

**MEMORANDUM OF AGREEMENT  
BETWEEN THE U.S. DEPARTMENT OF ENERGY/NATIONAL NUCLEAR SECURITY  
ADMINISTRATION'S OFFICE OF DEFENSE NUCLEAR NONPROLIFERATION AND THE  
U.S. NUCLEAR REGULATORY COMMISSION'S OFFICE OF NUCLEAR REACTOR  
REGULATION ON THE ENVIRONMENTAL REVIEW RELATED TO THE ISSUANCE OF AN  
AUTHORIZATION TO OPERATE SHINE MEDICAL TECHNOLOGIES, LLC MEDICAL  
ISOTOPE PRODUCTION FACILITY**

The U.S. Department of Energy/National Nuclear Security Administration (DOE/NNSA) and the U.S. Nuclear Regulatory Commission (NRC), as parties to this Memorandum of Agreement (MOA), hereby acknowledge and declare as follows. This MOA replaces in its entirety the previous "Memorandum of Agreement between the U.S. Department of Energy/National Nuclear Security Administration's Office of Defense Nuclear Nonproliferation and the U.S. Nuclear Regulatory Commission's Office of Nuclear Reactor Regulation on the Environmental Review Related to the Issuance of Authorizations to Construct and Operate SHINE Medical Technologies, Inc. Facility," dated February 3, 2015 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML13304B642).

**I. Introduction**

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

The DOE/NNSA and NRC developed this MOA to establish a cooperating agency relationship for environmental reviews and to streamline the respective processes regarding the regulatory requirements associated with the operation of the SHINE facility.

**II. Purpose and Background**

The purpose of this MOA is to establish a framework for early coordination and participation among the signatories to this agreement to support common goals in furthering each agency's regulatory responsibilities. The MOA signatories will comply with the requirements of the National Environmental Policy Act of 1969 (NEPA) and other related statutes in connection with the environmental review related to any DOE/NNSA and NRC decisions regarding the SHINE facility.

In 2013, SHINE (at the time known as SHINE Medical Technologies, Inc.) submitted an application to the NRC for a construction permit for the SHINE facility, which included an environmental report (ADAMS Accession No. ML13172A324).<sup>1</sup> Following the completion

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<sup>1</sup> A final version of the application, including the environmental report, was submitted in 2015 (ADAMS Accession No. ML15258A431; also available at <https://www.nrc.gov/info-finder/nonpower/shine-medical-tech.html>).

of its review of the application, the NRC issued the requested construction permit to SHINE on February 29, 2016 (ADAMS Accession No. ML16041A471), as supported by NUREG-2189, "Safety Evaluation Report Related to SHINE Medical Technologies, Inc. Construction Permit Application for a Medical Radioisotope Production Facility," dated August 2016 (ADAMS Accession No. ML16229A140), and NUREG-2183, "Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility," dated October 2015 (ADAMS Accession No. ML15288A046). On July 17, 2019, SHINE submitted an application to the NRC for an operating license for the SHINE facility, which included a supplement to the environmental report provided as part of the construction permit application (ADAMS Accession No. ML19211C143). SHINE subsequently supplemented its operating license application on November 14, 2019 to address design changes and correct administrative errors (ADAMS Accession No. ML19331A832).

Both agencies have responsibilities under NEPA to analyze the environmental impacts of their respective actions. This MOA designates the NRC as the lead agency and the DOE/NNSA as a cooperating agency in the development of a supplement to NUREG-2183, herein referred to as a supplemental environmental impact statement (SEIS), for both agencies' reviews of the SHINE operating license application. Consistent with 10 CFR 51.95(b), the SEIS will only cover matters that differ from NUREG-2183 or that reflect significant new information concerning matters discussed in NUREG-2183. However, circumstances may arise where both agencies will be better served by a different form of coordination, such as if each agency needs to prepare its own environmental review document. This MOA does not preclude such arrangements.

