UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

SECRETARY

August 26, 2014

COMMISSION VOTING RECORD

DECISION ITEM: SECY-14-0061

TITLE: DIRECT FINAL RULE: ADDING SHINE MEDICAL TECHNOLOGIES, INC.'S ACCELERATOR-DRIVEN SUBCRITICAL OPERATING ASSEMBLY TO THE DEFINITION OF UTILIZATION FACILITY

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of August 26, 2014.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Macfarlane
Commissioner Svinicki
Commissioner Magwood
Commissioner Ostendorff
OGC
EDO
PDR

VOTING SUMMARY - SECY-14-0061

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MACFARLANE	X				X	7/20/14
COMR. SVINICKI	X				X	8/5/14
COMR. MAGWOOD	X				X	8/19/14
COMR. OSTENDORFF	X				X	8/7/14

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Chairman Allison M. Macfarlane

SUBJECT: SECY-14-0061 – DIRECT FINAL RULE: ADDING SHINE MEDICAL TECHNOLOGIES, INC.'S ACCELERATOR-DRIVEN SUBCRITICAL OPERATING ASSEMBLY TO THE DEFINITION OF UTILIZATION FACILITY

Approved XX Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached XX None ___

SIGNATURE

7/28/14

DATE

Entered on "STARS" Yes XX No ___

Chairman Macfarlane's Comments
SECY-14-0061, "Direct Final Rule: Adding Shine Medical Technologies, Inc.'s Accelerator-Driven Subcritical Operating Assembly to the Definition of Utilization Facility"

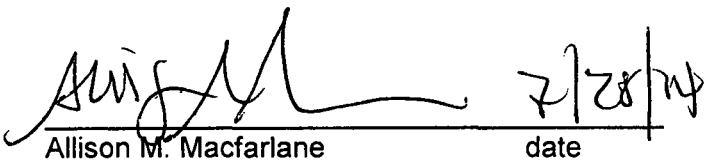
I commend the staff for their significant effort to identify an efficient licensing approach for applications for Molybdenum-99 production facilities. The American Medical Isotope Production Act established a technology-neutral program to support the production of Mo-99 for medical uses in the United States by non-federal entities. It also calls for the United States to phase out the export of highly enriched uranium for the production of medical isotopes. The responsibility to license the isotope production facilities falls on the Nuclear Regulatory Commission.

The question before the Commission is whether to approve a direct final rule to add the Shine Medical Technologies Inc.'s accelerator-driven subcritical operating assembly to the definition of utilization facility in 10 CFR 50.2. Shine Medical Technologies has advanced a design that includes the use of accelerator-driven subcritical generators to fission low-enriched uranyl sulfate solution that is maintained in a subcritical target chamber.

The Shine accelerator units, as stand-alone units, do not meet the definition of a production facility under Part 50. Additionally, because the accelerator units operate as subcritical units, they do not meet the definition of a reactor, and therefore do not meet the definition of a utilization facility. The current definition for a utilization facility under 10CFR50.2 is "any nuclear reactor other than one designed or used primarily for the formation of plutonium or U-233." Because the accelerator units are designed as subcritical components, they do not meet the definition of a reactor.

The staff critically analyzed the option of licensing the Shine accelerator units under Part 70 and concluded that, because of the differences between the Shine units and the facilities currently licensed under Part 70 and their similarities to research and test reactors, it would be more efficient to license them under part 50 as utilization facilities. I agree with the staff's conclusion.

Therefore, I approve the staff's recommendation to proceed to direct final rulemaking to include the Shine accelerator-driven subcritical operating assembly to the definition of utilization facilities.



Allison M. Macfarlane date

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER SVINICKI

SUBJECT: SECY-14-0061 – DIRECT FINAL RULE: ADDING SHINE MEDICAL TECHNOLOGIES, INC.'S ACCELERATOR-DRIVEN SUBCRITICAL OPERATING ASSEMBLY TO THE DEFINITION OF UTILIZATION FACILITY

Approved XX **Disapproved** _____ **Abstain** _____

Not Participating _____

COMMENTS: **Below** XX **Attached** XX **None** ___

I approve for publication in the *Federal Register* the direct final rule and companion proposed rule (Enclosures 1 and 2 to SECY-14-0061) adding SHINE Medical Technologies, Inc.'s (SHINE) proposed accelerator-driven subcritical operating assemblies to the definition of a "utilization facility" in 10 CFR 50.2, under "Definitions", subject to the attached edits. After review and consideration of the staff's regulatory analysis and discussion of options, I conclude that this rule of particular applicability presents the superior option for addressing the unique technology presented by SHINE within a regulatory process that will be efficient and effective, while avoiding over inclusion or other unintended effects to existing or future licensees, which could possibly occur under a rule of general applicability. Consistent with this approach, the edits to Section VII, Backfitting and Issue Finality, tailor the basis of that discussion directly to the sole entity, i.e., the applicant SHINE, encompassed within the scope of the rule.

SIGNATURE

08/ 5 /14
DATE

Entered on "STARS" Yes ✓ No ___

KLS Edits

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[NRC-2013-0053]

RIN 3150-AJ18

Definition of a Utilization Facility

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final 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: This final rule is effective **[INSERT DATE 75 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**, unless a significant adverse comment is received by **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. If the rule is withdrawn as a result of such comments, timely notice of the withdrawal will be published 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: Please refer to Docket ID NRC-2013-0053 when contacting the NRC about the availability of information for this direct final rule. You may access publicly-available information related to this direct final rule by any of the following methods:

- **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. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.
- **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, at 301-415-4737, or by e-mail to 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.
- **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: Steven Lynch, Office of Nuclear Reactor Regulation; telephone: 301-415-1524; e-mail: Steven.Lynch@nrc.gov; U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

TABLE OF CONTENTS:

I. Procedural Background.

Because the NRC considers this action to be non-controversial, the NRC is using the "direct final rule process" for this rule. The amendment to the rule will become effective on **[INSERT DATE 75 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. However, if the NRC receives a significant adverse comments on this direct final rule by **[INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]**, then the NRC will publish a document that withdraws this action and will subsequently address the comments received in a final rule. as a response to theA companion proposed rule published in the Proposed Rule section of this issue of the *Federal Register* will serve as the basis for the final rule, if it is necessary. Absent significant modifications to the proposed revisions amendments requiring republication, the NRC will not initiate a second comment period on this action.

