50-608

THIS LETTER CONTAINS PROPRIETARY INFORMATION
IN ACCORDANCE WITH 10 CFR 2.390

December 11, 2018

2018-SMT-0133
10 CFR 50.80
10 CFR 50.90

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

References: (1) NRC letter to SHINE Medical Technologies, Inc., "SHINE Medical Technologies, Inc. - Issuance of Construction Permit for Medical Isotope Facility," dated February 26, 2016 (ML16041A473)

Application for Order Approving Indirect Transfer of Control of Construction Permit and Conforming Administrative Construction Permit Amendment

In accordance with Section 184 of the Atomic Energy Act of 1954, as amended, and 10 CFR 50.80, SHINE Medical Technologies, Inc. (SHINE) hereby submits the enclosed application requesting that the NRC consent to the indirect transfer of control of Construction Permit No. CPMIF-001 (Reference 1) for the SHINE Medical Isotope Production Facility held by SHINE and approve a conforming administrative amendment to the permit to reflect SHINE's new name, SHINE Medical Technologies, LLC. The indirect transfer of control would result from the creation of a new parent holding company, Illuminated Holdings, Inc. (Illuminated), a Delaware corporation, which would be owned by the current owners of SHINE.

Enclosure 1 provides a non-public (proprietary) version of the application. SHINE requests that the NRC withhold Enclosure 1 from public disclosure under 10 CFR 2.390.

Enclosure 2 provides a public (non-proprietary) version of the application.

Enclosure 3 provides an affidavit supporting the proprietary treatment of the SHINE proprietary information pursuant to 10 CFR 2.390. SHINE requests that the NRC withhold Enclosure 1 from public disclosure under 10 CFR 2.390. Upon removal of Enclosure 1, this letter is uncontrolled.

SHINE respectfully requests that the NRC review the enclosed application and complete the requested action expeditiously. SHINE requests NRC issue an order granting its consent to the proposed indirect transfer of control of the permit by February 28, 2019. SHINE is prepared to work closely with the NRC Staff to facilitate the staff's review.

If you have any questions, please contact Mr. Jeff Bartelme, Licensing Manager, at 608/210-1735.

Enclosure 1 contains proprietary information.
Withhold from public disclosure under 10 CFR 2.390.
Upon removal of Enclosure 1, this letter is uncontrolled.

YG01
NRR

I declare under the penalty of perjury that the foregoing is true and correct.
Executed on December 11, 2018.

Very truly yours,

James Costedio
Vice President of Regulatory Affairs and Quality
SHINE Medical Technologies, Inc.
Docket No. 50-608

Enclosures

cc: Project Manager, USNRC
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health
(w/o Enclosure 1)

ENCLOSURE 3

SHINE MEDICAL TECHNOLOGIES, INC.

APPLICATION FOR ORDER APPROVING INDIRECT TRANSFER OF CONTROL OF CONSTRUCTION PERMIT AND CONFORMING ADMINISTRATIVE CONSTRUCTION PERMIT AMENDMENT

AFFIDAVIT OF JAMES COSTEDIO

2 Pages Follow

SHINE®
Medical Technologies

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 by letter 2018-SMT-0133 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 2018-SMT-0133 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 2018-SMT-0133 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 December 11, 2018.

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

ENCLOSURE 2

SHINE MEDICAL TECHNOLOGIES, INC.

APPLICATION FOR ORDER APPROVING INDIRECT TRANSFER OF CONTROL OF CONSTRUCTION PERMIT AND CONFORMING ADMINISTRATIVE CONSTRUCTION PERMIT AMENDMENT

CONSTRUCTION PERMIT TRANSFER APPLICATION
(PUBLIC)

18 Pages Follow

SHINE Medical Technologies, Inc.
Application for Order Approving Indirect Transfer of Control of Construction Permit and Conforming Administrative Construction Permit Amendment