### III. Authority

- A. **The Atomic Energy Act of 1954 (42 USC 2011 *et seq.*)** is the fundamental United States (U.S.) law on both the civilian and the military uses of nuclear materials. Pursuant to Chapters 6, 7, 8, 10, and 16 of the Act and the rules and regulations issued pursuant thereto, the NRC is authorized to license and regulate the construction and operation of, among other things, production and utilization facilities from the standpoint of promoting the common defense and security and protecting public health and safety and the environment.
- B. **NEPA (42 USC § 4321 *et seq.*)** requires all agencies of the Federal government to prepare a detailed statement for major Federal actions significantly affecting the quality of the human environment that includes discussion of the environmental impact of the proposed action, adverse environmental effects which cannot be avoided should the proposal be implemented, and alternatives to the proposed action.
- C. **The Energy Reorganization Act of 1974 (42 USC § 5801 *et seq.*)** abolished the Atomic Energy Commission, reorganizing certain functions of the federal government into a new Energy Research and Development Administration (ERDA) and NRC. Specifically, Section 201 of the Act established the NRC and transferred to the NRC all the licensing and related regulatory functions of the Atomic Energy Commission. Section 101 of the Act established ERDA which became the Department of Energy with the passage of the Department of Energy Act of 1977

(42 USC § 7101 *et seq.*). The mission of the Department of Energy is to ensure America's security and prosperity by addressing its energy, environmental, and nuclear challenges through transformative science and technology solutions.

- D. The National Nuclear Security Administration Act (50 U.S.C. § 2401 *et seq.*)** established the NNSA as a semi-autonomous agency within the DOE. The NNSA is responsible for the management and security of the nation's nuclear weapons, nuclear nonproliferation, and naval reactors programs.
- E. American Medical Isotopes Production Act of 2012 (42 USC § 2065)** directs DOE to establish sustainable domestic production of Mo-99 for medical use by carrying out a technology-neutral program to support non-federal entities in the U.S. in developing capabilities to produce Mo-99 without the use of highly enriched uranium (HEU). The Act directs the DOE and NRC to ensure, to the maximum extent practicable, that environmental reviews for facilities to produce medical isotopes are complementary and not duplicative.

#### **IV. Roles and Responsibilities**

**DOE/NNSA.** The DOE/NNSA, through the Office of Material Management and Minimization, has awarded cooperative agreements to multiple commercial entities, including SHINE, to accelerate establishing reliable domestic supplies of Mo-99 to meet U.S. medical needs. The DOE/NNSA provided financial assistance for the early stages of the SHINE project, primarily for research and development. The DOE/NNSA has not provided financial assistance for the construction or operation of the SHINE facility. While there is currently no proposal before the DOE/NNSA regarding financial support for the construction or operation of the SHINE facility, it is possible that the DOE/NNSA could receive such a proposal in the future. Additionally, the DOE/NNSA served as a cooperating agency with respect to the final 2015 environmental impact statement for construction of the SHINE facility. For these reasons and in accordance with the American Medical Isotopes Production Act of 2012, the DOE/NNSA is acting as cooperating agency for the preparation of the SEIS for the SHINE operating license application.

**NRC.** Through its role as the regulator for civilian use of radioactive materials, the NRC is responsible for the preparation of the evaluation and decisions regarding whether to license production and utilization facilities, such as those comprising the SHINE facility.

**NRC as NEPA Lead Federal Agency.** NEPA requires public disclosure and consideration by the federal agency of the potential environmental impacts, unavoidable adverse environmental effects, and alternatives to the proposed action, before irrevocable commitments of resources are made. This agreement supports these principles and the NRC and the DOE/NNSA acknowledge their respective responsibilities for complying with the requirements of NEPA. To prevent the duplication of efforts by Federal agencies and to further support integration of agency processes, NEPA allows for the designation of a lead Federal agency for the preparation of environmental impact statements. Other agencies that have an action on the same project may serve as cooperating agencies on the environmental impact statement.<sup>2</sup>

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<sup>2</sup> See 10 CFR 51.10(b)(2); 40 CFR 1501.5; 40 CFR 1501.6.

As the agency with the approval/disapproval authority for the licensing of production and utilization facilities under Sections 103 and 104 of the Atomic Energy Act, the NRC shall serve as the lead agency for the preparation of the SEIS for the SHINE operating license application. This MOA encourages early involvement among the NRC, the DOE/NNSA, the public, and other government agencies during the NEPA evaluation process.