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 it meets the following criteria:

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 detailed instructions on submitting comments, please see the companion proposed rule published in the Proposed Rule section of this issue of the *Federal Register*.

II. Background.

By letters dated February 14, 2011, and May 3, 2011,[1] SHINE notified the NRC of its intent to submit applications to construct, and operate, a medical isotope production ~~system~~facility. SHINE's medical isotope production facility would include an irradiation facility

[1] Letter from Gregory Piefer, PhD, SHINE, to Mr. John Kinnemann, Office of Nuclear Material Safety and Safeguards (NMSS), "Notice of Intent to Submit License Application, Request for Regulatory Interpretations, and Request for Public Meetings," dated February 14, 2011 (ADAMS Accession No. ML110490138); and Letter from Gregory Piefer, PhD, SHINE, to Mr. John Kinnemann, NMSS, "Updated Request for Regulatory Interpretations," dated May 3, 2011 (ADAMS Accession No. ML11138A220), respectively.

and a radioisotope production facility housed in a single building, and is proposed to be built in Wisconsin, an Agreement State.

The SHINE preliminary safety analysis report (PSAR)[2] states that the irradiation facility consists of eight irradiation units. Each irradiation unit is an accelerator-driven subcritical operating assembly and, would be used for the irradiation of a uranium solution.[3] The irradiation would result in the production of Mo-99 and other fission products. Based on initial discussions with SHINE prior to the submission of its application, the NRC staff understood that the proposed irradiation units were not nuclear reactors as defined in § 50.2 of Title 10 of the *Code of Federal Regulations* (10 CFR). The NRC staff believed that the irradiation units, including the accelerators, were an integral part of the radioisotope production facility. Therefore, the NRC staff believed that the SHINE irradiation units and radioisotope production facility could be jointly licensed under the third part of the production facility definition found in 10 CFR 50.2. Based on these assumptions, the NRC staff relayed to the Commission on May 11, 2012, that no rulemaking was required to license SHINE's proposed medical isotope production facility.[4]

In 2012, the NRC staff published interim staff guidance (ISG)[5] to augment NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors." The ISG noted that a subcritical multiplier reaction vessel containing special nuclear material (SNM), similar to the irradiation units proposed by SHINE, could be

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2 PSAR, Chapter 4 - Irradiation Unit and Radioisotope Production Facility Description (May 31, 2013) (ADAMS Accession No. ML13172A265).

3 SHINE's preliminary safety analysis report describes each irradiation unit containing uranium solution as "...an accelerator-driven subcritical operating assembly used for the irradiation of an aqueous uranyl sulfate target solution, resulting in the production of molybdenum-99 (Mo-99) and other fission products." (ADAMS Accession No. ML13172A265).

4 Transcript of NRC Briefing on Potential Medical Isotope Production Licensing Actions, pages 55-56, 61-62 (May 11, 2012) (ADAMS Accession No. ML121370084).

5 NUREG-1537, "Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," October 17, 2012 (ADAMS Accession No. ML12156A069).

licensed as a production facility pursuant to 10 CFR part 50.[6] Based on the guidance provided in the ISG, on March 26, 2013, and May 31, 2013, SHINE submitted a two-part construction permit application for a production facility as defined in 10 CFR 50.2.[7] SHINE's application describes its proposed medical isotope production facility as including two distinct operations: 1) the irradiation of SNM in eight irradiation units in the irradiation facility and 2) the extraction of radioisotopes in the radioisotope production facility. From this description, the NRC staff recognized that the irradiation units could be distinct and separate from the radioisotope production facility. Therefore, the NRC staff no longer believes that the irradiation units can be licensed pursuant to 10 CFR 50.2 as production facilities since the irradiation units are neither integral to the operation of the radioisotope production facility nor functionally independent as production facilities.

Moreover, the irradiation units cannot be licensed as utilization facilities because they do not meet the current definition in 10 CFR 50.2. As currently defined in 10 CFR 50.2, a utilization facility is a nuclear reactor, and irradiation units are not nuclear reactors because they are not designed or used to sustain nuclear fission in a self-supporting chain reaction. Therefore, the current 10 CFR part 50 regulations governing licensing of production and utilization facilities do not apply to SHINE's irradiation facility or irradiation units.[8]

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[6] The ISG noted that a "subcritical multiplier reaction vessel containing SNM by definition is not a nuclear reactor because it cannot sustain a chain reaction. It may be included in a 10 CFR part 50 production facility license as an assembly containing SNM that is authorized for use in conjunction with the production facility." ISG page iv.

[7] *See* Letter from R. Vann Bynum, PhD, SHINE, to NRC dated March 26, 2013 (ADAMS Accession No. ML13088A192). This transmittal letter is in a document package (ADAMS Accession No. ML130880226), which includes part one of SHINE's application, consisting of portions of the PSAR, specifically Chapter 2, Site Characteristics and Chapter 19, Environmental Report (ER).

See also Letter from R. Vann Bynum, PhD, SHINE, to NRC dated May 31, 2013 (ADAMS Accession No. ML13172A361). A document package consisting of a public version of all 19 chapters of SHINE's PSAR (with proprietary information redacted) is also available in ADAMS, Accession No. ML13172A324.

[8] *See* 10 CFR 50.1, "Basis, purpose, and procedures applicable" (defining scope of 10 CFR part 50 to include only the licensing of production and utilization facilities).

However, the NRC staff maintains its initial position that SHINE's radioisotope production facility ~~should be considered~~is analogous to a "production facility~~.~~" and therefore should be licensed under part 50. Specifically, the radioisotope production facility is a facility designed or used for the processing of irradiated materials containing SNM and does not meet any of the exceptions found in the definition of production facility in 10 CFR 50.2.