TABLE OF CONTENTS

I. INTRODUCTION

In accordance with Section 184 of the Atomic Energy Act of 1954, as amended, and 10 CFR 50.80, SHINE Medical Technologies, Inc. (SHINE) hereby submits this application (Application) requesting that the U.S. Nuclear Regulatory Commission (NRC) consent to the indirect transfer of control of Construction Permit No. CPMIF-001 (Permit) (Reference 1) for the SHINE Medical Isotope Production Facility (SHINE Facility) held by SHINE and approve a conforming administrative amendment to the Permit to reflect SHINE's new name, SHINE Medical Technologies, LLC. The indirect transfer of control would result from the creation of a new parent holding company, Illuminated Holdings, Inc. (Illuminated), a Delaware corporation, which would be owned by the current owners of SHINE.

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.

Additional information pertaining to the proposed transfer of the Permit, including the information required under 10 CFR 50.80, is included in this Application. This information demonstrates that: (1) SHINE will continue to have the requisite managerial, technical, and financial qualifications to be the holder of the Permit; (2) the SHINE organization and the material terms of the Permit will not be affected; and (3) the creation of Illuminated as a parent holding company of SHINE will not result in any impermissible foreign ownership, control, or domination.

The proposed transfer of the Permit will not be inimical to the common defense and security or result in any undue risk to public health and safety, and the transfer will be consistent with the requirements of the Atomic Energy Act and the NRC regulations.

II. STATEMENT OF PURPOSE OF THE TRANSFER AND NATURE OF THE TRANSACTION MAKING THE TRANSFER NECESSARY OR DESIRABLE

The purpose of the transfer of the Permit resulting from creation of a holding company is to facilitate the financing arrangement, whereby Deerfield would provide up to $150 million to support the development and construction of the SHINE Facility. SHINE will engage in a restructuring transaction, whereby it will create a parent holding company, Illuminated, that will be owned by the current owners of SHINE. SHINE will become a limited liability company through conversion by operation of law, and it will operate as a wholly-owned subsidiary of Illuminated.

The proposed holding company structure is required by the terms of the financing arrangement entered into with Deerfield. Deerfield is providing financing that SHINE will be able to draw upon in several tranches over time. [

Proprietary Information

]

The holding company structure will also facilitate a potential future initial public offering (IPO) of SHINE. If SHINE undertakes an IPO, it will issue shares to the public and control may be transferred from the current owners to the general public. SHINE does not plan to seek 10 CFR 50.80 consent for an IPO, unless purchases of stock involved a concentration of ownership by an entity or group of entities under common control that could amount to control of the publicly traded company.

Following the creation of the holding company structure, SHINE will operate as a wholly owned subsidiary of Illuminated. NRC's approval is required for the resulting indirect transfer of control of the Permit held by SHINE.

III. GENERAL CORPORATE INFORMATION REGARDING ILLUMINATED HOLDINGS, INC. AND SHINE MEDICAL TECHNOLOGIES, LLC

The general corporate information required by 10 CFR 50.33(d)(3) regarding Illuminated and SHINE is provided in Attachment 1. Attachment 1 includes information regarding the current and planned Principal Executive Personnel of Illuminated and SHINE. Attachment 1 also includes the planned Board of Directors of Illuminated and Board of Directors of SHINE, indicating that SHINE will be member-managed by Illuminated. All of these Directors and Principal Executive Personnel are U.S. citizens, except as indicated otherwise.

IV. FOREIGN OWNERSHIP, CONTROL, OR DOMINATION

SHINE is a private corporation that currently has approximately [Proprietary Information] shareholders. In addition, employees of SHINE participate in a stock option plan and hold options to purchase shares in the future. To the best of SHINE's knowledge, current shareholders holding 1 percent or more of SHINE's stock are U.S. citizens or entities owned or controlled by U.S. citizens. Current SHINE employees holding stock options are U.S. citizens.

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 current compliance with the requirements regarding foreign ownership, control, or domination in 10 CFR 50.38.

