RULEMAKING ISSUE
AFFIRMATION

June 16, 2014 SECY-14-0061

FOR: The Commissioners

FROM: Mark A. Satorius
Executive Director for Operations

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

PURPOSE:

To obtain Commission approval to publish a direct final rule and companion proposed rule that adds SHINE Medical Technologies, Inc.'s (SHINE) proposed accelerator-driven subcritical operating assemblies to the definition of a "utilization facility" in § 50.2 of Title 10 of the *Code of Federal Regulations* (10 CFR), "Definitions." This rule would allow the U.S. Nuclear Regulatory Commission (NRC) staff to conduct an efficient and effective licensing review of the SHINE construction permit application and subsequent operating license application under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." This paper does not address any new commitments.

SUMMARY:

The NRC staff has determined that the regulations for utilization facilities in 10 CFR Part 50 provide the most appropriate, efficient, and effective licensing process for the SHINE irradiation units. However, while it is within the NRC's authority to designate each of SHINE's proposed irradiation units as a utilization facility under the Atomic Energy Act of 1954, as amended (AEA), the irradiation units do not meet the current definition of utilization facility in 10 CFR 50.2. To

CONTACTS: Alexander Adams, Jr., NRR/DPR
301-415-1127

Steven Lynch, NRR/DPR
301-415-1524

address this issue, the NRC staff recommends the publication of a direct final rule and companion proposed rule. The rule would add SHINE's irradiation units to the definition of utilization facility in 10 CFR 50.2. This change would allow the NRC staff to apply the most appropriate licensing and technical review standards to the SHINE irradiation units, meet review milestones, and ultimately make a final determination to either grant or deny a construction permit (and if requested in the future, an operating license) to SHINE. The rule would also clarify the appropriate regulatory requirements to SHINE, interested members of the public, federal, state, and local government representatives, and other interested stakeholders.

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 facility. SHINE's medical isotope production facility would include an irradiation facility and a radioisotope production facility housed in a single building, and is proposed to be built in Wisconsin, an Agreement State.

As summarized in SHINE's preliminary safety analysis report (PSAR),[2] 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. The irradiation would result in the production of molybdenum-99 (Mo-99) and other fission products. Based on initial discussions with SHINE prior to the submission of its application, the NRC staff recognized that the proposed irradiation units were not nuclear reactors as defined in 10 CFR 50.2. 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 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.[3]

In 2012, the NRC staff published interim staff guidance (ISG)[4] to augment NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors."

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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 (Agency Document Access Management System (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.

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

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

4 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).

The ISG noted that a subcritical multiplier reaction vessel containing special nuclear material[5] (SNM), similar to the irradiation units proposed by SHINE, could be 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]

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.

DISCUSSION:

Because, as described in more detail below, each irradiation unit is similar to a non-power reactor, the NRC staff believes that the regulations contained in 10 CFR Part 50 are the most appropriate to apply in the review of this proposed technology. Therefore, the NRC staff recommends the issuance of a direct final rule amending the definition of utilization facility in 10

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5 Special nuclear material is defined to include "uranium enriched in the isotope 233 or in the isotope 235." *See* AEA section 11aa, 42 U.S.C. 2014 (2005).

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 (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).

CFR 50.2 to include SHINE's proposed irradiation units. This rule would be a rule of particular applicability, which means that it would apply only to SHINE and would not affect any other NRC licensees or applicants. The direct final rule (Enclosure 1) and the companion proposed rule (Enclosure 2) are provided for Commission approval.

SHINE's Irradiation Units Are Not Production Facilities

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

Production facility is defined in Section 11v. of the AEA as:

> (1) any equipment or device *determined by rule of the Commission* to be capable of the *production of special nuclear material* in such a quantity as to be of significance to the common defense and security, or in such manner as to affect the health and safety of the public; or (2) any important component part especially designed for such equipment or device as determined by the Commission. (emphasis added)

Both Section 11 of the AEA and 10 CFR 50.2 define the term "produce," as used in relation to SNM, to mean "(1) to manufacture, make, produce, or refine special nuclear material; (2) to separate special nuclear material from other substances in which such material may be contained; or (3) to make or to produce new special nuclear material." SHINE's irradiation units do not perform any of these activities, and therefore do not meet the intent of the AEA definition of a production facility.