III. Discussion.

A. What Action is the NRC Taking?

The NRC is amending its regulations to add SHINE's accelerator-driven subcritical operating assemblies described in the application assigned docket number 50-608 to the definition of utilization facility in 10 CFR 50.2.

B. What is the Purpose of the Direct Final Rule?

The purpose of the direct final rule is to add SHINE's accelerator-driven subcritical operating assemblies to the definition of utilization facility in 10 CFR 50.2. This change will allow the NRC staff to review and, if approved, license the irradiation units housed in SHINE's irradiation facility under the regulations in 10 CFR part 50.

C. What is the NRC's Authority to make this Rule Change?

Section 11cc. of the Atomic Energy Act of 1954, as amended (AEA), specifies that the Commission may determine by rule what constitutes a utilization facility. The licensing requirements for utilization facilities are in 10 CFR part 50. This rulemaking will resolve any licensing uncertainty concerning the applicable regulations for licensing the construction and

operation of the SHINE irradiation units, as well as expedite the NRC staff's technical review of the SHINE construction permit application.

D. Why are the SHINE Irradiation Units not Considered Production Facilities?

The NRC has determined that SHINE's irradiation units are not integral to the operation of the radioisotope production facility. In addition, the irradiation units do not meet any of the existing definitions of production facility in the AEA or in 10 CFR 50.2; therefore, they cannot be licensed as production facilities.

Pursuant to Section 11v. of the AEA, the Commission has determined by rule in 10 CFR 50.2 that three types of facilities constitute production facilities. First, "production facility" is defined as any nuclear reactor designed or used primarily for the formation of plutonium or uranium-233. The proposed irradiation units do not meet this definition because they are not nuclear reactors designed or used primarily for the formation of plutonium or uranium-233. Rather, the irradiation units are designed and used primarily to fission uranium for the production of fission products. Additionally, in contrast to nuclear reactors, the proposed irradiation units are designed to operate in the subcritical regime, and are not designed or used to sustain a self-supporting chain reaction.

Second, "production facility" is defined as any facility designed or used for the separation of the isotopes of plutonium. SHINE's proposed irradiation units do not meet this definition because they are designed to irradiate a uranium solution, not separate the isotopes of plutonium.

Third, "production facility" is defined as any facility designed or used for the processing of irradiated materials containing SNM. While "processing," as used in the definition of production facility, is not defined in the regulations, the NRC staff does not consider processing to include the irradiation and fission of materials, whether previously irradiated or not, containing

SNM. For example, all fuel in existing utilization facilities, including both power and non-power reactors, undergoes irradiation and fission, beginning with its first use to start-up a reactor. Furthermore, it is common practice in existing utilization facilities to offload irradiated fuel from the reactor core for refueling outages and maintenance. When it is time to refuel the reactor following an outage or maintenance, much of the irradiated fuel is returned to the reactor core for continued irradiation and fission. This treatment of reactor fuel is analogous to SHINE's treatment of its target solution. Following irradiation, SHINE offloads the target solution from the irradiation units. The target solution is then transferred to SHINE's radioisotope production facility for a period of time before it is returned to the irradiation units for continued irradiation and fission.

Since all existing power and non-power reactors are regulated as utilization facilities, it is clear that continuing to irradiate and fission previously irradiated reactor fuel does not constitute the processing of irradiated materials containing SNM, otherwise all existing reactors would be classified as production facilities per 10 CFR 50.2. Therefore, given this precedent and the similarities between the treatment of SHINE's target solution and the fuel in existing power and non-power reactors, the NRC staff does not consider ~~what will be occurring in~~ the irradiation units' functions to constitute the processing of irradiated materials. Consequently, based on the NRC staff's assessment, SHINE's proposed irradiation units cannot be considered production facilities.

E. Why do the SHINE Irradiation Units not fit the Current Definition of a Utilization Facility?

SHINE's proposed irradiation units do not meet the current definition of a utilization facility. They do not meet this definition because the units do not, singly or collectively sustain nuclear fission in a self-supporting chain reaction. As a result, the NRC staff concluded that the

current regulatory definition of utilization facility does not apply to the irradiation units, and they cannot currently be licensed as utilization facilities as defined in 10 CFR 50.2.

F. Why should the SHINE Irradiation Units be Licensed as 10 CFR Part 50 Utilization Facilities?

The premise of the SHINE technology is that the irradiation units will not be operated such that the effective neutron multiplication factor (k_{eff}) is greater than or equal to 1.0, a range for which nuclear reactors are designed, analyzed, and licensed to operate safely. Instead, the irradiation units will only operate in a minimally subcritical range of k_{eff}. To operate safely within this margin of subcriticality, the irradiation units are designed with several features of a nuclear reactor except that, by design, the target solution vessels have insufficient reactivity to sustain a chain reaction.

In addition, the accelerator and neutron multiplier add sufficient external neutrons to the target solution vessel to achieve a fission rate with a thermal power level comparable to non-power reactors typically licensed under 10 CFR part 50 as utilization facilities.[9] Given this fission power, the irradiation units also have many safety considerations similar to those of non-power reactors, including the following:

- Provisions for removal of fission heat during operation.
- Consideration of decay heat generation after shutdown.
- Reactivity feedback mechanisms similar to non-power reactors.
- Control of fission gas release during operation and subsequent gas management engineering safety features.
- Control of radiolytic decomposition of water and generated oxygen and hydrogen gases.

[9] Non-power reactors currently licensed to operate by the NRC range in thermal power from 5 watts to 20 megawatts. In the past, the NRC has licensed 12 aqueous homogeneous reactors (AHRs) with thermal power levels ranging from 5 watts to 50 kilowatts. An AHR is similar to the SHINE target solution vessel in that both contain fissile material in an aqueous solution; the difference is that the target solution vessel has insufficient fissile material to support a sustained chain reaction.

- Control of fission product inventory buildup.
- Accident scenarios similar to non-power reactors, such as loss of coolant, reactivity additions, and release of fission products.