Deerfield is a U.S. limited partnership. [Proprietary Information] and if it were to exercise rights provided under the financing arrangements to acquire additional ownership interests in Illuminated, it still would not be able to exercise control

over SHINE. Thus, Deerfield's financing of SHINE does not involve any issue implicating foreign ownership, control, or domination.

SHINE is not acting as an agent or representative of another person in filing this Application.

Accordingly, the proposed indirect transfer of control of the Permit at issue in this Application does not raise any issues related to foreign ownership, control, or domination within the meaning of the Atomic Energy Act of 1954, as amended. It also is not inimical to the common defense and security of the United States.

V. TECHNICAL QUALIFICATIONS

The Commission has previously concluded that "SHINE is technically and financially qualified to engage in the activities authorized" under the terms of the Permit (Reference 2). The creation of a new holding company does not make any change to SHINE's technical qualifications, and SHINE will remain technically qualified to carry out its responsibilities under the Permit.

VI. FINANCIAL QUALIFICATIONS

As noted above, the Commission has determined that SHINE is financially qualified to receive the Permit. The proposed creation of the holding company structure will have no adverse impact upon SHINE's financial qualification. Implementation of this structure is required by the financing arrangement with Deerfield that provides up to $150 million towards the development and construction of the SHINE Facility. The following represents the budgetary estimate of the costs for the construction of the SHINE Facility and related fuel cycle costs:

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

SHINE has obtained financing for its development and construction project using various sources of financing, including equity, debt, and government grants. At present, SHINE has the following financing commitments remaining for use in the project:

Existing cash-on-hand:	[Proprietary Information]
Deerfield financing commitment:	$150 million
City of Janesville loan packages/guarantees:	$7 million
90 acres of land for the building site provided by Janesville:	$2 million

[

Proprietary Information

]

VII. MISCELLANEOUS

A. Restricted Data and Classified National Security Information

This Application does not contain any Restricted Data or other classified National Security Information, and it is not expected that such information will become involved in SHINE's licensed activities. However, in the event that such information does become involved, and in accordance with 10 CFR 50.37, SHINE continues to agree that it will appropriately safeguard such information and will not permit any individual to have access to such information until the individual has been appropriately approved for such access under the provisions of 10 CFR Part 25 and/or 10 CFR Part 95.

B. Antitrust Information

The Atomic Energy Act of 1954, as amended, Section 105, Subsection (c)(9), states that the need for a NRC antitrust review "does not apply to an application for a license to construct or operate a utilization facility or production facility under section 103 or 104b. that is filed on or after the date of enactment of this paragraph." For similar reasons as those stated in Reference 3, transfers of construction permits are exempt from antitrust review. See also Reference 4 which states, "In light of the Wolf Creek decision, no ["significant changes"] analysis or antitrust review is undertaken when there is a license transfer application, regardless of whether it involves a direct or indirect license transfer." Accordingly, the Atomic Energy Act does not require or authorize antitrust reviews of this Application.

C. Price-Anderson Indemnity and Nuclear Insurance

Pursuant to 10 CFR Part 140, SHINE will file with the Commission proof of the financial protection required by the Commission before the Commission issues it an Operating License under 10 CFR Part 50.

D. Environmental Review

The requested consent to the indirect transfer of control of SHINE's Permit is exempt from environmental review because it falls within the categorical exclusion contained in 10 CFR 51.22(c)(21) for which neither an Environmental Assessment nor an Environmental Impact Statement is required. Moreover, the proposed transfer does not directly affect the actual conduct of activities under the Permit in any substantive way. The proposed transfer does not involve an increase in the amounts, or a change in the types, of any radiological effluents that may be released off-site, and involves no increase in the amounts or change in the types of non-radiological effluents that may be released off-site. Further, there is no increase in the individual or cumulative operational radiation exposure. The proposed indirect transfer has no environmental impact.