Pursuant to Section 11v. of the AEA, the Commission has determined by rule 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 (U-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 U-233. Rather, the irradiation units are designed and used primarily to fission uranium for the production of fission products. A nuclear reactor is defined in 10 CFR 50.2 as "an apparatus…designed or used to sustain nuclear fission in a self-supporting chain reaction." In contrast, 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 also 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 also 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 AEA or the regulations,[9] 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 follows that continuing to irradiate and fission previously irradiated reactor fuel is not considered "processing of irradiated materials containing SNM." Based on the NRC staff's assessment, SHINE's irradiation units do not "produce" SNM, nor do they "separate special nuclear material from other substances," and are not nuclear reactors "designed or used primarily for the formation of plutonium or uranium-233." Consequently, SHINE's proposed irradiation units cannot be considered production facilities under the existing regulations.

The SHINE Irradiation Units Do Not Meet the Current 10 CFR Part 50 Definition of Utilization Facilities

As defined in 10 CFR 50.2, "utilization facility" means "any nuclear reactor other than one designed or used primarily for the formation of plutonium or U-233." SHINE's proposed irradiation units do not meet the definition of nuclear reactor because they do not 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, therefore, cannot currently be licensed as utilization facilities as defined in 10 CFR 50.2.

The SHINE Irradiation Units Resemble 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

[9] A 1955 proposed rule that would have defined "processing" to include chemical, mechanical, and metallurgical processing, gives some insight into what might be considered. Licensing of Production and Utilization Facilities (20 *Federal Register* 2486, 2487; April 15, 1955) (proposed rule). However, the final rule as published eliminated these qualifiers. Licensing of Production and Utilization Facilities (21 FR 355, 356; January 19, 1956) (final rule).

reactors typically licensed under 10 CFR Part 50 as utilization facilities.[10] Given this fission power, the irradiation units also have many safety considerations similar to those of non-power reactors, including:

- 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
- 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

Therefore, 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 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 AEA provides authority for the NRC to add the SHINE irradiation units to the regulatory definition of a utilization facility. As provided in Section 11cc. of the AEA, the Commission is given authority to define utilization facilities by rule.[11] Specifically, Section 11cc. provides that a utilization facility is:

> (1) *any equipment or device, except an atomic weapon, determined by rule of the Commission to be capable of making use of special nuclear material in such quantity as to be of significance to the common defense and security, or in such manner as to affect the health and safety of the public*, or peculiarly adapted for making use of atomic energy in such quantity as to be of significance to the

[10] 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 with thermal power levels ranging from 5 watts to 50 kilowatts. An aqueous homogeneous reactor 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.

[11] 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).

> common defense and security, or in such manner as to affect the health and safety of the public; or (2) any important component part especially designed for such equipment or device as determined by the Commission. (emphasis added)

The NRC staff, as part of its ongoing review of the SHINE PSAR, has determined that each irradiation unit proposed by SHINE makes use of special nuclear material "in such quantity as to be of significance to the common defense and security" and "in such a manner as to affect 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.

10 CFR Part 70 Should Not Be Applied to Review or License the SHINE Irradiation Units[12]

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 special nuclear material. 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.[13]

The facilities conducting the types of activities typically regulated under 10 CFR Part 70 are generally referred to as fuel cycle facilities. 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 (Enclosure 3[14]). This operating state more closely resembles the effective neutron multiplication factor of nuclear reactors than fuel cycle facilities. 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.

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[12] Note that this section addresses only the construction permit and operating license of a facility; it does not address the license of SNM in the facility. Similar to other licensed utilization facilities, SHINE would receive a 10 CFR Part 70 license to receive, possess and use the SNM needed to operate the irradiation units.

[13] Although the NRC staff believes that the regulations of 10 CFR Part 50 are most appropriate for regulation of the proposed SHINE irradiation units, if the Commission determined that the irradiation units should be licensed under 10 CFR Part 70, a rulemaking to change the definition of utilization facility in 10 CFR 50.2 would not be necessary.

[14] Enclosure 3, "Margin of Subcriticality in SHINE Irradiation Units," contains proprietary information and has, thus, been designated as non-publicly available.

Recommend Rulemaking to Amend 10 CFR Part 50 Definition of Utilization Facility to Include the SHINE Irradiation Units

While 10 CFR 50.2 currently contains a definition of utilization facility that only applies to nuclear reactors, SHINE's proposed irradiation units can be designated as utilization facilities through Commission rulemaking under the AEA.[15] As noted above, the NRC staff finds that each irradiation unit makes use of SNM in such quantity as to be of significance to the common defense and security and in such manner as to affect the health and safety of the public.