Although SHINE's proposed irradiation units closely resemble non-power reactors, which are licensed as utilization facilities under 10 CFR part 50, the irradiation units cannot currently be licensed as utilization facilities because they are not nuclear reactors. Therefore, while 10 CFR part 50 would be appropriate to apply from a technical and licensing review process standpoint, the irradiation units cannot be licensed as utilization facilities under the current regulations.

The NRC staff believes, however, that based on the safety considerations associated with operation of the irradiation units, the NRC should define and license each of the irradiation units as a utilization facility. Section 11cc. of the AEA provides that the Commission may determine what a utilization facility is by rule.[10] Section 11cc. of the AEA provides that a utilization facility is any equipment or device determined by rule of the Commission to be capable of making use of special nuclear material in a quantity that is of significance to the common defense and security or in a manner that affects the health and safety of the public. Therefore, it would be within the Commission's authority to designate the SHINE irradiation units, by rule, as utilization facilities.

G. *Who has Jurisdiction over the Accelerator?*

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[10] Likewise, the Commission may by rule define what constitutes a production facility, AEA Section 11v. The Commission has previously used the rulemaking process to amend its definition of production facility. *See* Licensing of Production and Utilization Facilities (21 FR 355; January 19, 1956), Definition of Production Facility (26 FR 4989, 4990; June 6, 1961), and Exemption for Facilities Processing Irradiated Materials Containing Limited Quantities of Special Nuclear Material (39 FR 4871; February 8, 1974).

Because the accelerator is integral to the operation of the irradiation unit, and the Commission must retain authority and responsibility with respect to regulation of the entire utilization facility per Section 274c.(1) of the AEA, the Commission has jurisdiction over the accelerator.

The NRC staff has engaged with the state of Wisconsin regarding licensing of the SHINE irradiation units because an accelerator that is not part of an NRC licensed facility might be regulated under state law. Based on the NRC staff's informal discussions with Agreement State counterparts, the NRC staff does not expect the state of Wisconsin to object to the rule or licensing review process for the SHINE construction permit application.

H. *Why is 10 CFR Part 70 Not Appropriate to Review or License the SHINE Irradiation Units?*

The NRC staff considered whether it should review SHINE's irradiation units under 10 CFR part 70, "Domestic Licensing of Special Nuclear Material," which regulates the issuance of licenses to receive title to, own, acquire, deliver, receive, possess, use, and transfer SNM. From a regulatory perspective, 10 CFR part 70 could be applied because SHINE will acquire, receive, possess, use, and transfer SNM. The requirements of 10 CFR part 70, subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear material," could also be applied because SHINE will possess a critical mass of SNM, and will engage in an activity that could significantly affect public health and safety.

The facilities conducting the types of activities typically regulated under 10 CFR part 70, generally referred to as fuel cycle facilities, have a common objective of avoiding criticality by maintaining a significant margin from criticality under normal operating and accident conditions. Specifically, 10 CFR 70.61(d) calls for "... use of an approved margin of subcriticality for safety." SHINE's irradiation units have a proposed routine operating margin of subcriticality of less than what has been previously approved for other 10 CFR part 70 licensees. This operating state

more closely resembles the effective neutron multiplication factor of nuclear reactors than fuel cycle facilities.[11] SHINE states that its proposed margin of subcriticality is needed to carry out efficient production of Mo-99, and proposes to control reactivity through administrative and engineered controls, including careful control of the amount of SNM initially placed in the target solution vessels. Also, in order to operate safely at SHINE's proposed margin of subcriticality, the irradiation units are designed with inherent negative reactivity feedback mechanisms similar to those of nuclear reactors. Because SHINE proposes to operate each irradiation unit in a manner similar to a nuclear reactor, the NRC staff has determined that it would be most appropriate to use the regulations contained in 10 CFR part 50 to perform its technical review of the irradiation units.

I. *Who will this Action Affect?*

The direct final rule will apply only to the irradiation units proposed by SHINE under docket number 50-608. This rulemaking will affect SHINE by bringing the licensing of its proposed facility, including both its irradiation facility and radioisotope production facility, entirely within the regulations of 10 CFR part 50. As a result of this rulemaking, the NRC will have exclusive jurisdiction over the SHINE facility, including the licensing and oversight of the accelerators associated with the irradiation units. Since Agreement States typically regulate accelerators, the direct final rule will also affect the state of Wisconsin. The rulemaking will not impact the public's opportunity to comment or participate in a hearing on the pending SHINE construction permit application or, if submitted, any future operating license application.

J. *What is the Reason for the Change?*

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[11] PSAR, Chapter 4 - Irradiation Unit and Radioisotope Production Facility Description (May 31, 2013) (ADAMS Accession No. ML13172A265).

The rulemaking will allow the NRC staff to conduct its licensing review of the proposed SHINE irradiation units following regulations designed for technologies with similar radiological, health, and safety considerations. While the proposed irradiation units do not currently fit the 10 CFR part 50 definitions of production or utilization facilities, it is within the NRC's authority under the AEA to determine by rule that the SHINE irradiation units are utilization facilities. The Commission has found that 10 CFR part 50 is the most appropriate regulation to apply to the licensing of the SHINE irradiation units.

K. *Why is a Direct Final Rule Appropriate?*

The NRC believes that a direct final rule is appropriate for the following reasons:

1. From a health and safety standpoint the requirements in 10 CFR part 50 are the most appropriate for the licensing and technical review of the proposed irradiation units.

2. Designating each proposed irradiation unit, by rule, as a utilization facility is within the Commission's authority under the AEA.

3. The proposed irradiation units share many characteristics of non-power reactors, which are licensed as utilization facilities under 10 CFR part 50.

4. SHINE has submitted a construction permit application that contains the majority of regulatory information required of utilization facilities.

