15.0 FINANCIAL QUALIFICATIONS

Financial qualifications (FQs) for an application for an operating license establish whether the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated operation costs for the period of the license. The applicant must submit estimates for total annual operating costs for each of the first five years of operation of the facility and indicate the source(s) of funds to cover these costs. The applicant must also submit information related to the funding for decommissioning; foreign ownership, control, or domination (FOCD); and nuclear insurance and indemnity.

This chapter of the SHINE Medical Technologies, LLC (SHINE, the applicant) operating license application safety evaluation report (SER) describes the review and evaluation by the U.S. Nuclear Regulatory Commission (NRC, the Commission) staff of SHINE's FQs and information submitted related to the funding for decommissioning, FOCD, and nuclear insurance and indemnity, as presented in chapter 15, "Financial Qualifications," of the SHINE final safety analysis report (FSAR) and Enclosure 2 of the SHINE operating license application, "General and Financial Information" (Agencywide Documents Access and Management System Accession No. ML19211C089).

15.1 Areas of Review

SER chapter 15 provides an evaluation of SHINE's FQs and information submitted related to the funding for decommissioning, FOCD, and nuclear insurance and indemnity.

The NRC staff reviewed SHINE FSAR section 15.2, "Financial Ability to Operate the SHINE Facility," section 15.3, "Financial Ability to Decommission the SHINE Facility," section 15.4, "Foreign Ownership, Control, or Domination," and section 15.5, "Nuclear Insurance and Indemnity," and Enclosure 2 of the SHINE operating license application against applicable statutory and regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the operating license application with respect to FQs, funding for decommissioning, FOCD, and nuclear insurance and indemnity for the issuance of an operating license.

Areas of review included (1) estimates for total annual operating costs for each of the first five years of operation of the SHINE facility and sources of funds to cover these costs, (2) a cost estimate for decommissioning the facility, the method that will be used to cover this cost estimate, and the means of periodically adjusting this cost estimate and associated funding level, (3) information related to FOCD, and (4) information related to insurance and indemnity. Although the applicant provided in SHINE FSAR section 15.1, "Financial Ability to Construct the SHINE Facility," information related to FQs for constructing the SHINE facility, this information is not required in an operating license application and the issue was previously reviewed by the NRC staff as part of its review of the SHINE construction permit application.

15.2 Summary of Application

SHINE FSAR section 15.1 references updated information already submitted to the NRC related to SHINE's financial ability to construct its facility.

SHINE FSAR section 15.2 presents information to demonstrate that SHINE possesses, or has reasonable assurance of obtaining, the funds necessary to cover estimated operation costs for the period of the operating license. SHINE provides estimates for total annual operating costs for each of the first five years of operation of the facility and indicates the sources of funds to cover these costs.

SHINE FSAR section 15.3 presents information on the estimated cost to decommission the facility, the method to provide funds for decommissioning, and the means of periodically adjusting the decommissioning cost estimate and associated funding level.

SHINE FSAR section 15.4 and Enclosure 2 of the SHINE operating license application present information regarding the corporate identity of SHINE, including its state of incorporation, address, directors and principal officers, and relevant citizenship information, as well as whether it is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government or acting as an agent or representative of another person in filing its application.

SHINE FSAR section 15.5 provides that the nuclear insurance and indemnity requirements of the Price-Anderson Act (section 170 of the Atomic Energy Act of 1954, as amended (AEA)) apply to SHINE and that those requirements will be satisfied.

15.3 Statutory and Regulatory Requirements and Guidance and Acceptance Criteria

The NRC staff reviewed SHINE FSAR chapter 15 against the applicable statutory and regulatory requirements, using appropriate regulatory guidance and acceptance criteria, to assess the sufficiency of the information provided by SHINE for the issuance of an operating license.

15.3.1 Applicable Statutory and Regulatory Requirements

The applicable statutory and regulatory requirements for the evaluation of SHINE's FQs and information submitted related to the funding for decommissioning, FOCD, and nuclear insurance and indemnity are as follows:

- AEA § 103, "Commercial Licenses," paragraph d
- AEA § 170, "Indemnification and Limitation of Liability"
- Title 10 of the *Code of Federal Regulations* (10 CFR) 50.33, "Contents of applications; general information"
- 10 CFR 50.38, "Ineligibility of certain applicants"
- 10 CFR 50.40, "Common standards"
- 10 CFR 50.57, "Issuance of operating license"
- 10 CFR 50.75, "Reporting and recordkeeping for decommissioning planning"

- 10 CFR Part 140, “Financial Protection Requirements and Indemnity Agreements”

15.3.2 Applicable Regulatory Guidance and Acceptance Criteria

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

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

- NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” issued February 1996.

- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.

- “Final Interim Staff Guidance Augmenting NUREG-1537, Part 2, ‘Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,’ for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors,” dated October 17, 2012.

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

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

15.4 Review Procedures, Technical Evaluation, and Evaluation Findings

The NRC staff performed a review of the information presented in SHINE FSAR chapter 15 and Enclosure 2 of the SHINE operating license application to assess the sufficiency of SHINE’s FQs and information submitted related to the funding for decommissioning, FOCD, and nuclear insurance and indemnity for the issuance of an operating license. The sufficiency of this

information is determined by ensuring that it meets applicable statutory and regulatory requirements and guidance and acceptance criteria, as discussed in section 15.3, “Statutory and Regulatory Requirements and Guidance and Acceptance Criteria,” of this SER. The findings of this evaluation are described in section 15.5, “Review Findings,” of this SER.

15.4.1 Financial Ability to Construct the SHINE Facility

Consistent with the regulatory requirements discussed in section 15.3.1, “Applicable Statutory and Regulatory Requirements,” of this SER, the NRC staff reviewed the information regarding SHINE’s financial ability to construct the SHINE facility, as described in SHINE FSAR section 15.1, using the guidance and acceptance criteria from section 15.1, “Financial Ability to Construct a Non-Power Reactor,” of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

The NRC staff previously concluded in its SER for the SHINE construction permit application that SHINE is financially qualified to construct the SHINE facility (ML16229A140). As part of its operating license application, SHINE referenced updated financial qualification information related to construction that SHINE had provided to the NRC in an application for transfer of control of the SHINE construction permit (ML18347A215 and ML19071A055). A further determination regarding SHINE’s financial ability to construct the SHINE facility is not required under 10 CFR 50.33 for the issuance of an operating license.

15.4.2 Financial Ability to Operate the SHINE Facility

Consistent with the regulatory requirements discussed in section 15.3.1 of this SER, the NRC staff evaluated the sufficiency of SHINE’s financial ability to operate the SHINE facility, as described in SHINE FSAR section 15.2, using the guidance and acceptance criteria from section 15.2, “Financial Ability to Operate a Non-Power Reactor,” of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

The applicant supplied financial information for the estimates of operating costs and the sources of funds to cover these costs. The first five years of estimated operating costs are provided in SHINE FSAR table 15.2-1, “Operating Costs for the First Five Years of Operation.” These costs are divided into two primary categories: costs of goods sold and organizational expenses. The applicant provided the bases for each of these categories of costs, which include existing contracts and quotes from providers.

Per the application, SHINE intends to cover the estimated operating costs through the sale of medical isotopes, primarily molybdenum-99 (Mo-99). SHINE has entered into contracts to sell Mo-99 to three customers: GE Healthcare; Lantheus Medical Imaging, Inc.; and HTA Co., Ltd. SHINE FSAR table 15.2-2, “Estimated Funding for the First Five Years of Operation,” estimates the first five years of Mo-99 sales covered under these contracts (both the minimum and maximum contract revenues), as well as the excess production capacity available within this timeframe, and the minimum projected additional sales needed based on available production capacity. The application also discusses the ability of SHINE to obtain additional financing. The application concludes that, based on existing sales contracts and the facility’s excess production capacity that will allow SHINE to expand its existing sales contracts or enter into new sales contracts, the funds necessary to cover operating costs will be obtained.

The NRC staff reviewed the financial ability of the applicant to operate the SHINE facility in accordance with NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537,

Parts 1 and 2. This guidance provides that an applicant should estimate the first five years of operating costs and give a reliable basis for the estimate and should discuss the sources of funding for operating costs, the amount of funding that is committed, and the amount that is potentially available; the applicant should confirm committed sources and discuss conditions under which potential sources of funding would become committed and how the facility can be safely operated if some potential sources of funding are not realized. The SHINE operating license application satisfies this guidance because the application estimates the first five years of operating costs and discusses the sources of funding for these costs. The staff finds that the estimates of operating costs are reasonable because the applicant gives a reliable basis for them. The staff finds that there is reasonable assurance that the applicant will obtain the funds necessary to cover the estimates of operating costs because the applicant confirms committed sources of contract revenue and discusses the amount of excess production capacity available to cover the remaining operating costs. Finally, the applicant discusses how the safety of the facility will be assured if some potential sources of funding are not realized by stating that in the unlikely event that SHINE fails to obtain additional financing or is unable to establish additional Mo-99 sales contracts, SHINE will not be able to operate the facility.