This rulemaking will resolve any licensing uncertainty concerning the applicable regulations and licensing procedures for the irradiation units, as well as expedite the NRC staff's technical review of the SHINE construction permit application. This rulemaking will not impact the public's opportunity to comment or request a hearing on the application. Furthermore, the state of Wisconsin has not objected to the NRC's assertion of regulatory authority over the proposed SHINE irradiation units, including the accelerators.

As explained above, 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 10 CFR Part 70 under the regulatory scope of 10 CFR Part 50, which would reduce the NRC's regulatory efficiency.

The NRC staff recommends that the direct final rule change the definition of utilization facility in 10 CFR 50.2 to read: "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."

The NRC staff believes that this approach 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.

[15] As standard procedure for direct final rule packages, this paper provides both a direct final rule and a companion proposed rule for publication in the *Federal Register*. The direct final rule would become effective 75 days after publication in the *Federal Register,* unless significant adverse comments are received within 30 days after publication in the *Federal Register*. Should any significant adverse comments be received, the direct final rule would be withdrawn, and the comments would be addressed during preparation of a traditional final rule package. As part of this process, the NRC would not initiate a separate comment period for the proposed rule.

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 NRC staff 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 proposing to use 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. While there could be local opposition to SHINE's facility itself, such objections are unlikely to substantively challenge this rulemaking and, therefore, would not be considered significant adverse comments. Any safety or environmental concerns related to the licensing of the proposed SHINE facility will be addressed in any hearing held on the application itself, which is separate from this rulemaking. The direct final rule is expected to be non-controversial because the proposed irradiation units fall within the statutory bounds of the AEA's definition of a utilization facility; the rule is designed to allow the NRC staff to review the application by applying the most appropriate licensing and technical review standards for protection of the health and safety of the public; and the inclusion of SHINE's docket number 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 technologies similar to SHINE's irradiation units,[16] that application will be considered on a case-by-case basis, and a distinct docket number will be assigned to each application. Additionally, the inclusion of a description of the SHINE irradiation unit technology further narrows the scope of the rule. 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.

In addition, the NRC staff notes that the January 2013 enactment of the National Defense Authorization Act for fiscal year 2013, Title XXXI, Subtitle F, known as the American Medical Isotopes Production Act of 2012 (AMIPA), encourages the domestic production of significant quantities of Mo-99 for medical uses without the use of highly-enriched uranium, and acknowledges that this can be done with non-reactor subcritical assemblies like those SHINE proposes to construct and operate.[17] In alignment with the objectives of AMIPA, 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.[18]

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[16] 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.

[17] AMIPA, Sec. 3173.(f) Improving the Reliability of Domestic Medical Isotope Supply (page 582).

[18] Transcript of USNRC Briefing on Potential Medical Isotope Production Licensing Actions pages 43-44, 49, dated May 11, 2012 (ADAMS Accession No. ML121370084).

Impact of Rulemaking and Status of SHINE Construction Permit Application

Because of similarities in regulatory requirements, SHINE's construction permit application for a production facility already includes the majority of information necessary for the review of a utilization facility under 10 CFR Part 50. Under this rule change, SHINE's irradiation units would, if licensed, be regulated as 10 CFR Part 50 utilization facilities. Based on the current content of the SHINE construction permit application, the NRC staff believes that any necessary application supplement addressing these requirements should be minimal. For example the conditions of 10 CFR 50.55a(a)(1) are only applicable to utilization facilities and would need to be addressed in a supplement to the current construction permit application. Also, as a Part 50 facility, any operating license application for the irradiation facility would need to address the requirements of 10 CFR Part 55, "Operator's Licenses," which requires that any individual who operates the controls of a utilization facility licensed under 10 CFR Part 50 be licensed.

Although not required by 10 CFR 51.20, "Criteria for and identification of licensing and regulatory actions requiring environmental impact statements," the NRC staff plans to prepare an environmental impact statement, addressing the proposed construction, operation, and decommissioning of the proposed SHINE facility. The NRC staff decided that an environmental impact statement would most appropriately cover the unique considerations of SHINE's first-of-a-kind application for a medical isotope production facility and allow greater public involvement in the environmental review process. In support of the development of the environmental impact statement, the NRC staff conducted two public scoping meetings in Janesville, Wisconsin in July 2013[19]. These meetings provided an overview of the environmental review process, and an opportunity for interested government agencies, organizations, and individuals to submit comments or suggestions on the environmental issues or the proposed scope of the environmental impact statement.

