



AFFIDAVIT OF JAMES COSTEDIO

STATE OF WISCONSIN)
) ss.
COUNTY OF ROCK)

I, James Costedio, Vice President of Regulatory Affairs and Quality of SHINE Medical Technologies, Inc. (SHINE), do hereby affirm and state:

1. I am authorized to execute this affidavit on behalf of SHINE. I am authorized to review information submitted to or discussed with the Nuclear Regulatory Commission (NRC) and apply for the withholding of information from public disclosure. The purpose of this affidavit is to provide the information required by 10 CFR 2.390(b) in support of SHINE's request for proprietary treatment of certain confidential commercial and financial information submitted in the application for order approving indirect transfer of control of construction permit response to request for additional information by letter 2019-SMT-0015 with enclosures. SHINE requests that the confidential information contained in Enclosure 1 be withheld from public disclosure in its entirety.
2. I have knowledge of the criteria used by SHINE in designating information as sensitive, proprietary, or confidential.
3. Pursuant to the provisions of paragraph (a)(4) of 10 CFR 2.390, the following is furnished for consideration by the NRC in determining whether the information sought to be withheld from public disclosure should be withheld.
 - a. The information sought to be withheld from public disclosure contained in Enclosure 1 of 2019-SMT-0015 is owned by SHINE, its affiliates, or third parties to whom SHINE has an obligation to maintain its confidentiality. This information is and has been held in confidence by SHINE.
 - b. The information sought to be protected in Enclosure 1 is not available to the public to the best of my knowledge and belief.

- c. The information contained in Enclosure 1 is of the type that is customarily held in confidence by SHINE, and there is a rational basis for doing so. The information that SHINE is requesting to be withheld from public disclosure includes trade secret, commercial financial information, commercial information, or information that is subject to export controls. SHINE limits access to these elements to those with a "need to know," and subject to maintaining confidentiality.
- d. Public disclosure of the information in Enclosure 1 would create substantial harm to SHINE because it would reveal valuable business information regarding SHINE's competitive expectations, assumptions, processes, and current position. Its use by a competitor could substantially improve their competitive position in the design, manufacture, shipment, installation, assurance of quality, or licensing of a similar product.
- e. The information contained in Enclosure 1 of 2019-SMT-0015 is transmitted to the NRC in confidence and under the provisions of 10 CFR 2.390; it is to be received in confidence by the NRC. The information is properly marked.

I declare under the penalty of perjury that the foregoing is true and correct.
Executed on March 8, 2019.



James Costedio
Vice President of Regulatory Affairs and Quality
SHINE Medical Technologies, Inc.

ENCLOSURE 2

SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR ORDER APPROVING INDIRECT TRANSFER OF CONTROL OF CONSTRUCTION PERMIT RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION (PUBLIC)

The NRC staff determined that additional information was required (Reference 1) to enable the continued review of the SHINE Medical Technology, Inc. (SHINE) application for an order approving the indirect transfer of control of Construction Permit No. CPMIF-001 and conforming administrative construction permit amendment (Reference 2). The following information is provided by SHINE in response to the NRC staff's request.

RAI 1

The regulation, 10 CFR 50.33(f)(1), states, in part, that a construction permit applicant shall submit estimates of the total construction and related fuel cycle costs.

The total estimated costs of construction provided in Section VI, "Financial Qualifications," of SHINE's application for indirect license transfer and conforming amendment differ from the initial total estimated costs of construction provided initially in Section 15.1, "Financial Ability to Construct the SHINE Facility," in SHINE's preliminary safety analysis report (ADAMS Accession No. ML15258A385). Based on the information provided in SHINE's application for indirect license transfer and conforming amendment, the basis for SHINE's current estimated construction and related fuel cycle costs is not clear to the NRC staff. This information is necessary for the NRC staff to determine whether SHINE LLC would be financially qualified and would possess or have reasonable assurance of obtaining the funding necessary to cover estimated construction and related fuel cycle costs following the establishment of Illuminated.

Provide the basis for the current estimated construction and related fuel cycle costs provided in SHINE's application for indirect license transfer and conforming amendment. Include the basis for the estimates of total production plant costs, plant equipment, uranium inventory cost for the first year of operation, and the total estimated cost. The basis could include information related to construction and related fuel cycle costs for similar facilities; input and experience from SHINE's prime construction contractor; design changes; or other new information made available to or developed by SHINE since its initial construction cost estimates.

