. ML18166A178).

To meet the requirement of 10 CFR 50.33(f)(4)(i), SHINE provided the following information on the legal and financial relationship SHINE LLC would have with Illuminated as a result of the proposed indirect transfer of control of Construction Permit No. CPMIF-001:

On November 20, 2018, SHINE entered into a financing arrangement with Deerfield Management Company, L.P. (Deerfield), a Delaware series limited partnership (Series C). The transaction involved a \$150 million financing commitment to SHINE. This transaction did not involve any change of control of SHINE, and therefore, it did not require NRC's prior written consent pursuant to 10 CFR 50.80. Notably, NRC's creditor regulations in 10 CFR 50.81 provide NRC's consent "without individual application" to financing arrangements that include "the creation of any mortgage, pledge or other lien upon any production or utilization facility."

In connection with this transaction, SHINE agreed that it would create a parent holding company and implement a restructuring in which the current capital stock and equity rights in SHINE would be exchanged for rights in the holding company, Illuminated. In this restructuring, SHINE would be converted by operation of Delaware law from a corporation into a single-member limited liability company, owned and controlled by Illuminated. Pursuant to 10 CFR 50.80, NRC's prior written consent is required for the creation of Illuminated.

As described in Attachment 1 of Enclosure 1 to SHINE's indirect license transfer application, SHINE LLC would be member-managed by Illuminated. SHINE LLC would maintain the same members on its board of directors and principal executive personnel as SHINE. The proposed members of the board of directors and principal executive personnel for Illuminated would be the same members of the board of directors and principal executive personnel as those for SHINE LLC.

While Illuminated and SHINE LLC are to be newly formed entities, as described above, the information provided in SHINE's 2018 year end statement of assets, liabilities, and capital structure as of the date of the application and historical annual financial statements demonstrate the ability of Illuminated and SHINE LLC to meet any contractual obligation to SHINE which has been incurred or is proposed to incur as required by 10 CFR 50.33(f)(4)(ii). In particular, the balance sheet for SHINE's year end statement shows current assets of [ ] [ ], which consist of [ ]

]], and current liabilities of [[ ]]. Furthermore, the financial statements in SHINE's 2017 annual financial report were [[

]]

Based on the above, the NRC staff finds that the application contained information sufficient to demonstrate the financial qualifications of Illuminated as the owner of SHINE LLC and SHINE LLC as the holder of Construction Permit No. CPMIF-001. Specifically, pursuant to 10 CFR 50.33(f)(1), the application included estimates for the total cost of construction and related fuel cycle costs and demonstrated that the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated construction costs and related fuel cycle costs. And, consistent with the requirements for newly formed entities in 10 CFR 50.33(f)(4) and Section II of Appendix C to 10 CFR Part 50, SHINE described the relationship between SHINE LLC and Illuminated; demonstrated the ability of Illuminated and SHINE LLC to meet any contractual obligation to SHINE which has been incurred or is proposed to incur; and provided a statement of assets, liabilities, and capital structure as of the date of the application. Therefore, the NRC staff concludes that the summation of the information submitted demonstrates that the proposed establishment of the holding company, Illuminated, and indirect transfer of Construction Permit No. CPMIF-001 would not affect the financial qualifications of SHINE LLC to hold the license.

#### 5.0 DECOMMISSIONING FUNDING

Pursuant to 10 CFR 50.33(f)(1), the areas of review for a construction permit are estimates of construction costs, estimates of related fuel cycle costs, and sources of funds to cover these costs. Therefore, information related to the financial ability of SHINE LLC to decommission the SHINE Medical Isotope Production Facility is outside the scope of the financial qualifications necessary for transferring control of Construction Permit No. CPMIF-001. Instead, information related to the licensee's ability to decommission the facility will be evaluated during the review of an operating license application.

#### 6.0 TECHNICAL QUALIFICATIONS

According to the application, as supplemented, the establishment of a holding company, Illuminated, and the conversion of SHINE from a corporation into a single-member limited liability company, SHINE LLC, would not impact the management, staff, or technical qualifications of SHINE LLC. The current owners of SHINE would own both Illuminated and SHINE LLC. The indirect transfer of Construction Permit No. CPMIF-001 would not result in changes in the membership or qualifications of the current SHINE board of directors or principal executive personnel. Since the issuance of the construction permit, SHINE has hired additional staff, including engineering staff, and updated the design of the facility, including the elimination of complex processes. SHINE continues to develop its technical qualifications through the construction and ongoing testing of a prototype of the accelerator to be used with its commercial irradiation units. SHINE has also established partnerships with Baker, Rock Creek Innovations, LLC, and Phoenix, which are companies specializing in construction, instrumentation and control protection systems, and accelerator hardware, respectively.

Based on the above, the NRC staff finds that SHINE has provided the information required by 10 CFR 50.34(a)(9) regarding technical qualifications. Specifically, the NRC staff finds that the information in the indirect license transfer application describing the management, staffing, ongoing design of the SHINE Medical Isotope Production Facility, construction and testing of a



prototype accelerator, and key industry partnerships is sufficient to demonstrate the technical qualifications of SHINE LLC to hold Construction Permit No. CPMIF-001 and to construct the SHINE Medical Isotope Production Facility.

#### 7.0 FOREIGN OWNERSHIP, CONTROL, OR DOMINATION

Section 103d of the AEA, as implemented by 10 CFR 50.38, prohibits the issuance of a license to any entity which the Commission knows or has reason to believe is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government.

As stated above, the NRC staff evaluates license transfer applications in a manner that is consistent with the guidance provided in the SRP on FOCD to determine whether the proposed transferee is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government. Consistent with 10 CFR 50.33(d) and the guidance, the NRC staff confirmed that the application included a statement as to whether the applicant is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government.

