

**NUCLEAR REGULATORY COMMISSION**

**[Docket No. 50-608; NRC-2013-0053]**

**SHINE Medical Technologies, Inc.; Notice of Hearing**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Construction permit application; Notice of hearing.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC or the Commission) will convene an evidentiary session to receive testimony and exhibits in the uncontested proceeding regarding the application from SHINE Medical Technologies, Inc. (SHINE), for a construction permit (CP) to construct a medical radioisotope production facility in Janesville, Wisconsin. This mandatory hearing will consider safety and environmental matters relating to the requested CP.

**DATES:** The hearing will be held on December 15, 2015, beginning at 9:00 a.m. Eastern Time. For the schedule for submitting pre-filed documents and deadlines affecting Interested Government Participants, see Section VI of the **SUPPLEMENTARY INFORMATION** section of this document.

**ADDRESSES:** Please refer to Docket ID 50-608 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- **NRC's Electronic Hearing Docket:** You may obtain publicly available documents related to this hearing on line at <http://www.nrc.gov/about-nrc/regulatory/adjudicatory.html>.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[ADAMS Public Documents](#)," and then select "[Begin Web-based ADAMS Search](#)." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The ADAMS accession number for each document referenced (if that document is available in ADAMS) is provided the first time that a document is referenced.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

**FOR FURTHER INFORMATION CONTACT:** Denise McGovern, Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-0681; e-mail: [Denise.McGovern@nrc.gov](mailto:Denise.McGovern@nrc.gov).

**SUPPLEMENTARY INFORMATION:**

**I. BACKGROUND**

The Commission hereby gives notice that, pursuant to Section 189a of the Atomic Energy Act (AEA) of 1954, as amended (the Act), it will convene an evidentiary session to receive testimony and exhibits in the proceeding regarding the SHINE application for a CP

under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), to construct a medical radioisotope production facility in Janesville, Wisconsin.

Part one of the SHINE's CP application was submitted by letter dated March 26, 2013 (ADAMS Accession No. ML13088A192), and by letter dated May 31, 2013 (ADAMS Accession No. ML13172A361), SHINE submitted the second and final part of its two-part application for a CP. By letter dated September 25, 2013 (ADAMS Accession No. ML13269A378), SHINE supplemented this submission with a discussion of preliminary plans for coping with emergencies, as required by 10 CFR 50.34(a)(10), completing its application for a CP. The construction permit application, including the environmental report, may be viewed in its entirety at ADAMS Accession No. ML13172A324. This mandatory hearing will concern safety and environmental matters relating to the requested CP application, as more fully described below.

## **II. EVIDENTIARY UNCONTESTED HEARING**

The Commission will conduct this hearing beginning at 9:00 a.m., Eastern Time on December 15, 2015, at the Commission's headquarters in Rockville, Maryland. The hearing will continue on subsequent days, if necessary.

## **III. PRESIDING OFFICER**

The Commission is the presiding officer for this proceeding.

## **IV. MATTERS TO BE CONSIDERED**

The matter at issue in this proceeding is whether the review of the SHINE CP application by the Commission's staff has been adequate to support the findings found in 10 CFR 50.35, 50.40, 50.50, and 10 CFR 51.105. Those findings are as follows:

## **Issues Pursuant to the Atomic Energy Act of 1954, as Amended**

With respect to the CP: (1) whether 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; (2) whether 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 (3) whether safety features or components, if any, which require research and development have been described by the applicant and the applicant has identified, and there will be conducted, a research and development program reasonably designed to resolve any safety questions associated with such features or components; (4) whether 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 completion of construction of the proposed facility and (ii) taking into consideration the site criteria contained in 10 CFR part 100, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public; (5) whether there is reasonable assurance (i) that the construction of the facility will not endanger the health and safety of the public, and (ii) that construction activities can be conducted in compliance with the Commission's regulations; (6) whether the applicant is technically and financially qualified to engage in the proposed activities in accordance with the Commission's regulations in chapter I of title 10 of the CFR; (7) whether the issuance of a permit for the construction of the facility to the applicant will not, in the opinion of the Commission, be inimical to the common defense and security or to the health and safety of the public; and (8) whether the application meets the standards and requirements of the AEA and the Commission's regulations, and that notifications, if any, to other agencies or bodies have been duly made.