E. Regulatory Safety Analysis

The changes proposed for the Permit are provided in Attachment 2 and clean pages are provided in Attachment 3. The changes conform the Permit to reflect the new name of SHINE, as SHINE Medical Technologies, LLC. Consistent with the generic determination in 10 CFR 2.1315(a), the proposed conforming permit amendment involves no significant hazards consideration because it does no more than conform the Permit to reflect the transfer action. The proposed permit amendment does not involve any change in the design, licensing basis, or status of the SHINE Facility, or the requirements of the Permit. Therefore, the proposed

approval does not: (1) involve an increase in the probability or consequences of an accident previously analyzed; (2) create the possibility of a new or different kind of accident from the accidents previously evaluated; or (3) involve a significant reduction in a margin of safety.

F. Effective Date

Subject to the receipt of the required regulatory approvals, SHINE would like to proceed with the proposed transaction as expeditiously as possible. Accordingly, SHINE respectfully requests that the NRC review this Application on a schedule that will support the NRC's issuance of an Order consenting to the transfer and approving a conforming Permit amendment as promptly as possible and in any event by February 28, 2019.

SHINE is prepared to work closely with the NRC staff to help expedite the review of the Application. SHINE further requests that the consent to the transfer of the Permit be immediately effective upon issuance and that it authorize the proposed transaction to be implemented at any time within one year of the date of approval of this Application or such later date as the NRC may approve.

VIII. CONCLUSION

In summary, the proposed indirect transfer of control of SHINE's Permit will be consistent with the requirements of the Atomic Energy Act, NRC regulations, and regulatory guidance. Upon creation of its parent holding company, SHINE will be a wholly owned subsidiary of Illuminated. There will be no adverse impact on public health and safety. The indirect transfer of control of the Permit will not be inimical to the common defense and security and does not involve foreign ownership, control, or domination. SHINE therefore requests that the NRC consent to the transfer of the Permit in accordance with 10 CFR 50.80.

IX. REFERENCES

1. U.S. Nuclear Regulatory Commission, "SHINE Medical Technologies, Inc. - Issuance of Construction Permit for Medical Isotope Facility," dated February 26, 2016 (ML16041A473)

2. U.S. Nuclear Regulatory Commission Memorandum and Order, CLI-16-04, In the Matter of SHINE Medical Technologies, Inc. (Medical Radioisotope Production Facility), dated February 25, 2016 (ML16056A094)

3. U.S. Nuclear Regulatory Commission Memorandum and Order, CLI-99-19, In the Matter of Kansas Gas & Electric Co. (Wolf Creek Generating Station), dated June 18, 1999 (ML020560606)

4. U.S. Nuclear Regulatory Commission, NUREG-1574, Standard Review Plan on Transfer and Amendment of Antitrust License Conditions and Antitrust Enforcement, Revision 2, dated December 2007 (ML072260035)

ENCLOSURE 2
ATTACHMENT 1

SHINE MEDICAL TECHNOLOGIES, INC.

APPLICATION FOR ORDER APPROVING INDIRECT TRANSFER OF CONTROL OF CONSTRUCTION PERMIT AND CONFORMING ADMINISTRATIVE CONSTRUCTION PERMIT AMENDMENT

GENERAL CORPORATE INFORMATION REQUIRED BY 10 CFR 50.33(d)(3)

1 Page Follows

ILLUMINATED HOLDINGS, INC.

NAME:	Illuminated Holdings, Inc.
STATE OF INCORPORATION & CORPORATE FORM:	A Delaware corporation
BUSINESS ADDRESS (Illuminated, SHINE, Directors, and Executives):	101 E. Milwaukee St., Suite 600 Janesville, WI 53545
BOARD OF DIRECTORS:	Dr. Gregory Piefer Dr. Thomas "Rock" Mackie * Philip M. Halpern Todd Asmuth Gregory OD Smith Brad Wucherpfennig Gordon Gunnlaugsson
LIST OF PRINCIPAL EXECUTIVE PERSONNEL:	Dr. Gregory Piefer, Chief Executive Officer Todd Asmuth, President & Chief Financial Officer Steve Miltenberger, Chief Operating Officer