SHINE Response

The estimated construction and related fuel cycle costs provided in Section VI of Reference 2 is an update of the estimate provided in the SHINE Response to RAI FA-1 (Reference 3). The basis for the current estimated construction and related fuel cycle costs are described below for each of the cost estimate line items delineated in Reference 2.

Total production plant costs (including support facilities)

The total production plant cost estimates are comprised of two elements: (1) Facility structure, support facilities, and mechanical, electrical, plumbing, and piping systems; and (2) Process-oriented systems. The basis for the cost estimate of each element is below.

1. Facility structure, support facilities, and mechanical, electrical, plumbing, and piping systems

SHINE's prime construction contractor, Baker Concrete Construction, Inc. (Baker), prepared a cost estimate for the facility structure, support facilities, and mechanical, electrical, plumbing, and piping systems. Baker's estimate was derived using drawings and specifications prepared by SHINE as well as input from potential subcontractors and vendors. This serves as the basis for the cost estimate of this element of SHINE's total production plant costs.

2. Process-oriented systems

SHINE personnel have completed a cost estimating process for process-oriented systems based on the development of over 180 preliminary equipment specifications. SHINE used these equipment specifications to initiate a request for quote process with prospective equipment vendors. The vendors provided SHINE with quotes for the cost of fabricating SHINE's process-oriented systems. These vendor quotes serve as the basis for the cost estimate of SHINE's process-oriented systems.

Plant equipment

The plant equipment cost estimate is specific to the neutron driver assembly systems that SHINE intends to purchase from Phoenix, LLC (Phoenix). SHINE has a binding contract with Phoenix that specifies the cost of the neutron driver assembly systems on a firm-fixed basis. SHINE's binding contract with Phoenix serves as the basis for the plant equipment cost estimate.

Uranium inventory cost for first year of operation

The estimated costs of low enriched uranium are based on information provided by the U.S. Department of Energy, National Nuclear Security Administration (NNSA) Production Office and Y-12 National Security Complex in Oak Ridge, Tennessee. SHINE has had an ongoing, constructive dialogue with the NNSA to help provide a rough order of magnitude estimate to serve as the basis for the SHINE uranium inventory cost for the first year of operation.

The SHINE uranium inventory cost for first year of operation is based on the total amount of uranium required for the initial target solution batches and includes enough uranium to operate during the startup, testing, and initial operating cycle, as well as spare material to provide ample operational flexibility.

Total estimated cost

The total estimated cost is a summation of the cost estimate line items described above.

RAI 2

The regulation, 10 CFR 50.33(f)(1), states, in part, that a construction permit applicant shall submit information to demonstrate that it possesses or will possess the funds necessary to cover estimated construction and related fuel cycle costs. Applicants are also to provide the source(s) of the funds to cover these costs. Additionally, 10 CFR Part 50, Appendix C, Section II, "Applicants which are newly formed entities," states, in part, that for each source of funding, the applicant should describe in detail the legal and financial relationships upon which it is relying for financial assistance. This may include copies of agreements or contracts, as necessary.

While SHINE has provided the amounts of financing commitments remaining for use in its development and construction project, its application for indirect license transfer and conforming amendment does not 1) indicate the amount of this funding dedicated to covering construction and related fuel cycle costs or 2) provide the basis for determining that there is reasonable assurance that amount of currently committed and future funding will be sufficient to cover estimated total construction and related fuel cycle costs. It is also unclear whether previously committed funding will be used for construction and related fuel cycle costs. This information is necessary for NRC staff to determine that SHINE LLC would possess or have reasonable assurance of obtaining the funding necessary to cover estimated construction and related fuel cycle costs following the establishment of Illuminated.