The Commission has stated that it will accept financial assurances based on plausible assumptions and forecasts, even though the possibility is not insignificant that things will turn out less favorably than expected (ML16195A533). Based on this standard and the information provided by the applicant, the NRC staff concludes that the applicant has shown, by a preponderance of the evidence, that it satisfies 10 CFR 50.33(f) and is financially qualified to carry out the activities for which the operating license is sought.

15.4.3 Financial Ability to Decommission the SHINE Facility

Consistent with the regulatory requirements discussed in section 15.3.1 of this SER, the NRC staff evaluated the sufficiency of SHINE's financial ability to decommission the SHINE facility, as described in SHINE FSAR section 15.3, using the guidance and acceptance criteria from section 15.3, "Financial Ability to Decommission the Facility," of NUREG-1537, Parts 1 and 2, and the ISG augmenting NUREG-1537, Parts 1 and 2.

The applicant supplied a decommissioning cost estimate for the SHINE facility of $50,058,000. The estimate considers costs for activities necessary to decommission and release the site for unrestricted use, including planning and preparation, decontamination and dismantling of facility components, equipment and supplies, radioactive waste characterization, waste packaging and shipment, waste disposal, contingency costs, contractor costs, and radiation surveys. The estimate assumes that decommissioning activities begin immediately after radioisotope production activities and operations involving radioactive materials cease. The applicant stated that the method that will be used to cover the decommissioning cost estimate will be to maintain an external escrow account in which deposits will be made periodically, coupled with a surety method, insurance, or some other form of guarantee. Finally, the applicant stated that the decommissioning cost estimate and associated funding level will be adjusted every three years, or when the amounts or types of materials at the facility change. These triennial adjustments will account for inflation, for other changes in the prices of goods and services, for changes in facility conditions or operations, and for changes in expected decommissioning procedures, as well as for other changes at the site such as leaks or spills of radioactive material.

The NRC staff reviewed the decommissioning cost estimate, the method that will be used to cover this estimate, and the means of periodically adjusting this estimate and associated funding level in accordance with NUREG-1537, Parts 1 and 2, and the ISG augmenting

NUREG-1537, Parts 1 and 2. The staff finds that the applicant discussed the decommissioning method to be used for the facility in sufficient detail to permit cost estimates to be developed and that the applicant estimated decommissioning costs and took into account the decommissioning method to be used. Because the applicant adequately addressed and evaluated the activities required to decommission the facility and their costs, the staff concludes that the applicant's estimate of the costs required for decommissioning the facility appears to be reasonable.

The applicant proposed a method of funding decommissioning costs that meets the requirements of the NRC's regulations. Specifically, the applicant identified the NRC-approved external sinking fund method of 10 CFR 50.75(e)(1)(ii) and surety method, insurance, or other guarantee method of 10 CFR 50.75(e)(1)(iii). The applicant also provided a description of the means of adjusting the decommissioning cost estimate and associated funding level periodically over the life of the facility based on actual changes or changes in cost indices. The NRC's regulations require power reactor licensees and non-power reactor licensees to continually provide reasonable assurance that funds will be available for the decommissioning process through certifying to a decommissioning amount, periodically updating that decommissioning amount, and covering that amount by an NRC-approved method. To apply similar requirements to SHINE as committed to in its application, the SHINE operating license will be conditioned as follows:

> The SHINE operating license application provided a decommissioning cost estimate for the SHINE facility. This cost estimate must be adjusted every three years or when the amounts or types of materials at the SHINE facility change, whichever is less, and the adjustment must account for, among others, the factors discussed in the SHINE operating license application, as appropriate. The decommissioning cost estimate, as adjusted, must be covered by the external sinking fund method of 10 CFR 50.75(e)(1)(ii) and/or the surety method, insurance, or other guarantee method of 10 CFR 50.75(e)(1)(iii). The licensee must also comply with the requirements of 10 CFR 50.75(f)–(h) that are applicable to non-power reactor licensees.