SHINE MEDICAL TECHNOLOGIES, LLC

NAME:	SHINE Medical Technologies, LLC
STATE OF INCORPORATION & CORPORATE FORM:	A Delaware limited liability company
BUSINESS ADDRESS (Illuminated, SHINE, Directors, and Executives):	101 E. Milwaukee St., Suite 600 Janesville, WI 53545
BOARD OF DIRECTORS:	Dr. Gregory Piefer Dr. Thomas "Rock" Mackie * Philip M. Halpern Todd Asmuth Gregory OD Smith Brad Wucherpfennig Gordon Gunnlaugsson
Member Manager:	Illuminated Holdings, Inc.
LIST OF PRINCIPAL EXECUTIVE PERSONNEL:	Dr. Gregory Piefer, Chief Executive Officer Todd Asmuth, President & Chief Financial Officer Steve Miltenberger, Chief Operating Officer

* Canadian Citizen and U.S. Permanent Resident

ENCLOSURE 2
ATTACHMENT 2

SHINE MEDICAL TECHNOLOGIES, INC.

APPLICATION FOR ORDER APPROVING INDIRECT TRANSFER OF CONTROL OF CONSTRUCTION PERMIT AND CONFORMING ADMINISTRATIVE CONSTRUCTION PERMIT AMENDMENT

CONSTRUCTION PERMIT (CHANGES)
MEDICAL ISOTOPE PRODUCTION FACILITY
CONSTRUCTION PERMIT NO. CPMIF-001

4 Pages Follow

SHINE MEDICAL TECHNOLOGIES, ~~INC.~~LLC

DOCKET NO. 50-608

MEDICAL ISOTOPE PRODUCTION FACILITY

CONSTRUCTION PERMIT

Construction Permit No. CPMIF-001

1. The Nuclear Regulatory Commission (NRC or the Commission) has found that:

   A. The application for a construction permit, as supplemented and revised (the application), filed by SHINE Medical Technologies, ~~Inc.~~LLC (SHINE, the applicant), complies with the requirements of the Atomic Energy Act of 1954, as amended (the Act), and the rules and regulations of the Commission set forth in Title 10 of the *Code of Federal Regulations* (10 CFR) Chapter I – Nuclear Regulatory Commission. There is reasonable assurance that the activities authorized by the permit will be conducted in compliance with the rules and regulations of the Commission, and all required notifications to other agencies or bodies have been duly made;

   B. The applicant has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public;

   C. Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report;

   D. Safety features or components, if any, which require research and development have been described by the applicant. The applicant has identified, and will conduct, a research and development program reasonably designed to resolve any safety questions associated with such features or components;

   E. On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for the completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100,[1] the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public;

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1 While the site criteria contained in 10 CFR Part 100 are applicable to nuclear power reactors, and not the SHINE facility, the staff considered in Chapter 2 of its safety evaluation report, site-specific conditions similar to those listed in 10 CFR Part 100. Using the guidance in NUREG-1537, the staff evaluated SHINE's analysis of site geography and demography; nearby industrial, transportation, and military facilities; site meteorology; site hydrology; and site geology, seismology, and geotechnical engineering to ensure that issuance of the permit will not be inimical to the common defense and security or to the health and safety of the public.

F. The processes to be performed provide reasonable assurance the applicant will comply with the regulations in 10 CFR Chapter I, including the regulations in 10 CFR Part 20, and that the health and safety of the public will not be endangered.;

G. SHINE is technically qualified to design and construct the facility in accordance with the Commission's regulations set forth in 10 CFR Chapter I;

H. SHINE is financially qualified to design and construct the facility in accordance with the Commission's regulations set forth in 10 CFR Chapter I;

I. The issuance of a permit for the construction of the facility will not be inimical to the common defense and security or to the health and safety of the public; and

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

2. On the basis of the foregoing findings regarding this facility, construction permit No. CPMIF-001 is hereby issued to SHINE pursuant to Sections 103 and 185a of the Act and 10 CFR Part 50 for eight utilization facilities and one production facility designed for the production of medical radioisotopes, as described in the application, filed in this matter by the applicant and as more fully described in the evidence received at the public hearing upon that application. The facility, known as the SHINE Medical Isotope Production Facility, owned by SHINE Medical Technologies, ~~Inc.~~LLC, will be located on previously undeveloped agricultural property in Rock County, Wisconsin, within the southern corporate boundaries of the City of Janesville, and is described in the application.