The NRC staff has developed an initial set of requests for additional information based on the technical content of SHINE's PSAR; however, in order to fully develop a safety evaluation report, meet with the Advisory Committee on Reactor Safeguards, and conduct a hearing in support of the SHINE construction permit application, the NRC staff must have a clear licensing foundation for its review. Therefore, this rulemaking would help the NRC staff effectively license the SHINE irradiation units, meet the milestones in the NRC staff's proposed technical review schedule (Enclosure 4[20]), and ultimately make a final determination of whether to grant or deny a construction permit to SHINE.

Hearing Process Applicable for Licensing

Pursuant to 10 CFR 50.58, "Hearings and report of the Advisory Committee on Reactor Safeguards," the Commission will hold a mandatory hearing on each application for a construction permit for a production or utilization facility used for industrial or commercial

[19] Summary of Public Scoping Meetings Conducted Related to the Review of the Proposed SHINE Medical Technologies, Inc. Radioisotope Production Facility, dated September 23, 2013 (ADAMS Accession No. ML13227A391).

[20] Enclosure 4, "Proposed Technical Review Schedule," contains sensitive internal information and has, thus, been designated as non-publicly available.

purposes as described in 10 CFR 50.22, “Class 103 licenses; for commercial and industrial facilities.” Unless, the Commission directs otherwise, a proceeding on whether to license SHINE would be conducted under 10 CFR Part 2, “Agency Rules of Practices and Procedure,” Subpart L, “Simplified Hearing Procedures for NRC Adjudications,” and hearing petitioners/requestors could indicate their selection of hearing procedures under 10 CFR 2.310, “Selection of hearing procedures.” The Commission, presiding officer, or Atomic Safety and Licensing Board designated to rule would determine whether to grant or deny any intervention petition or hearing request pursuant to the requirements of 10 CFR 2.309(a). The hearing would address findings required by 10 CFR Parts 50 and 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.”

RECOMMENDATION:

That the Commission:

1. Approve for publication in the *Federal Register* the direct final rule and companion proposed rule (Enclosures 1 and 2).

2. 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). This certification is included in the enclosed direct final rule.

Note

a. An Environmental Assessment (Enclosure 5) and Regulatory Analysis (Enclosure 6) have been prepared as a part of this rule.

b. This action is not a rule as defined in the Congressional Review Act (5 U.S.C. 801-808).

c. 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.).

d. The appropriate Congressional committees will be informed.

e. The contents of this paper were the subject of an Advisory Committee on Reactor Safeguards Informational Briefing on June 11, 2014.

RESOURCES:

The estimated resources to complete the rule are estimated to be less than 0.1 full time equivalent.

COORDINATION:

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.

The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections.

/RA/

Mark A. Satorius
Executive Director
for Operations

Enclosures:
1. Direct Final Rule: Definition of a Utilization Facility
2. Proposed Rule: Definition of a Utilization Facility
3. Margin of Subcriticality in SHINE Irradiation Units (non-public)
4. Proposed Technical Review Schedule (non-public)
5. Environmental Assessment and Finding of No Significant Impact
6. Regulatory Analysis

[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, 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 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.

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 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. SHINE's medical isotope production facility would include an irradiation facility and a radioisotope production facility housed in a single building, and is proposed to be built in Wisconsin, an Agreement State.

[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.

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 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 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 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:

- 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 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?*

[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?*

[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.

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 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,[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.

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

[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.

appropriate regulatory requirements governing SHINE's requested licensing action to SHINE; 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.

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 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 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 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. 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.

[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, 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 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.

ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT FOR THE DIRECT FINAL RULE AMENDING 10 CFR PART 50: DEFINITION OF A UTILIZATION FACILITY

Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Month 2014

I. Introduction

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" under Part 50 of Title 10 of the Code of Federal Regulations (10 CFR), "Domestic Licensing of Production and Utilization Facilities." 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 the NRC staff to apply appropriate regulations to the application and conduct an efficient and effective licensing review of the irradiation facility described in the SHINE construction permit application and any subsequent operating license application 10 CFR Part 50. Therefore, in support of this rulemaking, and as required by 10 CFR 51.21, the NRC staff has performed an environmental assessment.