5. The proposed rulemaking only affects the irradiation units proposed by SHINE under docket number 50-608.

~~6. The state of Wisconsin has not objected to the NRC's statements that the NRC should have exclusive jurisdiction over the SHINE facility, including the licensing and oversight of the accelerators associated with the irradiation units.~~

The NRC staff is using a direct final rule because it considers this rulemaking to be non-controversial, it does not expect to receive significant adverse comments, and using the

direct final rule process would allow the rulemaking to proceed in the most efficient manner. The direct final rule is expected to be non-controversial because the NRC has the authority under the AEA to define what constitutes a utilization facility; interested parties, including SHINE, have not objected to discussions and published guidance proposing licensing under 10 CFR part 50; the rule does not affect the ability of the public to comment and request a hearing on the application; and the inclusion of SHINE's docket number as well as a description of the SHINE irradiation unit technology limits the applicability of the rule to SHINE's proposed irradiation units, ensuring no impact to other existing or future facilities. If, in the future, any applicant proposes a technology similar to SHINE's irradiation units,[12] that application would be considered on a case-by-case basis, and a distinct docket number would be assigned to each application. Should SHINE propose a technology other than the irradiation units currently described in its PSAR, the rule would no longer apply to SHINE, and the NRC staff would pursue an alternative licensing approach.

As previously explained, because the irradiation units are similar to non-power reactors, the NRC staff finds the 10 CFR part 50 regulations most appropriate to apply in the review of this proposed technology. To limit the scope of this rulemaking, the NRC staff is recommending that this rule be made applicable to only the SHINE facility. A generic rulemaking has potential for unintended consequences on the regulation of other licensees. Expansion of the definition of utilization facility generically could result in inclusion of technologies appropriately regulated by Agreement States or under 10 CFR part 70 ~~under~~within the regulatory scope of 10 CFR part 50, which would reduce the NRC's regulatory efficiency.

~~The NRC staff is using a direct final rule because it considers this rulemaking to be non-controversial, it does not expect to receive significant adverse comments, and using the~~

[12] At this time, the NRC staff does not anticipate receiving any other applications for medical radioisotope production facilities that would propose a technology similar to SHINE's irradiation units.

~~direct final rule process would allow the rulemaking to proceed in the most efficient manner. The direct final rule is expected to be non-controversial because the NRC has the authority under the AEA to define what constitutes a utilization facility; interested parties, including SHINE, have not objected to discussions and published guidance proposing licensing under 10 CFR part 50; the rule does not affect the ability of the public to comment and request a hearing on the application; and the inclusion of SHINE's docket number as well as a description of the SHINE irradiation unit technology limits the applicability of the rule to SHINE's proposed irradiation units, ensuring no impact to other existing or future facilities. If, in the future, any applicant proposes a technology similar to SHINE's irradiation units,[13] that application would be considered on a case-by-case basis, and a distinct docket number would be assigned to each application. Should SHINE propose a technology other than the irradiation units currently described in its PSAR, the rule would no longer apply to SHINE, and the NRC staff would pursue an alternative licensing approach.~~

By identifying 10 CFR part 50 as the licensing framework to review and evaluate the irradiation units in the SHINE construction permit application, this rulemaking would clarify the appropriate regulatory requirements governing SHINE's requested licensing action ~~to SHINE~~for the applicant; interested members of the public; federal, state, and local government representatives; and other interested stakeholders. Additionally, in alignment with the objectives of the American Medical Isotopes Production Act of 2012, this rulemaking will provide the most efficient and effective pathway to reviewing and licensing SHINE's proposed irradiation units and will support the national effort to establish a reliable domestic supply of Mo-99 utilizing low enriched uranium technologies.

~~[13] At this time, the NRC staff does not anticipate receiving any other applications for medical radioisotope production facilities that would propose a technology similar to SHINE's irradiation units.~~

L. *Will the NRC Issue Guidance for this Rule?*

No, the NRC does not plan to issue guidance specific to this rule. The guidance provided in NUREG-1537 (ADAMS Accession No. ML12251A353), NUREG-1520 (ADAMS Accession No. ML101390110), and the Final Interim Staff Guidance Augmenting NUREG-1537 (ADAMS Accession No. ML12156A069) is sufficient to support the review of SHINE's construction permit application under the regulations in 10 CFR part 50. However, the NRC staff is preparing a revision to NUREG-1537, which will incorporate the content of the ISG, including any necessary corrections.

IV. Discussion of Amendments by Section.

§ 50.2 Definitions.

The definition for *utilization facility* will be changed to add: 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.

Authority Citation.

The authority citation for 10 CFR part 50 is being revised to include Section 11 of the AEA because Subsection 11cc. provides the Commission's authority to add to, or otherwise alter, the definition of utilization facility. In addition, minor editorial changes were made to the authority citation.

V. Regulatory Flexibility Certification.

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. The direct final rule will impact one applicant for a construction permit, who may subsequently apply for an ~~and potential~~ operating license. Although this company falls within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810), the rule is intended to facilitate NRC staff review of the company's construction permit application and subsequent operating license application.

VI. Regulatory Analysis.

The NRC has prepared a final regulatory analysis (ADAMS Accession No. ML14052A115) on this regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC.

VII. Backfitting and Issue Finality.

The NRC has determined that the backfit rule, 10 CFR 50.109, ~~and~~ the issue finality provisions in 10 CFR part 52, and the backfitting provisions in 10 CFR 70.76, 72.62, or 76.76 do not apply to this direct final rule ~~because this rulemaking does not affect entities who are applicants for or holders of licenses for nuclear power reactors, who are accorded backfitting and issue finality protection under those provisions~~because the only affected entity, SHINE, is currently an applicant for a construction permit. These backfitting and issue finality provisions, with exceptions not applicable here, do not apply to applicants. ~~The NRC has also determined that the backfitting provisions in 10 CFR 70.76, 72.62, or 76.76 do not apply to this direct final rule because this rulemaking does not affect entities who are accorded backfitting protection~~

~~under these backfit rules.~~ For these reasons, the NRC did not prepare either a backfit analysis or documentation addressing issue finality provisions in 10 CFR part 52 for this direct final rule.

VIII. Plain Writing.

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. 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).

IX. Environmental Assessment and Finding of No Significant Environmental Impact.

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, that this rule would not be a major Federal action significantly affecting the quality of the human environment~~,~~ and therefore, an environmental impact statement is not required. The rule changes the definition of utilization facility to include the SHINE irradiation units for the purposes of facilitating the licensing review of one proposed facility. The rule will not affect radiological or non-radiological releases, nor will it affect occupational or public exposure. The determination of this environmental assessment is that there will be no significant offsite impact to the public from this action.