## **Issues Pursuant to the National Environmental Policy Act (NEPA) of 1969**

With respect to the CP: (1) determine whether the requirements of Sections 102(2)(A), (C), and (E) of NEPA and the applicable regulations in 10 CFR part 51 have been met; (2) independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken; (3) determine, after weighing the environmental, economic, technical, and other benefits against environmental and other costs, and considering reasonable alternatives, whether the construction permit should be issued, denied, or appropriately conditioned to protect environmental values; and (4) determine whether the NEPA review conducted by the NRC staff has been adequate.

### **V. SCHEDULE FOR SUBMITTAL OF PRE-FILED DOCUMENTS**

No later than November 24, 2015, unless the Commission directs otherwise, the NRC staff and the applicant shall submit a list of its anticipated witnesses for the hearing.

No later than November 24, 2015, unless the Commission directs otherwise, the applicant shall submit its pre-filed written testimony. The NRC staff submitted its pre-filed testimony on October 23, 2015.

The Commission may issue written questions to the applicant or the NRC staff before the hearing. If such questions are issued, an order containing such questions will be issued no later than November 10, 2015. Responses to such questions are due November 24, 2015, unless the Commission directs otherwise.

### **VI. INTERESTED GOVERNMENT PARTICIPANTS**

No later than November 9, 2015, any interested State, local government body, or Federally-recognized Indian tribe may file with the Commission a statement of any issues or

questions that the State, local government body, or Indian tribe wishes the Commission to give particular attention as part of the uncontested hearing process. Such statement may be accompanied by any supporting documentation that the State, local government body, or Indian tribe sees fit to provide. Any statements and supporting documentation (if any) received by the Commission using the agency's E-filing system<sup>1</sup> by the deadline indicated above will be made part of the record of the proceeding. The Commission will use such statements and documents as appropriate to inform its pre-hearing questions to the NRC staff and applicant, its inquiries at the oral hearing, and its decision following the hearing. The Commission may also request, prior to November 17, 2015, that one or more particular States, local government bodies, or Indian tribes send one representative each to the evidentiary hearing to answer Commission questions and/or make a statement for the purpose of assisting the Commission's exploration of one or more of the issues raised by the State, local government body, or Indian tribe, in the pre-hearing filings described above. The decision whether to request the presence of a representative of a State, local government body, or Indian tribe at the evidentiary hearing to make a statement and/or answer Commission questions is solely at the Commission's discretion. The Commission's request will specify the issue or issues that each representative should be prepared to address.

Many of the procedures and rights applicable to the inherently adversarial nature of NRC's contested hearing process are not available in this uncontested hearing. Participation in the NRC's contested hearing process is governed by 10 CFR 2.309 (for persons or entities,

---

<sup>1</sup> The process for accessing and using the agency's E-filing system is described in the March 12, 2015, notice of hearing (80 FR 13036) that was issued by the Commission for this proceeding. Participants who are unable to use the electronic information exchange (EIE), or who will have difficulty complying with EIE requirements in the time frame provided for submission of written statements, may provide their statements by electronic mail to [hearingdocket@nrc.gov](mailto:hearingdocket@nrc.gov).

including a State, local government, or Indian tribe seeking to file contentions of their own) and 10 CFR 2.315(c) (for an interested State, local government, or Federally-recognized Indian tribe seeking to participate with respect to contentions filed by others). Participation in this uncontested hearing does not affect the right of a State, a local government, or an Indian tribe to participate in the separate contested hearing process.

Dated at Rockville, Maryland, this 27th day of October, 2015.

For the Nuclear Regulatory Commission.

*/RA/*

Annette L. Vietti-Cook,  
Secretary of the Commission.