II. Environmental Assessment

Facility Site and Environs:

If licensed, the SHINE facility would be constructed and operated on a 91 acre (36.8 hectare) site in Rock County, approximately 4 miles (6.4 kilometers) south of the Janesville, WI city center.

Identification of the Action:

The action will amend the NRC's regulations in 10 CFR 50.2 to add SHINE's accelerator-driven subcritical operating assemblies, as described in the application assigned docket number 50-608, to the definition of utilization facility in 10 CFR 50.2.

The action allows the NRC staff to review the irradiation facility described in SHINE's construction permit application in docket number 50-608 (the NRC's Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML130880226 and ML13172A324) under the regulations in 10 CFR Part 50.

The Need for the Action:

As summarized in SHINE's Preliminary Safety Analysis Report (PSAR), SHINE has proposed to construct eight irradiation units to be collectively housed in an irradiation facility. Each irradiation unit is an independent accelerator-driven subcritical operating assembly used for the irradiation of an aqueous uranyl sulfate target solution, resulting in the production of Mo-99 and other fission products. The proposed irradiation units do not fit the definitions of either production facility or utilization facility currently found in 10 CFR 50.2. However, based on SHINE's proposed use of special nuclear material, the Commission could use its authority under the Atomic Energy Act of 1954, as amended, to promulgate a rule that adds the SHINE irradiation units to the Commission's definition of utilization facility in 10 CFR Part 50. Furthermore, each irradiation unit has many of the attributes of existing non-power reactors, which are licensed as utilization facilities. Therefore, the NRC will modify the definition of utilization facility found in 10 CFR 50.2 to add SHINE's proposed accelerator-driven subcritical operating assemblies. The amended regulation allows the NRC staff to review the irradiation units discussed in SHINE's construction permit application using the most appropriate regulations to ensure protection of the public health and safety and promotion of the common defense.

Environmental Impacts of the Action:

This environmental assessment focuses on the environmental effects of the change to the NRC's regulation defining a utilization facility. This action will have no environmental effect on existing or future applications or licenses. As a result of this rule change, the accelerators integrated into the SHINE irradiation units will be considered part of the utilization facilities, and will be under the regulatory jurisdiction of the NRC. Because the rule is narrowly focused to only add the accelerator-driven subcritical operating assemblies proposed under docket number 50-608 to the definition of utilization facility in 10 CFR 50.2, this rule change only impacts the regulatory framework for the review of the SHINE construction permit application (and if requested in the future, an operating license), and therefore involves no adverse environmental impacts.

The principal effect of this action is to revise the definition of utilization facility to encompass the SHINE irradiation units, therefore enabling the NRC staff to conduct a technical review of the SHINE irradiation facility under the regulations that are most appropriate for adequate protection of the health and safety of the public. This action does not authorize the issuance of a construction permit or operating license for the SHINE irradiation units and is not a determination that the SHINE irradiation units can meet the applicable requirements in 10 CFR Part 50. A determination of whether the SHINE irradiation units can be licensed under 10 CFR Part 50 will be evaluated separately by the NRC staff as part of the review of the SHINE preliminary and final safety analysis reports. Additionally, an opportunity for the public to request for leave to intervene and request a hearing on the application will be provided by a separate notice in the *Federal Register*. Therefore, the amendment to the regulations does not authorize any release of effluents, involve any individual or cumulative exposures, or create any potential for radiological accidents. In addition, the rule does not authorize any construction, land disturbance, or transportation. As a result, there are no significant radiological or non-radiological environmental impacts associated with the action.

Accordingly, the NRC staff has concluded that there are no significant radiological environmental impacts, non-radiological impacts, or cumulative impacts associated with this change to the definition of utilization facility in 10 CFR 50.2, and pursuant to 10 CFR 51.32, determined that the granting of this exemption will not have a significant effect on the quality of the human environment as it is administrative in nature. Therefore, the NRC concludes that there are no significant environmental impacts associated with the action.

Environmental Impacts of the Alternatives to the Action:

As an alternative to the action, the NRC staff considered not taking the action (i.e., the no action alternative). This alternative would result in no changes in environmental impacts. The no action alternative would result in the NRC staff reviewing the irradiation units under 10 CFR part 70. Reviewing the irradiation units under 10 CFR part 70 would have no different environmental impacts than reviewing them under 10 CFR part 50. In either case, the NRC staff would perform a thorough safety, environmental, and security review, and would determine whether to issue a construction permit or operating license using applicable regulatory and statutory requirements. Because this rulemaking does not authorize the issuance of a construction permit or operating license, any eventual licensing decisions would be a separate action from this rulemaking and the environmental impacts of those licensing actions, if authorized, would be evaluated separately.