The NRC has prepared a final Environmental Assessment and Finding of No Significant Impact (ADAMS Accession No. ML14052A097).

X. Paperwork Reduction Act Statement.

This direct final rule affects only one entity and therefore is not subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

Public Protection Notification.

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid Office of Management and Budget control number.

XI. Congressional Review Act.

This is a rule of particular applicability and, as such, this action is not a rule as defined in the Congressional Review Act (5 U.S.C. 801-808). Therefore, the NRC is not required to submit a rule report regarding this action under Section 801 of the Congressional Review Act.

XII. Compatibility of Agreement State Regulations.

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the *Federal Register* (62 FR 46517; September 3, 1997), this rule is classified as compatibility "NRC". Compatibility is not required for Category "NRC" regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act or the provisions of 10 CFR, and though an Agreement State may not adopt program elements reserved to the NRC, it may wish to inform its licensees of certain

requirements via a mechanism that is consistent with a particular State's administrative procedure laws, but does not confer regulatory authority on the State.

XIII. Voluntary Consensus Standards.

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113), requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this direct final rule, the NRC will revise the definition of utilization facility found in 10 CFR 50.2 to include the proposed SHINE irradiation units. This action does not constitute the establishment of a standard that establishes generally applicable requirements.

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 the preamble 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 adopting the following amendments to 10 CFR part 50.

PART 50 -- DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for 10 CFR 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.

KLS Edits

[7590-01-P]

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. 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. 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; 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, at 301-415-4737, or by e-mail to 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 a 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 it meets the following criteria:

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

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MAGWOOD

SUBJECT: SECY-14-0061 – DIRECT FINAL RULE: ADDING SHINE MEDICAL TECHNOLOGIES, INC.'S ACCELERATOR-DRIVEN SUBCRITICAL OPERATING ASSEMBLY TO THE DEFINITION OF UTILIZATION FACILITY

Approved X **Disapproved** _____ **Abstain** _____

Not Participating _____

COMMENTS: **Below** ____ **Attached** X **None** ____

SIGNATURE

19 August 2014

DATE

Entered on "STARS" **Yes** X **No** ____

Commissioner Magwood's Comments on SECY-14-0061,
"Direct Final Rule: Adding SHINE Medical Technologies, Inc.'s Accelerator-Driven Subcritical Operating Assembly to the Definition of Utilization Facility"

The staff has performed well in preparing for licensing applications arising from efforts spurred by the American Medicine Isotope Production Act to promote the production of the vital medical isotope molybdenum-99 without the use of highly enriched uranium. The application from SHINE Medical Technologies, Inc. is the first such application the agency will consider and it is one that relies upon a novel technology that presents unusual regulatory issues.

As staff explains in SECY-14-0061, the agency's consideration of SHINE's two-part construction permit application resulted in a determination that the facility should be licensed under 10 CFR Part 50. While the extraction of isotopes in the radioisotope production facility can be licensed as a production facility under the current 10 CFR Part 50 definition, the portion of the facility in which special nuclear material is irradiated can only be licensed under 10 CFR Part 50 if a change is made in the definition of utilization facility. Staff has requested that the Commission approve a direct final rule for this specific matter.

After reviewing all of the information and analyses performed by the staff, I approve the staff's recommendation to add SHINE's accelerator-driven subcritical operating assembly to the definition of utilization facility. I also approve for publication in the *Federal Register* the direct final rule and companion proposed rule and certify that this rule, if issued, will not have significant impact on a substantial number of small entities to satisfy the requirement of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

While I approve the staff's recommendation in this unique circumstance, I am troubled by the need to reference a specific docket number in any rule. Rulemakings should be structured to provide generic applicability; another facility applying a technically similar approach would require yet another change in the rule to be considered under 10 CFR Part 50. I would prefer for staff to analyze the effect of its proposed rules carefully and craft them to be both generic and evasive of unintended consequences.

That said, sending this proposal back to the staff for further work would take considerable time. I support the present request only out of fairness to applicant, which has submitted its application in good faith and deserves a timely response from the agency, and the important national need to pursue methods of molybdenum-99 production.

8/19/14

William D. Magwood, IV **Date**

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER OSTENDORFF

SUBJECT: SECY-14-0061 – DIRECT FINAL RULE: ADDING SHINE MEDICAL TECHNOLOGIES, INC.'S ACCELERATOR-DRIVEN SUBCRITICAL OPERATING ASSEMBLY TO THE DEFINITION OF UTILIZATION FACILITY

Approved _X_ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached _X Comment and edits_ None ___

_____
SIGNATURE

8/7/14
DATE

Entered on "STARS" Yes _x__ No ___

Commissioner Ostendorff's Comments on SECY-14-0061,
"Direct Final Rule; Adding Shine Medical Technologies, Inc.'s Accelerator-Driven Subcritical Operating Assembly to the Definition of Utilization Facility"

I commend the staff for working within our current regulatory structure to address this first-of-a-kind facility. I understand that addressing the SHINE facility will require rulemaking to amend the definition of "utilization facility," which the Atomic Energy Act allows. To address the unique aspect of the SHINE irradiation facility, the staff is amending the definition of a "utilization facility" in 10 CFR 50.21 by adding a technical description and docket number specific to the SHINE facility. I agree that addressing the SHINE irradiator as a utilization facility is the most efficient way to review SHINE's license application. Therefore, I approve publication of the Direct Final Rule and its accompanying proposed rule subject to the comment below and attached edits.

The staff should provide a cost analysis of the "No Action" alternative in the regulatory analysis to demonstrate clearly that this rulemaking is efficient and effective.