This MOA acknowledges that it is critically important to an efficient environmental review procedure that the NRC and the DOE/NNSA share project-specific information on the potential environmental impacts of operating the proposed SHINE facility. Documentation shall be developed in accordance with the Parties' disclosure and decision-making procedures. This Agreement establishes a process to facilitate timely preparation of the SEIS in connection with the SHINE operating license application, whereby both agencies will do the following:

- Work together and consider input from the applicant and other stakeholders, as appropriate.
- Identify and resolve issues as quickly as possible.
- Attempt to build a consensus among governmental agencies and their stakeholders.
- Provide for the effective and efficient environmental review of the SHINE operating license application.

**Project Coordination.** As the lead agency under NEPA, the NRC is responsible for determining the purpose and need of the project for purposes of the SEIS and the NRC's licensing process. The DOE/NNSA may also draft a statement of the secondary purpose and need of the project for purposes of the DOE/NNSA's involvement in the project pursuant to the American Medical Isotopes Production Act of 2012, for inclusion in the SEIS. The NRC should coordinate early on the scope of the NEPA analysis for all activities under Federal purview and ensure that the purpose and need, the suite of alternatives, and the evaluation presented in the SEIS adequately reflect the views of the DOE/NNSA. The DOE/NNSA will complete an independent decision in carrying out its responsibilities, as necessary.

**Specific Agency Roles.** The NRC and the DOE/NNSA may develop additional guidance to ensure that the preparation of the SEIS is coordinated so as not to impair schedule to the maximum extent practicable. When the NRC provides to the DOE/NNSA its preliminary draft environmental review documents, the DOE/NNSA shall review and provide written comments on the relevant portions of those documents, as appropriate, in accordance with the timelines established. NRC preliminary draft environmental review documents may include advance copies of the purpose and need section, as well as advance copies of the draft and final SEIS. The DOE/NNSA's reviews of NRC preliminary draft environmental review documents will be completed and coordinated with the NRC as stated in the NRC SEIS schedule for this project. Each agency has responsibility for its own decision document, if necessary. Upon completion of the final SEIS, the

DOE/NNSA will commence its process for considering adoption of the SEIS or completing any required additional NEPA reviews in accordance with agency regulations and policy.

The DOE/NNSA and the NRC hereby agree to work with each other to ensure that timely decisions with respect to the preparation of the SEIS are made and that the responsibilities of each agency are met. Specifically, each agency agrees to do the following:

**A. Communication**

1. The agencies agree to communicate throughout the environmental review process to ensure that issues are raised as soon as possible and shared between both agencies. The NRC will coordinate and share information with all relevant participating agencies.
2. The agency contacts are the following:

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3. Each agency agrees to meet with the applicant and other agencies, when requested by the applicant, the NRC, or the DOE/NNSA, to identify areas of potential concern and to assess the need for and availability of agency resources to address issues related to the environmental review of the SHINE operating license application. If the NRC is not involved in a meeting, the DOE/NNSA will inform the NRC of any significant results from the meeting.
4. The DOE/NNSA shall consult with the NRC, as the lead agency, regarding the schedule for the review. Regarding this schedule, the NRC and the DOE/NNSA will strive to ensure that their review activities occur on a concurrent, rather than sequential, basis, with the objective of avoiding unnecessary delays in the process and the schedule established by the NRC. If at any point during the consultation process the DOE/NNSA or the NRC anticipates an inability to comply with the agreed-upon schedule, it will communicate the reason for this inability to the other agency as soon as possible. The agencies will then work together to help mitigate the impacts of the anticipated delay when appropriate.

**B. Proactive Participation.** As soon as possible after this MOA is signed, the DOE/NNSA will do the following:

1. Identify the issues and concerns related to the proposed project that need to be addressed in the SEIS for the DOE/NNSA to meet its obligations.
2. Identify issues and concerns and attempt to resolve them while draft documentation is being developed.

**C. Sharing of Data.** The agencies will share the information gathered, considered, and relied upon by each of them with all other relevant agencies. Specifically, the NRC and the DOE/NNSA agree to do the following:

1. Cooperate in the preparation of requests for additional information, studies, or data to avoid duplicative requests and to compile a consistent set of information on which all of the agencies will rely.
2. Cooperate in identifying and developing the information at the level of detail required to complete the environmental review.

