

**NUCLEAR REGULATORY COMMISSION**

**10 CFR Part 50**

**[NRC-2013-0053]**

**RIN 3150-AJ18**

**Definition of a Utilization Facility**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to add SHINE Medical Technologies, Inc.'s (SHINE) proposed accelerator-driven subcritical operating assemblies to the NRC's definition of a "utilization facility." In 2013, SHINE submitted a two-part construction permit application for a medical radioisotope production facility that SHINE proposes to build in Janesville, Wisconsin. The proposed accelerator-driven subcritical operating assemblies, to be housed in SHINE's irradiation facility, would be used to produce molybdenum-99 (Mo-99), a radioisotope used in medical imaging. This rule allows NRC staff to conduct an efficient and effective licensing review of the SHINE construction permit application and any subsequent operating license application.

**DATES:** Submit comments by **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the NRC staff is able to ensure consideration only for comments received on or before this date.

**ADDRESSES:** You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2013-0053. Address questions about NRC dockets to Carol Gallagher; telephone: 301-287-3422; e-mail: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov). For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.
- **E-mail comments to:** [Rulemaking.Comments@nrc.gov](mailto:Rulemaking.Comments@nrc.gov). If you do not receive an automatic e-mail reply confirming receipt, then contact us at 301-415-1677.
- **Fax comments to:** Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.
- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.
- **Hand deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301-415-1677.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the SUPPLEMENTARY INFORMATION section of this document.

**FOR FURTHER INFORMATION CONTACT:** Steven Lynch, Office of Nuclear Reactor Regulation; telephone: 301-415-1524, e-mail: [Steven.Lynch@nrc.gov](mailto:Steven.Lynch@nrc.gov); U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

**SUPPLEMENTARY INFORMATION:**

## I. Obtaining Information and Submitting Comments.

### A. Obtaining Information

Please refer to Docket ID NRC-2013-0053 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2013-0053.

- **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 it is available in ADAMS) is provided the first time that it is mentioned in the SUPPLEMENTARY INFORMATION section. SHINE's construction permit application, submitted May 31, 2014, is publicly available in ADAMS, Accession No. ML13172A324.

- **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.

### B. Submitting Comments

Please include Docket ID NRC-2013-0053 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <http://www.regulations.gov> as well as enter the comment submissions into ADAMS, and the NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

## **II. Procedural Background.**

Because the NRC considers this action to be non-controversial, the NRC is publishing this proposed rule concurrently as a direct final rule in the Rules and Regulations section of this issue of the *Federal Register*. The direct final rule will become effective on **[INSERT DATE 75 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. However, if the NRC receives significant adverse comments on this proposed rule by **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**, then the NRC will publish a document that withdraws the direct final rule. If the direct final rule is withdrawn, the NRC will address the comments received in response to these proposed revisions in a subsequent final rule. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action in the event the direct final rule is withdrawn.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

a) The comment causes the NRC staff to reevaluate (or reconsider) its position or conduct additional analysis;

b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

c) The comment raises a relevant issue that was not previously addressed or considered by the NRC staff.

2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

3) The comment causes the NRC staff to make a change (other than editorial) to the rule.

For procedural information and the regulatory analysis, see the direct final rule published in the Rules and Regulations section of this issue of the *Federal Register*.

### **III. Plain Writing.**

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, well-organized manner that also follows other best practices appropriate to the subject or field and the intended audience. The NRC has written this

document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, "Plain Language in Government Writing," published June 10, 1998 (63 FR 31883). The NRC requests comment on the proposed rule with respect to clarity and effectiveness of the language used.

### **List of Subjects in 10 CFR Part 50**

Antitrust, Classified information, Criminal penalties, Fire protection, Intergovernmental relations, Isotopes, Medical isotopes, Molybdenum-99, Nuclear materials, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements, Utilization facility.

For the reasons set out in this preamble and the preamble to the companion direct final rule being published concurrently with this proposed rule and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is proposing to adopt the following amendment to 10 CFR part 50.

### **PART 50 -- DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES**

1. The authority citation for part 50 is revised to read as follows:

**Authority:** Atomic Energy Act secs. 11, 102, 103, 104, 105, 147, 149, 161, 181, 182, 183, 186, 189, 223, 234 (42 U.S.C. 2014, 2132, 2133, 2134, 2135, 2167, 2169, 2201, 2231, 2232, 2233, 2236, 2239, 2273, 2282); Energy Reorganization Act secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); Nuclear Waste Policy Act sec. 306 (42 U.S.C. 10226); Government

Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. 109–58, 119 Stat. 194 (2005). Section 50.7 also issued under Pub. L. 95–601, sec. 10, as amended by Pub. L. 102–486, sec. 2902 (42 U.S.C. 5851). Section 50.10 also issued under Atomic Energy Act secs. 101, 185 (42 U.S.C. 2131, 2235); National Environmental Policy Act sec. 102 (42 U.S.C. 4332). Sections 50.13, 50.54(d), and 50.103 also issued under Atomic Energy Act sec. 108 (42 U.S.C. 2138).

Sections 50.23, 50.35, 50.55, and 50.56 also issued under Atomic Energy Act sec. 185 (42 U.S.C. 2235). Appendix Q also issued under National Environmental Policy Act sec. 102 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204 (42 U.S.C. 5844). Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97–415 (42 U.S.C. 2239). Section 50.78 also issued under Atomic Energy Act sec. 122 (42 U.S.C. 2152). Sections 50.80 - 50.81 also issued under Atomic Energy Act sec. 184 (42 U.S.C. 2234).

2. In § 50.2, revise the definition of utilization facility to read as follows:

**§ 50.2 Definitions.**

\* \* \* \* \*

*Utilization facility* means: (1) any nuclear reactor other than one designed or used

primarily for the formation of plutonium or U-233; or (2) an accelerator-driven subcritical operating assembly used for the irradiation of materials containing special nuclear material and described in the application assigned docket number 50-608.

Dated at Rockville, Maryland, this \_\_\_\_\_ day of \_\_\_\_\_, 2014.

For the Nuclear Regulatory Commission,

---

Annette Vietti-Cook,  
Secretary of the Commission.