

**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**

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:

I. Introduction

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 construction and operation of SHINE Medical Technologies, Inc.'s (SHINE) proposed medical isotope production facility.

II. Purpose

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 preparation of environmental review documents involving the DOE's and the NRC's decisions regarding SHINE's proposed facility.

On March 26, 2013, SHINE submitted part one of a two-part application to the NRC for a construction permit for a medical isotope production facility in Janesville, Wisconsin (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14052A349). This submittal included SHINE's environmental report. The NRC accepted part one of the construction permit application on July 1, 2013 (78 FR 39342). Both agencies have responsibilities under NEPA to analyze the environmental impacts of their respective actions. This MOA is intended to designate NRC as the lead agency and DOE-NNSA as a cooperating agency in the development of a single environmental impact statement (EIS) for both agencies' reviews. 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. Statutory Background

A. The Atomic Energy Act of 1954 (42 USC 2011 *et seq.*) is the fundamental U.S. law on both the civilian and the military uses of nuclear materials. Pursuant to the Atomic Energy Act of 1954, as amended (42 U.S.C. §§ 2011 *et seq.*),

Chapters 6, 7, 8, 10, and 16; 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 and alternatives to the proposed action.¹
- 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 Nuclear Regulatory Commission (NRC). Section 201 of that Act established the NRC and transferred to the NRC all the licensing and related regulatory functions of the Atomic Energy Commission. Section 101 of that 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 reactor programs.
- E. American Medical Isotopes Production Act of 2012 (42 USC § 2065 et. seq.)** directs DOE to establish sustainable domestic production of molybdenum-99 (Mo-99) for medical use by carrying out a technology-neutral program to support non-federal entities in the United States 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

NRC. Through its role as the regulator for civilian applications of nuclear power and non-power reactors, isotope enrichment facilities, nuclear medicine, industrial and research applications of radioisotopes, and radioactive waste disposal, the NRC is responsible for the preparation of the analysis and decisions regarding whether to license production and utilization facilities.

¹ 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," Subpart A, "National Environmental Policy Act—Regulations Implementing Section 102(2)"

DOE and NNSA. The NNSA, through the Office of Nuclear Nonproliferation's Global Threat Reduction Initiative, has awarded cooperative agreements to four commercial entities to accelerate the dual objectives of eliminating the use of proliferation-sensitive HEU in the production of medical isotopes and establishing reliable domestic supplies of Mo-99 to meet U.S. medical needs. As such, DOE-NNSA is responsible for ensuring appropriate completion of these objectives by the awardees.

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 irretrievable commitments of resources are made. This agreement supports these principles, and the NRC and 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 EISs. Other agencies that have an action on the same project may serve as cooperating agencies on the EIS.²

As the agency with the approval/disapproval authority for the licensing of production and utilization facilities, including SHINE, the NRC shall serve as the lead agency for the preparation of the EIS. This MOA encourages early involvement among the NRC, DOE, the public, and other government agencies during the NEPA evaluation process.

This MOA acknowledges that it is critically important for an efficient environmental review procedure that the NRC and DOE-NNSA share project-specific information on the potential environmental impacts of building and 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 environmental review document in connection with the SHINE facility, 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 for the SHINE facility.

²

Title 10 of the *Code of Federal Regulations* (CFR), Part 51.10(b)(2), "Purpose and scope of subpart; application of regulations of Council on Environmental Quality"; 40 CFR 1501.5, "NEPA and Agency Planning—Lead Agencies"; 40 CFR 1501.6, "NEPA and Agency Planning—Cooperating Agencies"

Project Purpose and Need Coordination. As the lead agency under NEPA, the NRC is responsible for determining the purpose and need of the project for purposes of the NRC's environmental review document and the NRC licensing process. DOE-NNSA may also draft a statement of the secondary purpose and need of the project for purposes of DOE-NNSA's involvement in the project pursuant to the American Medical Isotopes Production Act of 2012, for inclusion in the environmental review document. 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 NEPA document adequately reflect the views of the DOE-NNSA. The DOE-NNSA will complete an independent decision in carrying out its responsibilities.