According to the application, SHINE is a private corporation that has approximately      shareholders. To the best of SHINE's knowledge, shareholders holding 1 percent or more of SHINE's stock are U.S. citizens or entities owned or controlled by U.S. citizens and SHINE employees holding stock options are U.S. citizens. Additionally,     , Deerfield would not be able to exercise control over SHINE even if it were to exercise rights provided under the financing arrangements to acquire additional ownership interests in Illuminated.

Furthermore, SHINE states that one of the seven directors on SHINE's Board is a Canadian citizen with U.S. permanent resident status. The appointment of one citizen of Canada as a director of SHINE has no material impact on SHINE's compliance with the requirements regarding FOCD in 10 CFR 50.38. Finally, SHINE states that it is not acting as an agent or representative of another person in filing the license transfer application.

Based on the above statements, the NRC staff has determined that the level of detail provided on FOCD considerations in the application satisfies the requirements of 10 CFR 50.33(d) and 50.38. Specifically, the NRC staff finds that SHINE is not, and that Illuminated and SHINE LLC would not be owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government.

#### 8.0 NUCLEAR INSURANCE AND INDEMNITY

Pursuant to 10 CFR 50.33(f)(1), the areas of review for a construction permit are estimates of construction costs, estimates of related fuel cycle costs, and sources of funds to cover these costs. At the time of the issuance of Construction Permit No. CPMIF-001, SHINE had not requested to possess SNM. Therefore, consistent with NRC implementation of Section 170, "Indemnification and Limitation of Liability," of the AEA in 10 CFR Part 140, "Financial Protection Requirements and Indemnity Agreements," the NRC staff deferred evaluation of information related to financial protection to such a time that SHINE applies for either an operating license or a license under 10 CFR Part 70 to possess SNM. Further, the construction permit includes a condition that an operating license will not be issued by the Commission unless SHINE submits proof of financial protection and executes an indemnity agreement with the NRC as required by Section 170 of the AEA.

Since the issuance of the construction permit, SHINE has neither applied for an operating license nor applied for a license under 10 CFR Part 70 to possess SNM. Therefore, information related to the ability of SHINE LLC to establish and maintain financial protection is outside the scope of the qualifications necessary for transferring control of a construction permit and thus not required to be evaluated as part of this review. Instead, information related to the licensee's ability to establish and maintain financial protection will be evaluated during the review of an operating license application or an application for a license under 10 CFR Part 70 to possess SNM.

#### 9.0 CONFORMING AMENDMENT

The applicant requested the issuance of an administrative, conforming amendment to Construction Permit No. CPMIF-001 and its Appendix A, "Environmental Protection Plan," to reflect the proposed indirect license transfer. Specifically, the applicant proposed to change all instances of the term "SHINE Medical Technologies, Inc." to "SHINE Medical Technologies, LLC." The NRC staff finds that this amendment involves no safety questions and accurately reflects the proposed transfer. Therefore, the amendment is acceptable and will be included in the order that approves the transfer.

#### 10.0 PUBLICATION OF OPPORTUNITY TO COMMENT, REQUEST A HEARING, AND PETITION FOR LEAVE TO INTERVENE

In accordance with the Commission's regulations, the NRC published its consideration of (1) the issuance of an order under 10 CFR 50.80 approving the indirect transfer of control of Construction Permit No. CPMIF-001 for the SHINE Medical Isotope Production Facility, currently held by SHINE, and (2) the amendment of the construction permit for administrative purposes to reflect the proposed license transfer in the *Federal Register* on February 20, 2019 (84 FR 5116) for a 30-day comment period and a 20-day request-for-hearing-and-petition-for-leave-to-intervene period. No comments or petitions were received during these periods.

#### 11.0 STATE CONSULTATION

The NRC staff notified the Wisconsin State officials of the proposed license transfer and issuance of conforming amendment by letter dated February 13, 2019 (ADAMS Accession No. ML19010A096). The State officials had no comments.

#### 12.0 ENVIRONMENTAL CONSIDERATION

The subject application is for the approval of an indirect transfer of control of a construction permit issued by the NRC and for a conforming amendment to the permit to reflect this transfer. Accordingly, the actions involved meet the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22, "Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review," paragraph (c)(21). Pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with approval of the application.

#### 13.0 SUMMARY AND CONCLUSION

Based on its review, which is summarized above, of the information provided in the indirect license transfer application, as supplemented, the NRC staff concludes that SHINE LLC is financially and technically qualified to be the holder of Construction Permit No. CPMIF-001.

Pursuant to 10 CFR 50.33(f)(1), the application included reasonable estimates for the total cost of construction and related fuel cycle costs and demonstrated that the applicant and proposed transferee possess or have reasonable assurance of obtaining the funds necessary to cover estimated construction costs and related fuel cycle costs. Additionally, the information in the application describing the management, staffing, ongoing design of the SHINE Medical Isotope Production Facility, construction and testing of a prototype accelerator, and key industry partnerships is sufficient to demonstrate the technical qualifications of SHINE LLC to hold Construction Permit No. CPMIF-001 and to construct the SHINE Medical Isotope Production Facility. The NRC staff further concludes that there are no disqualifying decommissioning funding assurance, foreign ownership, control, or domination, or nuclear insurance and indemnity issues associated with the proposed indirect license transfer.

Based on the considerations discussed above, the Commission has concluded that the proposed transferee is qualified to be the holder of the license and that transfer of the license is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto.

Principal Contributor: Steven Lynch

Date: Month XX, 2019