The applicant has supplied financial information for decommissioning costs of the facility in accordance with 10 CFR 50.75. The NRC staff has reviewed the decommissioning cost estimate submitted by the applicant and concludes that the cost estimate appears to be reasonable. The applicant has indicated the method or methods to be used to provide funds for decommissioning and has provided a description of the means of adjusting the cost estimate and associated funding level periodically over the life of the facility. The staff has reviewed the applicant's information provided on decommissioning funding assurance and finds that the applicant's financial assurance method to be used to provide funds for decommissioning is acceptable, and that the applicant's means of adjusting the cost estimate and associated funding level periodically over the life of the facility appears to be reasonable. The staff notes that any adjustment of the decommissioning cost estimate should incorporate, among other things, changes in costs resulting from the availability of disposal facilities. The above license condition ensures that these findings will be maintained. Therefore, the staff concludes that the applicant has provided reasonable assurance that funds will be available to decommission the SHINE facility.

15.4.4 Foreign Ownership, Control, or Domination

Consistent with the statutory and regulatory requirements discussed in section 15.3.1 of this SER, the NRC staff evaluated the sufficiency of SHINE's description of FOCD considerations, as presented in Enclosure 2 of the SHINE operating license application and SHINE FSAR section 15.4, using the guidance and acceptance criteria from section 15.4, "Foreign Ownership, Control, or Domination (FOCD)," of the ISG augmenting NUREG-1537, Parts 1 and 2.

Consistent with AEA § 103d. and 10 CFR 50.33(d) and 10 CFR 50.38 and the guidance in the ISG augmenting NUREG-1537, Parts 1 and 2, the NRC staff reviewed whether the application included all of the 10 CFR 50.33(d) information that is applicable to the applicant and 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 not owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government. SHINE is a single member, Delaware limited liability company, owned and controlled by Illuminated Holdings, Inc. (Illuminated), a Delaware corporation. The application states that to the best of SHINE's knowledge, current shareholders holding 1 percent or more of Illuminated stock are U.S. citizens or entities owned or controlled by U.S. citizens. The NRC staff notes that one individual on the Illuminated Board of Directors (BOD) is a foreign citizen (Canadian). The staff recognizes that a single foreign BOD member cannot exercise control over SHINE based on the makeup of the SHINE BOD. The staff conducted an independent analysis, including open-source research and verification of the information provided in the application related to the ownership of SHINE, and found no evidence of FOCD.

Based on the above, the NRC staff finds that the level of detail provided on FOCD considerations for operation of the SHINE facility is reasonable and satisfies the requirements of 10 CFR 50.33(d) and that the issuance of the operating license does not raise any issues related to FOCD within the meaning of AEA § 103d. and 10 CFR 50.38. Therefore, the staff concludes that it does not know or have reason to believe that SHINE is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government.

15.4.5 Nuclear Insurance and Indemnity

Consistent with the statutory requirements discussed in section 15.3.1 of this SER, the NRC staff evaluated the sufficiency of SHINE's description of nuclear insurance and indemnity considerations, as described in SHINE FSAR section 15.5, using the guidance and acceptance criteria from section 15.5, "Nuclear Insurance and Indemnity," of the ISG augmenting NUREG-1537, Parts 1 and 2.

By letter dated August 27, 2018 (ML18239A219), SHINE provided that section 170 of the AEA states that each license issued under section 103 of the AEA (including a SHINE operating license) shall have as a condition of the license a requirement that the licensee have and maintain financial protection of such type and in such amount as the NRC shall require to cover public liability claims. Section 170 of the AEA also states that the NRC shall, with respect to licenses for which it requires financial protection of less than $560 million, agree to indemnify and hold harmless the licensee from public liability arising from nuclear incidents that is in excess of the level of financial protection required of the licensee up to a specified amount. Section 170 of the AEA describes the considerations for the NRC's determination of the acceptable types and amounts of financial protection. SHINE provided that section 170 of the

AEA, though, does not directly specify the type or amount of financial protection applicable to the SHINE facility. Moreover, the NRC's regulations that implement section 170 of the AEA (10 CFR Part 140) do not specify the type or amount of financial protection applicable to the SHINE facility. However, 10 CFR 140.11, "Amounts of financial protection for certain reactors," does specify financial protection amounts applicable to nuclear reactors, including, at 10 CFR 140.11(a)(2), that nuclear reactors authorized to operate at a thermal power level in excess of 10 kilowatts but not in excess of 1 megawatt are required to have and maintain financial protection in the amount of $1.5 million. And 10 CFR 140.14, "Types of financial protection," specifies the allowable types of financial protection for the amounts of financial protection under 10 CFR Part 140, including under 10 CFR 140.11(a)(2).