The NRC will be responsible for drafting sections of the SEIS (and requesting additional information as necessary) that specifically relate to NRC activities that do not require the DOE/NNSA's involvement. The DOE/NNSA will be responsible for drafting sections of the SEIS (and requesting additional information as necessary) that specifically relate to DOE/NNSA activities that do not require the NRC's involvement. In areas where both agencies may have involvement, if the DOE/NNSA believes that additional analysis is needed, but the NRC does not agree that such analysis would be required under the regulatory procedures of the NRC, such analysis will be the responsibility of the DOE/NNSA. The NRC will assemble the draft and final SEIS with DOE/NNSA-specific sections prepared by the DOE/NNSA. The NRC will ask the DOE/NNSA to concur on the draft and final SEIS.

- D. Hearings.** On request, each agency will participate in any public meetings or hearings held by the other agency related to the environmental review. Particularly in the case of NRC adjudicatory hearings, the DOE/NNSA may provide expert testimony, as required, in those areas or sections covered in the SEIS in whose preparation the DOE/NNSA participated and in those areas of special DOE/NNSA expertise. The DOE/NNSA's participation in the NRC adjudicatory hearing process will be consistent with all relevant laws and regulations and coordinated with appropriate representatives.

## **V. Administration of the MOA**

- A.** While retaining ultimate responsibility for making determinations and exercising their individual responsibilities in accordance with existing statutory responsibilities, the NRC and the DOE/NNSA will consult with one another to resolve disputes using existing dispute resolution methods and in accordance with this agreement. If no agreement can be reached, either of the agencies may refer the matter to the Council on Environmental Quality in accordance with 40 CFR Part 1504, "Predecision Referrals to the Council of Proposed Federal Actions Determined to Be Environmentally Unsatisfactory." Notwithstanding any such referral, the NRC reserves the right to make a final decision on any matter within the NRC's regulatory authority.
- B.** This MOA may be modified, amended, or terminated upon written request of any party hereto and the subsequent written concurrence of the other party. Termination hereunder may become effective no earlier than 60 days after providing written notice of such termination to the non-terminating party.
- C.** The NRC and the DOE/NNSA acknowledge that the MOA does not alter the authority and responsibilities of the parties under their respective jurisdictions.
  - 1. This MOA is intended only to establish a strong working relationship between the participating agencies in connection with expeditious decisions with regard to an operating license application filed in connection with the SHINE facility and is not intended to, nor does it create, any right, benefit, or trust

responsibility, substantive or procedural, enforceable at law or equity by any person or party against the U.S., its agencies, its officers, or any other person.

2. This MOA is to be construed in a manner consistent with all applicable laws and regulations.
3. Neither this MOA nor any individual provision of this MOA shall be deemed to restrict, modify, or otherwise limit the application or enforcement of any laws of the U.S. with respect to matters specified herein, nor shall anything in the MOA be construed as modifying the existing authority of either agency.
4. The participating agencies intend to carry out fully the terms of this MOA. All provisions in this MOA, however, are subject to the availability of resources and appropriated funds. In addition, this MOA does not limit the ability of any of the participating agencies to review and respond to final applications.
5. If the applicant or other person makes a request under the Data Quality Act for a correction of information, the agency that disseminated the information will be responsible for processing the request.
6. This MOA cannot be used to obligate or commit funds or as the basis for the transfer of funds.
7. Nothing in this MOA, in and of itself, requires any signatory agency to enter into any contract, grant, or interagency agreement.

ACCORDINGLY, the parties have signed this MOA on the dates set forth below, to be effective for all purposes as of the date last signed. The signatures may be executed using counterpart original documents.

Original signed by J. Halse

Original signed by R. Taylor



**Jessica Halse**  
**Assistant Deputy Administrator for**  
**Material Management and Minimization**  
**National Nuclear Security Administration**

6/11/2020  
Date

  
**Robert M. Taylor**  
**Deputy Director**  
**Office of Nuclear Reactor Regulation**  
**U.S. Nuclear Regulatory Commission**

6/18/2020  
Date