3. This permit shall be deemed to contain and be subject to the conditions specified in 10 CFR 50.54(b)-(f), (h), (v), (aa), and (cc) and 10 CFR 50.55; is subject to all applicable provisions of the Act, and rules, regulations, and orders of the Commission now or hereafter in effect; and is subject to the conditions specified or incorporated below:

   A. The earliest date for the completion of the construction of the facility is December 31, 2017, and the latest date for completion is December 31, 2022.

   B. The facility shall be constructed and located at the site as described in the application, in the City of Janesville, Rock County, Wisconsin.

   C. The construction permit authorizes the applicant to construct the facility described in the application and the hearing record, in accordance with the principal architectural and engineering criteria and environmental protection commitments set forth therein.

   D. The permit is subject to, and SHINE shall comply with, the conditions specified and incorporated below:

      (1) Prior to the completion of construction, SHINE shall submit periodic reports to the NRC, at intervals not to exceed six months from the date of this permit, providing the following information related to nuclear criticality safety and radiation protection:

APPENDIX A

TO FACILITY CONSTRUCTION PERMIT NO. CPMIF-001

SHINE MEDICAL TECHNOLOGIES, ~~INC.~~LLC

MEDICAL ISOTOPE PRODUCTION FACILITY

DOCKET NO. 50-608

ENVIRONMENTAL PROTECTION PLAN

(NONRADIOLOGICAL)

February 29, 2016

TABLE OF CONTENTS

1.0 Objective of the Environmental Protection Plan

The Environmental Protection Plan's (EPP) objective is to ensure compliance with the Endangered Species Act of 1973, as amended (ESA), and to ensure that the Commission is kept informed of other environmental matters. The EPP is intended to be consistent with Federal, State, and local requirements for environmental protection.

2.0 Environmental Protection Issues

In the Final Environmental Impact Statement (final EIS) dated October 2015, the NRC staff considered the environmental impacts associated with the construction, operation, and decommissioning of the proposed SHINE Medical Technologies, ~~Inc.~~LLC (SHINE or the licensee) radioisotope production facility (SHINE facility). This EPP applies to SHINE's actions affecting the protected environmental resources evaluated in the final EIS and SHINE's actions that may affect any newly discovered protected environmental resources.

2.1 Ecological Resources Issues

Federal agencies other than the U.S. Nuclear Regulatory Commission (NRC), such as the U.S. Environmental Protection Agency and the U.S. Army Corps of Engineers, have jurisdiction to regulate aquatic resources under the Federal Water Pollution Control Act (Clean Water Act or CWA) and the Rivers and Harbors Appropriation Act of 1899 (RHA). Water quality environmental concerns identified in the final EIS including mitigation measures would be regulated under SHINE's CWA permits, such as the National Pollutant Discharge Elimination System. Nothing within this EPP shall be construed to place additional requirements on the regulation of aquatic resources.

The U.S. Fish and Wildlife Service (FWS) regulates matters involving migratory birds and their nests in accordance with the Migratory Bird Treaty Act. The FWS also regulates matters involving the protection and taking of bald and golden eagles in accordance with the Bald and Golden Eagle Protection Acts.

SHINE shall inform the NRC of events or situations concerning aquatic or terrestrial resources for which a news release is planned or notification to other government agencies has been or will be made. These notifications shall be made to the NRC Operations Center within four hours of discovery.