SHINE stated that the eight utilization facilities (i.e., the eight irradiation units that make up the irradiation facility (IF)) at the SHINE facility, although not nuclear reactors, are, in total, within the 10 CFR 140.11(a)(2) thermal power level range of 10 kilowatts to 1 megawatt and that the NRC staff has previously acknowledged for safety considerations the similarity of the SHINE facility and non-power reactors with comparable thermal power levels. SHINE also stated that the accident scenarios associated with the SHINE utilization facilities and the SHINE production facility (i.e., the radioisotope production facility (RPF)) are consequentially equivalent for the purpose of applying financial protection because the accident consequences for the IF and RPF are bounded by the same accident dose criterion and because the material at risk associated with the processes within the IF and RPF is largely the same. Therefore, SHINE concluded that the appropriate financial protection amount under section 170 of the AEA for the entire SHINE facility is the $1.5 million amount of 10 CFR 140.11(a)(2).

In its operating license application, SHINE stated that the financial protection requirements of section 170 of the AEA are applicable to SHINE and that SHINE has determined that maintaining financial protection in the amount of $1.5 million, covering each of the eight utilization facilities and the production facility, satisfies these financial protection requirements.

The NRC staff agrees with the analysis in SHINE's August 27, 2018, letter and finds, for the reasons provided in that analysis and discussed above, that section 170 of the AEA applies to the SHINE facility, that the appropriate amount of financial protection for the SHINE facility under section 170 of the AEA is $1.5 million, which is equivalent to the amount required for nuclear reactors in 10 CFR 140.11(a)(2), and that the types of financial protection provided in 10 CFR 140.14 as applying, in part, to the amount required under 10 CFR 140.11(a)(2), are also applicable to SHINE. Therefore, in the exercise of its licensing authority and responsibility and consistent with section 170 of the AEA and 10 CFR Part 140, the NRC conditions the SHINE operating license as follows:

> The licensee shall have and maintain financial protection of such type as provided by 10 CFR 140.14 and in the amount of $1.5 million to cover public liability claims in accordance with Section 170 of the Atomic Energy Act of 1954, as amended.

In its operating license application, SHINE also stated that it will maintain an indemnification agreement with the NRC that extends for the life of the license. Consistent with section 170 of the AEA, the NRC conditions the SHINE operating license as follows:

> The licensee shall execute and maintain an indemnification agreement in accordance with Section 170 of the Atomic Energy Act of 1954, as amended.

Based on the above, the NRC staff concludes that SHINE has provided sufficient information regarding nuclear insurance and indemnity in accordance with section 170 of the AEA.

15.5 Review Findings

The NRC staff reviewed the descriptions and discussions of SHINE's FQs, funding for decommissioning, FOCD, and nuclear insurance and indemnity, as described in SHINE FSAR chapter 15 and Enclosure 2 of the SHINE operating license application, against the applicable statutory and regulatory requirements and using appropriate regulatory guidance and acceptance criteria.

Based on its review of this information and independent confirmatory review, as appropriate, the NRC staff determined that:

(1) SHINE has submitted information that demonstrates that it possesses or has reasonable assurance of obtaining the funds necessary to cover estimated operation costs for the period of the license in accordance with 10 CFR 50.33(f);

(2) SHINE will provide reasonable assurance that funds will be available for the decommissioning process in accordance with 10 CFR 50.75;

(3) SHINE has submitted information that satisfies 10 CFR 50.33(d) with respect to FOCD considerations and the NRC does not know or have reason to believe that SHINE is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government in accordance with AEA § 103d. and 10 CFR 50.38; and

(4) SHINE has provided sufficient information regarding nuclear insurance and indemnity in accordance with section 170 of the AEA.

Based on the above determinations, the NRC staff finds that the descriptions and discussions of FQs, funding for decommissioning, FOCD, and nuclear insurance and indemnity are sufficient and meet the applicable statutory and regulatory requirements and guidance and acceptance criteria for the issuance of an operating license and that, therefore, consistent with 10 CFR 50.40, SHINE is financially qualified to engage in the proposed activities in accordance with the NRC's regulations.