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[NRC-2013-0053]

RIN 3150-AJ18

Definition of a Utilization Facility

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final 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, and other radioisotopes used for medical purposes. 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: This final rule is effective **[INSERT DATE 75 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**, unless a significant adverse comment is received by **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. If the rule is withdrawn as a result of such comments, timely notice of the withdrawal will be published in the *Federal*

Comment [TEB1]: Use consistently throughout – currently this changes between a comment and comments see page 4

I. Procedural Background.

Because the NRC considers this action to be non-controversial, the NRC is using the "direct final rule process" for this rule. The amendment to the rule will become effective on **[INSERT DATE 75 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. However, if the NRC receives a significant adverse comments on this direct final rule by **[INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]**, then the NRC will publish a document that withdraws this action and will subsequently address the comments received in a final rule as a response to the companion proposed rule published in the Proposed Rule section of this issue of the *Federal Register*. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action.

Comment [TEB2]: Change to singular consistent with the previous useage

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 and adverse if:

Formatted: Highlight

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 detailed instructions on submitting comments, please see the companion proposed rule published in the Proposed Rule section of this issue of the *Federal Register*.

II. Background.

By letters dated February 14, 2011, and May 3, 2011,[1] SHINE notified the NRC of its intent to submit applications to construct, and operate, a medical isotope ~~production~~ production facility~~system~~. SHINE's medical isotope production facility would include an irradiation facility

[1] Letter from Gregory Piefer, PhD, SHINE, to Mr. John Kinnemann, Office of Nuclear Material Safety and Safeguards (NMSS), "Notice of Intent to Submit License Application, Request for Regulatory Interpretations, and Request for Public Meetings," dated February 14, 2011 (ADAMS Accession No. ML110490138); and Letter from Gregory Piefer, PhD, SHINE, to Mr. John Kinnemann, NMSS, "Updated Request for Regulatory Interpretations," dated May 3, 2011 (ADAMS Accession No. ML11138A220), respectively.

However, the NRC staff maintains its initial position that SHINE's radioisotope production facility should be considered a "production facility." Specifically, the radioisotope production facility is a facility designed or used for the processing of irradiated materials containing SNM and does not meet any of the exceptions found in the definition of production facility in 10 CFR 50.2.

III. Discussion.

A. What Action is the NRC Taking?

The NRC is amending its regulations to add SHINE's accelerator-driven subcritical operating assemblies described in the application assigned docket number 50-608 to the definition of utilization facility in 10 CFR 50.2.

B. What is the Purpose of the Direct Final Rule?

The purpose of the direct final rule is to add SHINE's accelerator-driven subcritical operating assemblies to the definition of utilization facility in 10 CFR 50.2. This change will allow the NRC staff to review and, if approved, license the irradiation units housed in SHINE's irradiation facility under the regulations in 10 CFR part 50.

C. What is the NRC's Authority to make this Rule Change?

Section 11cc. of the Atomic Energy Act of 1954, as amended (AEA), specifies that the Commission may determine by rule what constitutes a utilization facility. The licensing requirements for utilization facilities are in 10 CFR part 50. This rulemaking will resolve any licensing uncertainty concerning the applicable regulations for licensing the construction review

and potential operation of the SHINE irradiation units, as well as expedite the NRC staff's technical review of the SHINE construction permit application.

D. Why are the SHINE Irradiation Units not Considered Production Facilities?

The NRC has determined that SHINE's irradiation units are not integral to the operation of the radioisotope production facility. In addition, the irradiation units do not meet any of the existing definitions of production facility in the AEA or in 10 CFR 50.2; therefore, they cannot be licensed as production facilities.

Pursuant to Section 11v. of the AEA, the Commission has determined by rule in 10 CFR 50.2 that three types of facilities constitute production facilities. First, "production facility" is defined as any nuclear reactor designed or used primarily for the formation of plutonium or uranium-233. The proposed irradiation units do not meet this definition because they are not nuclear reactors designed or used primarily for the formation of plutonium or uranium-233. Rather, the irradiation units are designed and used primarily to fission uranium for the production of fission products. Additionally, in contrast to nuclear reactors, the proposed irradiation units are designed to operate in the subcritical regime, and are not designed or used to sustain a self-supporting chain reaction.

Second, "production facility" is defined as any facility designed or used for the separation of the isotopes of plutonium. SHINE's proposed irradiation units do not meet this definition because they are designed to irradiate a uranium solution, not separate the isotopes of plutonium.

Third, "production facility" is defined as any facility designed or used for the processing of irradiated materials containing SNM. While "processing," as used in the definition of production facility, is not defined in the regulations, the NRC staff does not consider processing to include the irradiation and fission of materials, whether the material was irradiated previously

~~irradiated~~ or not, containing SNM. Given the similarities between the treatment of SHINE's target solution and the fuel in existing power and non-power reactors, the NRC staff does not consider what will be occurring in the irradiation units to constitute the processing of irradiated materials. For example, all fuel in existing utilization facilities, including both power and non-power reactors, undergoes irradiation and fission, beginning with its first use to start-up a reactor. Furthermore, it is common practice in existing utilization facilities to offload irradiated fuel from the reactor core for refueling outages and maintenance. When it is time to refuel the reactor following an outage or maintenance, much of the irradiated fuel is returned to the reactor core for continued irradiation and fission. This treatment of reactor fuel is analogous to SHINE's treatment of its target solution. Following irradiation, SHINE offloads the target solution from the irradiation units. The target solution is then transferred to SHINE's radioisotope production facility for a period of time before it is returned to the irradiation units for continued irradiation and fission.

Comment [TEB3]: Moved from below

Since all existing power and non-power reactors are regulated as utilization facilities, it is clear that continuing to irradiate and fission previously irradiated reactor fuel does not constitute the processing of irradiated materials containing SNM, otherwise all existing reactors would be classified as production facilities per 10 CFR 50.2. ~~Therefore, given this precedent and the similarities between the treatment of SHINE's target solution and the fuel in existing power and non-power reactors, the NRC staff does not consider what will be occurring in the irradiation units to constitute the processing of irradiated materials.~~ Consequently, based on the NRC staff's assessment, SHINE's proposed irradiation units cannot be considered production facilities.