2.2 Endangered Species Act of 1973

The NRC may be required to protect some aquatic resources and terrestrial resources in accordance with the Endangered Species Act of 1973 (ESA). If any Federally listed species or critical habitat occurs in an area affected by construction of the facility that was not previously identified as occurring in such areas, including species and critical habitat that were not previously Federally listed, the licensee shall inform the NRC within four hours of discovery. Similarly, the licensee shall inform the NRC within four hours of discovery of any take, as defined in the ESA, of a Federally listed species or destruction or adverse modification of critical habitat. These notifications shall be made to the NRC Operations Center. The licensee shall provide any necessary information to the NRC if the NRC initiates or reinitiates consultation under the ESA.

ENCLOSURE 2
ATTACHMENT 3

SHINE MEDICAL TECHNOLOGIES, INC.

APPLICATION FOR ORDER APPROVING INDIRECT TRANSFER OF CONTROL OF CONSTRUCTION PERMIT AND CONFORMING ADMINISTRATIVE CONSTRUCTION PERMIT AMENDMENT

CONSTRUCTION PERMIT (CLEAN)
MEDICAL ISOTOPE PRODUCTION FACILITY
CONSTRUCTION PERMIT NO. CPMIF-001

4 Pages Follow

SHINE MEDICAL TECHNOLOGIES, LLC

DOCKET NO. 50-608

MEDICAL ISOTOPE PRODUCTION FACILITY

CONSTRUCTION PERMIT

Construction Permit No. CPMIF-001

1. The Nuclear Regulatory Commission (NRC or the Commission) has found that:

   A. The application for a construction permit, as supplemented and revised (the application), filed by SHINE Medical Technologies, LLC (SHINE, the applicant), complies with the requirements of the Atomic Energy Act of 1954, as amended (the Act), and the rules and regulations of the Commission set forth in Title 10 of the *Code of Federal Regulations* (10 CFR) Chapter I – Nuclear Regulatory Commission. There is reasonable assurance that the activities authorized by the permit will be conducted in compliance with the rules and regulations of the Commission, and all required notifications to other agencies or bodies have been duly made;

   B. The applicant has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public;

   C. Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report;

   D. Safety features or components, if any, which require research and development have been described by the applicant. The applicant has identified, and will conduct, a research and development program reasonably designed to resolve any safety questions associated with such features or components;

   E. On the basis of the foregoing, there is reasonable assurance that: (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for the completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100,[1] the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public;

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1 While the site criteria contained in 10 CFR Part 100 are applicable to nuclear power reactors, and not the SHINE facility, the staff considered in Chapter 2 of its safety evaluation report, site-specific conditions similar to those listed in 10 CFR Part 100. Using the guidance in NUREG-1537, the staff evaluated SHINE's analysis of site geography and demography; nearby industrial, transportation, and military facilities; site meteorology; site hydrology; and site geology, seismology, and geotechnical engineering to ensure that issuance of the permit will not be inimical to the common defense and security or to the health and safety of the public.

F. The processes to be performed provide reasonable assurance the applicant will comply with the regulations in 10 CFR Chapter I, including the regulations in 10 CFR Part 20, and that the health and safety of the public will not be endangered.;

G. SHINE is technically qualified to design and construct the facility in accordance with the Commission's regulations set forth in 10 CFR Chapter I;

H. SHINE is financially qualified to design and construct the facility in accordance with the Commission's regulations set forth in 10 CFR Chapter I;

I. The issuance of a permit for the construction of the facility will not be inimical to the common defense and security or to the health and safety of the public; and

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

2. On the basis of the foregoing findings regarding this facility, construction permit No. CPMIF-001 is hereby issued to SHINE pursuant to Sections 103 and 185a of the Act and 10 CFR Part 50 for eight utilization facilities and one production facility designed for the production of medical radioisotopes, as described in the application, filed in this matter by the applicant and as more fully described in the evidence received at the public hearing upon that application. The facility, known as the SHINE Medical Isotope Production Facility, owned by SHINE Medical Technologies, LLC, will be located on previously undeveloped agricultural property in Rock County, Wisconsin, within the southern corporate boundaries of the City of Janesville, and is described in the application.