- a. Clarify the amounts of committed financing for each source described in Section VI of SHINE's application for indirect license transfer and conforming amendment dedicated to construction and related fuel cycle costs, including the dedicated amounts of existing cash-on-hand; the Deerfield Management Company, L.P. financing; the City of Janesville loan packages and guarantees; and 90 acres of land for the building site provided by the City of Janesville. For each source of funding, describe in detail the legal and financial relationships upon which SHINE is relying for financial assistance, including copies of agreements or contracts, as necessary.*
- b. Provide the amounts and sources of previously committed financing, if any, to be applied to construction and related fuel cycle costs.*
- c. Provide the basis for determining that there is reasonable assurance the amount of currently committed and future financing will be sufficient to cover the estimated total construction and related fuel cycle costs.*

SHINE Response

a. [

Proprietary Information

]

Additional details describing the legal and financial relationships associated with each source of funding is described below.

Existing cash-on-hand

The existing cash-on-hand includes amounts provided by previously committed financing. SHINE has full control of its existing cash-on-hand and it is not subject to any restrictions.

Deerfield financing commitment

The Deerfield financing is a binding financing commitment from Deerfield to SHINE. Under the financing agreement, Deerfield is obligated to provide SHINE with predetermined amounts of financing upon the achievement of certain business and construction milestones. The total binding financing commitment is \$150 million.

City of Janesville loan packages/guarantees and 90 acres of land for the building site provide by Janesville

This City of Janesville loan package/guarantees and 90 acres of land for the building site provided by Janesville (Janesville Agreement) are binding obligations. Once SHINE has met certain milestones described in the Janesville Agreement, the City of Janesville is obligated to provide SHINE with the loan package/guarantees and the 90 acres of land for the building site.

- b. The amounts and sources of previously committed financing are included in SHINE's existing cash-on-hand. SHINE intends to dedicate [Proprietary Information].
- c. The SHINE Response to RAI 1 describes the basis for the total construction and related fuel cycle cost estimates. [

Proprietary Information

] In addition, the Department of Energy's National Nuclear Security Administration has recently announced that SHINE has been chosen to enter into negotiations to receive an additional cooperative agreement award. [

Proprietary Information

] SHINE believes that there is reasonable assurance that its currently committed financing and future funding will be sufficient to cover the estimated total construction and related fuel cycle costs.

RAI 3

Appendix C, Section II of 10 CFR Part 50, requires that a newly formed entity include in its application a statement of its assets, liabilities, and capital structure as of the date of the application.

By letter dated June 13, 2018 (ADAMS Accession No. ML18166A178), SHINE submitted to the NRC its annual financial report, including certified financial statements, in accordance with the requirements of 10 CFR 50.71, "Maintenance of records, making of reports," paragraph (b). However, SHINE's application for indirect license transfer and conforming amendment does not indicate whether its most recent financial report reflects its current financial statements as of the date of its application. This information is necessary for the NRC staff to determine whether SHINE LLC would be financially qualified and would possess or have reasonable assurance of obtaining the funding necessary to cover estimated construction and related fuel cycle costs following the establishment of Illuminated.

Provide current financial statements, reflecting, as applicable, either balance sheets and operating statements covering the latest complete accounting year together with all pertinent notes thereto and certification by a public accountant or a statement of assets, liabilities, and capital structure as of the date of the application.

SHINE Response

Attachment 1 provides statements of assets, liabilities, and capital structure as of December 31, 2018.

RAI 4

The regulation, 10 CFR 50.34(a)(9), requires that an applicant provide its technical qualifications to engage in the activities proposed in its application in accordance with the regulations in 10 CFR, Chapter I.

While SHINE indicated in its application for indirect license transfer and conforming amendment that the formation of a holding company would not change the technical qualifications of SHINE LLC, it has not provided a basis for the technical qualifications of SHINE LLC as required in 10 CFR 50.34(a)(9) and 10 CFR 50.80(b)(1)(i). This information is necessary for the NRC staff to determine whether any changes in staffing and/or facility design may impact the technical qualifications of SHINE LLC to construct the proposed SHINE Medical Isotope Production Facility since the issuance of Construction Permit CPMIF-001 and following the establishment of Illuminated.

Provide the basis for SHINE's determination that SHINE LLC would be technically qualified to construct the proposed SHINE Medical Isotope Production Facility following the establishment of Illuminated, including the technical qualifications of key personnel and information indicating whether any staffing or design changes would impact the technical qualifications of SHINE LLC since the issuance of Construction Permit CPMIF-001.