Comment [TEB4]: Moved

E. Why do the SHINE Irradiation Units not fit the Current Definition of a Utilization Facility?

J. *What is the Reason for the Change?*

The rulemaking will allow the NRC staff to conduct its licensing review of the proposed SHINE irradiation units following regulations designed for technologies with similar radiological, health, and safety considerations. While the proposed irradiation units do not currently fit the 10 CFR part 50 definitions of production or utilization facilities, it is within the NRC's authority under the AEA to determine by rule that the SHINE irradiation units are utilization facilities. The Commission has found that 10 CFR part 50 is the most appropriate regulation to apply to the review of the SHINE construction application and application to operate, and, if approved, licensing of the SHINE irradiation units.

K. *Why is a Direct Final Rule Appropriate?*

The NRC believes that a direct final rule is appropriate for the following reasons:

1. From a health and safety standpoint the requirements in 10 CFR part 50 are the most appropriate for the licensing and technical review of the proposed irradiation units.

2. Designating each proposed irradiation unit, by rule, as a utilization facility is within the Commission's authority under the AEA.

3. The proposed irradiation units share many characteristics of non-power reactors, which are licensed as utilization facilities under 10 CFR part 50.

4. SHINE has submitted a construction permit application that contains the majority of regulatory information required of utilization facilities.

5. The proposed rulemaking only affects the irradiation units proposed by SHINE under docket number 50-608.

6. ~~The state of Wisconsin has not objected to the NRC's statements that the NRC should have exclusive jurisdiction over the SHINE facility, including the licensing and oversight of the accelerators associated with the irradiation units~~.

The NRC staff is using a direct final rule because it considers this rulemaking to be non-controversial, it does not expect to receive significant adverse comments, and using the direct final rule process would allow the rulemaking to proceed in the most efficient manner. The direct final rule is expected to be non-controversial because the NRC has the authority under the AEA to define what constitutes a utilization facility; interested parties, including SHINE, have not objected to discussions and published guidance proposing licensing under 10 CFR Part 50. Additionally, the rule does not affect the ability of the public to comment and request a hearing on the application; and the inclusion of SHINE's docket number as well as a description of the SHINE irradiation unit technology limits the applicability of the rule to SHINE's proposed irradiation units, ensuring no impact to other existing or future facilities. If, in the future, any applicant proposes a technology similar to SHINE's irradiation units,[12] the Commission would consider that application on a case-by-case basis, and assign a distinct docket number to each application. Should SHINE propose a technology other than the irradiation units currently described in its PSAR, the rule would no longer apply to SHINE, and the NRC staff would pursue an alternative licensing approach.

Comment [TEB5]: Moved from below

As previously explained, because the irradiation units are similar to non-power reactors, the NRC staff finds the 10 CFR part 50 regulations most appropriate to apply in the review of this proposed technology. To limit the scope of this rulemaking, the NRC staff is recommending that this rule be made applicable to only the SHINE facility. A generic rulemaking has potential for unintended consequences on the regulation of other licensees. Expansion of the definition

[12] At this time, the NRC staff does not anticipate receiving any other applications for medical radioisotope production facilities that would propose a technology similar to SHINE's irradiation units.

of utilization facility generically could result in inclusion of technologies appropriately regulated by Agreement States or 10 CFR part 70 under the regulatory scope of 10 CFR part 50, which would reduce the NRC's regulatory efficiency.

The NRC staff is using a direct final rule because it considers this rulemaking to be non-controversial, it does not expect to receive significant adverse comments, and using the direct final rule process would allow the rulemaking to proceed in the most efficient manner. The direct final rule is expected to be non-controversial because the NRC has the authority under the AEA to define what constitutes a utilization facility; interested parties, including SHINE, have not objected to discussions and published guidance proposing licensing under 10 CFR part 50; the rule does not affect the ability of the public to comment and request a hearing on the application; and the inclusion of SHINE's docket number as well as a description of the SHINE irradiation unit technology limits the applicability of the rule to SHINE's proposed irradiation units, ensuring no impact to other existing or future facilities. If, in the future, any applicant proposes a technology similar to SHINE's irradiation units,[13] that application would be considered on a case-by-case basis, and a distinct docket number would be assigned to each application. Should SHINE propose a technology other than the irradiation units currently described in its PSAR, the rule would no longer apply to SHINE, and the NRC staff would pursue an alternative licensing approach.

By identifying 10 CFR part 50 as the licensing framework to review and evaluate the irradiation units in the SHINE construction permit application, this rulemaking would clarify the appropriate regulatory requirements governing SHINE's requested licensing action to only SHINE; interested members of the public; federal, state, Tribal and local government representatives; and other interested stakeholders. Additionally, in alignment with the

[13] At this time, the NRC staff does not anticipate receiving any other applications for medical radioisotope production facilities that would propose a technology similar to SHINE's irradiation units.

objectives of the American Medical Isotopes Production Act of 2012, this rulemaking will provide the most efficient and effective pathway to reviewing and, if approved, licensing SHINE's proposed irradiation units and will support the national effort to establish a reliable domestic supply of Mo-99 utilizing low enriched uranium technologies.

L. *Will the NRC Issue Guidance for this Rule?*

No, the NRC does not plan to issue guidance specific to this rule. The guidance provided in NUREG-1537 (ADAMS Accession No. ML12251A353), NUREG-1520 (ADAMS Accession No. ML101390110), and the Final Interim Staff Guidance Augmenting NUREG-1537 (ADAMS Accession No. ML12156A069) is sufficient to support the review of SHINE's construction permit application under the regulation in 10 CFR part 50. However, the NRC staff is preparing a revision to NUREG-1537, which will incorporate the content of the ISG, including any necessary corrections.

IV. Discussion of Amendments by Section.

§ 50.2 Definitions.

The definition for *utilization facility* will be changed to add: 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.

Authority Citation.

The authority citation for 10 CFR part 50 is being revised to include Section 11 of the AEA because Subsection 11cc. provides the Commission's authority to add to, or otherwise

[7590-01-P]

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 and other radioisotopes used for medical purposes. 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.

Comment [TEB1]: Approve adding phrase that is consistent with wording proposed in Direct Final Rule text.

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.