Specific Agency Roles. The NRC and the DOE-NNSA may develop additional guidance to ensure that preparation of the EIS 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. Preliminary draft NRC NEPA documents include advance copies of the purpose and need sections, as well as advance copies of the draft and final environmental review documents. DOE-NNSA's reviews of NRC NEPA documents will be completed and coordinated with the NRC as stated in the NRC EIS schedule for this project. Each agency has responsibility for its own decision document. Upon completion of the final NEPA analysis, DOE will commence its process for considering adoption of the EIS, after which a record of decision may be prepared.

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 environmental review document are made and that the responsibilities of each agency are met. Specifically, each agency agrees to do the following:

A. Commit to Early Involvement

1. Conduct an early initial review. As soon as practicable.
2. Identify cooperating agency contacts for the proposed project. The agency contacts are the following:

U.S. Department of Energy
Ms. Rilla Hamilton, Mo-99 Program Manager
National Nuclear Security Administration
U.S. Department of Energy
1000 Independence Ave., SW
Washington, DC 20585
202-586-3354
Rilla.Hamilton@nnsa.doe.gov

Mr. Jeff Robbins, NEPA Compliance Officer
National Nuclear Security Administration
U.S. Department of Energy
P.O. Box 5400
Albuquerque, NM 87185
505-845-4426
Joseph.Robbins@nnsa.doe.gov

U.S. Nuclear Regulatory Commission
Mr. David Wrona, Chief
Environmental Review and Guidance
Update Branch
Division of License Renewal
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
301-415-2292
David.Wrona@nrc.gov

Ms. Michelle Moser, Project Manager
Environmental Review and Guidance
Update Branch
Division of License Renewal
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
301-415-6509
Michelle.Moser@nrc.gov

3. Meet with the applicant and other agencies, when requested by the applicant, the NRC, or 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 proposed project. If the NRC is not involved in a meeting, the DOE-NNSA will inform the NRC of any significant results from the meeting.
4. DOE-NNSA shall consult with the NRC, as the lead agency, regarding the schedule for the review. Regarding this schedule, the NRC and 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 and inform the NRC and the applicant which statutes, regulations, and policies apply to the DOE-NNSA process.
2. Identify the issues and concerns related to the proposed project that need to be addressed in the environmental review document in order for the DOE-NNSA to meet its obligations.
3. 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 EIS (and requesting additional information as necessary) that specifically relate to NRC activities that do not require DOE-NNSA's involvement. The DOE-NNSA will be responsible for drafting sections of the EIS (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 EIS with DOE-specific sections prepared by the DOE-NNSA. The DOE-NNSA will be asked to concur on the draft and final EIS.

D. Communicate informally. The agencies agree to communicate informally with each other throughout the environmental review document preparation 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.

Hearings. On request, each agency will participate in any public meetings or hearings³ held by the other agency related to the environmental review.

³

The Atomic Energy Act requires that a public hearing be held before a construction permit is issued for a Section 103 medical isotope production facility. The hearing will be conducted by the Commission or by a

Particularly in the case of NRC adjudicatory proceedings, the DOE-NNSA may provide expert testimony, as required, in those areas or sections covered in the NRC EIS in whose preparation the DOE-NNSA participated and in those areas of special DOE-NNSA expertise. The DOE-NNSA's participation in the NRC 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 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.** NRC and 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 applications 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 United States, 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. The MOA neither expands nor is in derogation of those powers and authorities vested in the participating agencies by applicable laws, statutes, or regulations.
 - 4. The terms of this MOA are not intended to be enforceable by any party other than the signatories hereto.

5. The participating agencies intend to carry out fully the terms of this MOA. All provisions in this MOA, however, are subject to available resources and funds. In addition, this MOA does not limit the ability of any of the participating agencies to review and respond to final applications.
6. If the applicant or other person requests a correction of information disseminated pursuant to this MOA, as authorized by Section 3516(b)(2)(B) of Title 44, United States Code, the process by which such request will be addressed will be that established by the agency that disseminated the information.
7. This MOA cannot be used to obligate or commit funds or as the basis for the transfer of funds.
8. Nothing in this MOA, in and of itself, requires any signatory agency to enter into any contract, grant, or interagency agreement.
9. All provisions in this MOA are subject to the availability of funds.

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 A. Harrington

Original signed by W.

Anne Harrington
Deputy Administrator for Defense
Nuclear Nonproliferation
National Nuclear Security Administration
U.S. Department of Energy

William M. Dean
Director
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission

November 20, 2014
Date

February 3, 2015
Date