3. This permit shall be deemed to contain and be subject to the conditions specified in 10 CFR 50.54(b)-(f), (h), (v), (aa), and (cc) and 10 CFR 50.55; is subject to all applicable provisions of the Act, and rules, regulations, and orders of the Commission now or hereafter in effect; and is subject to the conditions specified or incorporated below:

   A. The earliest date for the completion of the construction of the facility is December 31, 2017, and the latest date for completion is December 31, 2022.

   B. The facility shall be constructed and located at the site as described in the application, in the City of Janesville, Rock County, Wisconsin.

   C. The construction permit authorizes the applicant to construct the facility described in the application and the hearing record, in accordance with the principal architectural and engineering criteria and environmental protection commitments set forth therein.

   D. The permit is subject to, and SHINE shall comply with, the conditions specified and incorporated below:

      (1) Prior to the completion of construction, SHINE shall submit periodic reports to the NRC, at intervals not to exceed six months from the date of this permit, providing the following information related to nuclear criticality safety and radiation protection:

APPENDIX A

TO FACILITY CONSTRUCTION PERMIT NO. CPMIF-001

SHINE MEDICAL TECHNOLOGIES, LLC

MEDICAL ISOTOPE PRODUCTION FACILITY

DOCKET NO. 50-608

ENVIRONMENTAL PROTECTION PLAN

(NONRADIOLOGICAL)

February 29, 2016

TABLE OF CONTENTS

1.0 Objective of the Environmental Protection Plan

The Environmental Protection Plan's (EPP) objective is to ensure compliance with the Endangered Species Act of 1973, as amended (ESA), and to ensure that the Commission is kept informed of other environmental matters. The EPP is intended to be consistent with Federal, State, and local requirements for environmental protection.

2.0 Environmental Protection Issues

In the Final Environmental Impact Statement (final EIS) dated October 2015, the NRC staff considered the environmental impacts associated with the construction, operation, and decommissioning of the proposed SHINE Medical Technologies, LLC (SHINE or the licensee) radioisotope production facility (SHINE facility). This EPP applies to SHINE's actions affecting the protected environmental resources evaluated in the final EIS and SHINE's actions that may affect any newly discovered protected environmental resources.

2.1 Ecological Resources Issues

Federal agencies other than the U.S. Nuclear Regulatory Commission (NRC), such as the U.S. Environmental Protection Agency and the U.S. Army Corps of Engineers, have jurisdiction to regulate aquatic resources under the Federal Water Pollution Control Act (Clean Water Act or CWA) and the Rivers and Harbors Appropriation Act of 1899 (RHA). Water quality environmental concerns identified in the final EIS including mitigation measures would be regulated under SHINE's CWA permits, such as the National Pollutant Discharge Elimination System. Nothing within this EPP shall be construed to place additional requirements on the regulation of aquatic resources.

The U.S. Fish and Wildlife Service (FWS) regulates matters involving migratory birds and their nests in accordance with the Migratory Bird Treaty Act. The FWS also regulates matters involving the protection and taking of bald and golden eagles in accordance with the Bald and Golden Eagle Protection Acts.

SHINE shall inform the NRC of events or situations concerning aquatic or terrestrial resources for which a news release is planned or notification to other government agencies has been or will be made. These notifications shall be made to the NRC Operations Center within four hours of discovery.

2.2 Endangered Species Act of 1973

The NRC may be required to protect some aquatic resources and terrestrial resources in accordance with the Endangered Species Act of 1973 (ESA). If any Federally listed species or critical habitat occurs in an area affected by construction of the facility that was not previously identified as occurring in such areas, including species and critical habitat that were not previously Federally listed, the licensee shall inform the NRC within four hours of discovery. Similarly, the licensee shall inform the NRC within four hours of discovery of any take, as defined in the ESA, of a Federally listed species or destruction or adverse modification of critical habitat. These notifications shall be made to the NRC Operations Center. The licensee shall provide any necessary information to the NRC if the NRC initiates or reinitiates consultation under the ESA.