SHINE Response

SHINE Medical Technologies, Inc. is technically qualified to design and construct the proposed SHINE medical isotope production facility as stated within Construction Permit No. CPMIF-001.

The transition to Illuminated Holdings, Inc. and SHINE Medical Technologies, LLC (both of which would be owned by the current owners of SHINE) will have no impact on the management, staff, or technical qualifications of SHINE.

The primary basis for SHINE's technical qualification determination is the technical acumen of SHINE's management and staff. Technical qualifications of key personnel are provided in Attachment 2. Staffing changes since the issuance of the construction permit have resulted in overall staffing compliment growth, including expanded engineering department staff. The transition to Illuminated Holdings, Inc. and SHINE Medical Technologies, LLC, will have no impact on SHINE ownership, management, or staff, and therefore, will have no impact on SHINE's technical qualifications. Staffing changes (e.g., increased engineering staff) since the issuance of Construction Permit No. CPMIF-001 have positively impacted SHINE's technical qualifications.

The design of the SHINE medical isotope production facility has progressed since the issuance of Construction Permit No. CPMIF-001 and the resulting design changes are within the scope of SHINE's technical capabilities. Changes incorporated since the issuance of the construction permit have included simplification of the design and elimination of complex processes (e.g., elimination of the uranyl nitrate conversion system including the uranium extraction and thermal denitration subsystems). Design changes since the issuance of Construction Permit No. CPMIF-001 have positively impacted SHINE's technical qualifications.

Since the issuance of Construction Permit No. CPMIF-001 SHINE has constructed, and is in the process of testing, a prototype of the production facility accelerator. Design, procurement, construction, and testing of the prototype and supporting equipment has allowed SHINE to gain operating experience, train employees, and develop maintenance techniques prior to construction of the medical isotope production facility, positively impacting SHINE's technical qualifications.

Further enhancing SHINE's technical qualifications, SHINE has partnered with industry experts in several key technical areas. SHINE has chosen Baker to be the prime contractor for the construction of the medical isotope production facility. SHINE has chosen Rock Creek Innovations, LLC to lead design and implementation of the instrumentation and control protection systems for SHINE's medical isotope production facility. Additionally, SHINE and Phoenix have entered into an exclusive long-term development and supply agreement to provide the accelerator hardware needed to safely operate SHINE's medical isotope production facility. Each of these partnerships have positively impacted SHINE's technical qualifications.

Through the process of design progression, with the accompanying staffing compliment growth, prototype construction and testing, and partnerships with key industry experts, SHINE's technical qualifications have been enhanced since the issuance of Construction Permit No. CPMIF-001. The transition to Illuminated Holdings, Inc and SHINE Medical Technologies, LLC will have no impact on the technical qualifications of SHINE because this transition will not impact SHINE's management, staff, or partnerships.

References

- (1) NRC letter to SHINE Medical Technologies, Inc., dated February 13, 2019, SHINE Medical Technologies, Inc. – Request for Additional Information Regarding the Application for Indirect License Transfer and Conforming Amendment (EPID No. L-2018-LLM-0154) (ML19024A530)
- (2) SHINE Medical Technologies, Inc. letter to NRC, dated December 11, 2018, Application for Order Approving Indirect Transfer of Control of Construction Permit and Conforming Administrative Construction Permit Amendment (ML18347A215)
- (3) SHINE Medical Technologies, Inc. letter to NRC, dated October 15, 2014, SHINE Medical Technologies, Inc. Application for Construction Permit Response to Request for Additional Information (ML14296A189)

**ENCLOSURE 2
ATTACHMENT 1**

SHINE MEDICAL TECHNOLOGIES, INC.

**SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR ORDER APPROVING
INDIRECT TRANSFER OF CONTROL OF CONSTRUCTION PERMIT
RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION**

2018 YEAR END STATEMENT OF ASSETS, LIABILITIES, AND CAPITAL STRUCTURE

4 pages follow

Proprietary Information – Withheld from Public Disclosure Under 10 CFR 2.390(a)(4)

Proprietary Information – Withheld from Public Disclosure Under 10 CFR 2.390(a)(4)

Proprietary Information – Withheld from Public Disclosure Under 10 CFR 2.390(a)(4)

Proprietary Information – Withheld from Public Disclosure Under 10 CFR 2.390(a)(4)

**ENCLOSURE 2
ATTACHMENT 2**

SHINE MEDICAL TECHNOLOGIES, INC.

**SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR ORDER APPROVING
INDIRECT TRANSFER OF CONTROL OF CONSTRUCTION PERMIT
RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION**

BIOGRAPHIES OF OFFICERS AND DIRECTORS

OFFICERS

Dr. Gregory Piefer, Chief Executive Officer

Dr. Piefer is the founder and CEO of SHINE Medical Technologies and has 13 years of executive management experience at growth stage technology companies. Before SHINE, he served as the president of Phoenix Nuclear Labs, where he managed the development of high-output particle sources. He formerly served as the Chief Technical Officer to Gillware Inc., a leading data recovery and backup company. He holds a PhD in nuclear engineering, and BS degrees in physics and electrical and computer engineering from the University of Wisconsin-Madison. Greg has received numerous awards and honors including the prestigious University of Wisconsin-Madison Early Career award, is the primary inventor on multiple patents and author or co-author of numerous publications, and serves on the boards of several profit and non-profit entities. His passion is the growth of technology companies that take scientific advancement to commercialization, providing the opportunity to serve and better humanity.

Todd Asmuth, President

Mr. Asmuth has been a SHINE Board Member since 2013 and has over 20 years of experience as an operator, investor, and board member in early-stage companies. He joined SHINE as President in 2015 and his responsibilities include all investor and customer activities. Early in his career, he spent 4 years in management consulting with Booz Allen Hamilton on strategy engagements with Fortune 500 companies. In addition, he sits on the board of directors of multiple early-stage companies and non-profit organizations. Mr. Asmuth earned an MBA with honors from the Kellogg School of Management at Northwestern University and a B.S. in Mechanical Engineering from Yale University.

Steve Miltenberger, Chief Operations Officer

Mr. Miltenberger has over 30 years of nuclear industry experience in operations, maintenance, engineering, construction, project management, procurement, testing and various other roles. Before joining SHINE, he was responsible for Site Projects in the United Kingdom after completing the project management of Phases 2 & 3 for URENCO's National Enrichment Facility in Eunice, New Mexico. Mr. Miltenberger has worked in a variety of industries including: nuclear and coal power generation; nuclear fuel enrichment; and oil and gas, which included taking nine projects from new plant construction into operation. Mr. Miltenberger has his Bachelor of Electrical Engineering and Masters of Nuclear Engineering from the University of Missouri at Rolla, is a Certified Senior Reactor Operator and Professional Engineer in the states of Missouri, North Carolina, New Jersey, and New Mexico.

Eric Van Abel, Chief Technical Officer

Mr. Van Abel is Chief Technical Officer of SHINE and has been with SHINE since 2011. As CTO, Eric is responsible for expediting the path to commercial production through identification and reduction of technical risks, simplifying design requirements, and driving the development of innovative solutions. Mr. Van Abel has experience with the breadth of the SHINE facility design and extensive knowledge of the regulatory basis. Before his current role, Mr. Van Abel served as the first staff engineer at SHINE, design lead for the subcritical fission systems that generate the medical isotopes, then managed the design of the irradiation facility and associated systems, and then subsequently served as the engineering design manager for the entire project, including irradiation and chemical processing of isotopes. Before joining SHINE, Mr. Van Abel worked in nuclear reactor safety for Dominion Energy at the Kewaunee nuclear power plant and helped to ensure safe and reliable nuclear power plant operation. Mr. Van Abel holds M.S. and B.S. degrees in nuclear engineering from University of Wisconsin-Madison, where he graduated with highest distinction.

BOARD OF DIRECTORS

Dr. Thomas “Rock” Mackie

Dr. Mackie currently serves as Director of Medical Devices at the Morgridge Institute for Research and as a professor in the departments of Medical Physics, Human Oncology, and Engineering Physics at the University of Wisconsin–Madison. He is the author of more than 130 peer-reviewed publications, 25 patents, and has supervised more than 25 PhD students. With his expertise in radiation therapy treatment planning and intensity-modulated radiotherapy, his group developed the Pinnacle™ treatment planning system, now marketed by Philips Medical. He is a co-founder and Chairman of the Board of TomoTherapy, Inc., a Madison-based company employing 650 people. Dr. Mackie received his B.S. in Physics from the University of Saskatchewan in 1980 and his doctorate in Physics from the University of Alberta in 1984.

Dr. Gregory Piefer

(see above under Officers)

Philip M. Halpern

Mr. Halpern is the managing partner of the law firm of Collier, Halpern, Newberg, Nolletti & Bock, LLP, with offices in New York City, White Plains and Stamford, Connecticut. Mr. Halpern is a magna cum laude graduate of Fordham University, where he majored in economics, and is a graduate of Pace University School of Law where he obtained his juris doctor. Mr. Halpern is a Fellow of the American Bar Foundation and member of the Office of Court Administration’s Advisory Committee on Civil Practice. Mr. Halpern has been a member of the Advisory Council for the Board of Judges for the Southern District of New York. Mr. Halpern is a member of the Association of the Bar of the City of New York, the Committee on Federal Judiciary for the New York State Bar Association, the American Bar Association, the New York County Lawyers Association, New York State Trial Lawyers Association, the Association of Trial Lawyers of America, and the Federal Bar Council. Mr. Halpern began his legal career in 1980 as a law clerk to a federal judge in the Southern District of New York.

Todd Asmuth

(see above under Officers)

Gregory OD Smith

Gregory OD Smith joins the SHINE board with 39 years of leadership experience in the nuclear industry and a track record of creating effective partnerships. Gregory has served as the Chairman of URENCO UK and URENCO’s Chief Culture Officer. Prior to that, he served as Chairman of the Board and Chief Executive Officer for Louisiana Energy Services (LES), a uranium enrichment company wholly owned by URENCO. As CEO of LES, he oversaw the completion of construction and startup of the National Enrichment Facility in New Mexico. Before joining LES, Mr. Smith worked for Ontario Power Generation. During 2002-2006, he served as the Senior Vice President for the four-unit Darlington Nuclear station. From 1992-2002, he worked at Energy Northwest where he held several positions, including Operations Division Manager, Plant General Manager, Vice President Nuclear Operations, and Vice President Generation.

Brad Wucherpfennig

President of Baker Construction Enterprises. Prior to joining Baker in 2010, Mr. Wucherpfennig was a member of the Advisory Board for over ten years while serving as CEO of Phillips-Medisize, a global leader in outsource design, development, and technology-driven manufacturing providing drug delivery, medical device, and medical diagnostic products.

Mr. Wucherpfennig, a Wisconsin native, lived in Minneapolis for numerous years. He served as the Executive Vice President and COO of Schwing America, Inc., a member of the Schwing Group, a worldwide designer, manufacturer and distributor of concrete production and handling equipment. His career began with Ernst and Young in Minnesota, where as a CPA he performed client audits. After his time in public accounting, he served as the Director of International Finance for Synder General Corporation, a designer and manufacturer of commercial and industrial air conditioning and handling equipment. Mr. Wucherpfennig has a degree in Finance/Accounting from the University of Wisconsin and holds an MBA from the University of Minnesota. He has served on numerous boards in the construction, manufacturing, and medical technology industries.

Gordon Gunnlaugsson

Mr. Gunnlaugsson was employed at Marshall and Ilsley Corporation, an S&P 500 banking company, for thirty years, serving most recently as CFO and EVP and as a Director. Currently, he is a principal in Lakeview Equity Partners, a private equity firm in Milwaukee, Wisconsin.

Mr. Gunnlaugsson's other activities include serving as a director for a variety of other firms including West Bend Mutual Insurance Company, Fiduciary Management Mutual Funds, UAS Labs, and Renaissance Learning, Inc. He has also served as Chairman of the Milwaukee Economic Development Corporation, Chairman of the Medical College of Wisconsin Cardiovascular Center Advisory Board, Chairman of the University of Wisconsin School of Business Puelicher Center for Banking, and Chairman of the University of Wisconsin School of Business Dean's Advisory Board. He is a CPA and holds a BBA and MBA from the University of Wisconsin School of Business and is a recipient of their Distinguished Alumni Award.