Given that the direct final rule and the no action alternative do not constitute actions that authorize issuance of a construction permit or operating license, and hence, do not cause any radiological or non-radiological impacts, the environmental impacts of the action and the alternative actions are the same.

Alternative Use of Resources:

There are no irreversible commitments of resources determined in the environmental assessment of this rulemaking action.

Agencies and Persons Consulted:

No agencies or persons outside of the NRC were consulted about the potential environmental impacts of this rulemaking action.

III. Finding of No Significant Impact

The NRC is issuing a direct final rule that will amend 10 CFR Part 50 to add SHINE's accelerator-driven subcritical operating assemblies to the definition of utilization facility in 10 CFR 50.2. On the basis of the environmental assessment included in Section II of this document and incorporated by reference in this finding, the NRC concludes that the action will not have significant effects on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the action. Additional information on the SHINE environmental report submitted under docket No. 50-608 in support of the SHINE construction permit application is publicly available in ADAMS, Accession No. ML13172A324.

Regulatory Analysis for Adding SHINE Medical Technologies, Inc.'s Accelerator-Driven Subcritical Operating Assembly to the Definition of a Utilization Facility

U.S. Nuclear Regulatory Commission
Office of Nuclear Reactor Regulation
Division of Policy and Rulemaking

FOREWORD

The direct final rule titled, “Definition of a Utilization Facility,” addresses the licensing implications of modifying Part 50 of Title 10 of the *Code of Federal Regulations*, “Domestic Licensing of Production and Utilization Facilities,” related to the review of the construction permit application of SHINE Medical Technologies, Inc.

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ABBREVIATIONS AND ACRONYMS

U-233 – uranium-233

U-235 – uranium-235

Mo-99 – molybdenum-99

Tc-99m – metastable technicium-99

ADAMS – Agencywide Documents Access and Management System

AEA – Atomic Energy Act of 1954, as amended

Al_2O_3 - alumina

AMIPA – American Medical Isotopes Production Act of 2012

CFR – *Code of Federal Regulations*

DFR – direct final rule

ER – environmental report

FTE – full-time equivalent

FY – fiscal year

ISG – interim staff guidance

NMSS – Office of Nuclear Material Safety and Safeguards

NRC – U.S. Nuclear Regulatory Commission

OMB – Office of Management and Budget

PSAR – preliminary safety analysis report

RA – regulatory analysis

RA guidelines – NUREG/BR-0058, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” September 2004

RA Handbook – NUREG/BR-0184, “Regulatory Analysis Technical Evaluation Handbook,” January 1997

SHINE – SHINE Medical Technologies, Inc.

SNM – Special Nuclear Material

REGULATORY ANALYSIS

1. INTRODUCTION

1.1 Background[1]

The radioactive decay product of molybdenum-99 (Mo-99), metastable technicium-99 (Tc-99m), is one of the most widely used isotopes in nuclear medicine for diagnostic imaging. Mestastable technicium-99 has a half-life of about 6 hours and emits 140 kiloelectron volt photons when it decays to technicium-99, a radioactive isotope with about a 214,000-year half-life. At this energy, photons can be detected by scintillation instruments (e.g., gamma cameras) and provide detailed medical images. Clinical uses of Tc-99m enable the investigation, diagnosis, and evaluation of ailments and conditions affecting the respiratory, renal, musculoskeletal, cardiovascular, central nervous and other body systems[2].

Mestastable technicium-99 is produced in a multistep process, often beginning with the neutron irradiation of uranium-235 (U-235), usually contained in enriched uranium targets, in a nuclear reactor. This irradiation causes U-235 to fission which, among other fission products, produces Mo-99. Following irradiation, the targets are chemically processed to separate Mo-99 from other fission products. A solution containing the separated Mo-99 is then adsorbed onto an alumina (Al_2O_3) column. The columns are shipped to radiopharmaceutical companies and hospitals in radiation-shielded containers (technetium generators).

The Mo-99 in the technetium generator decays with about a 66-hour half-life to Tc-99m. The Tc-99m is typically recovered by passing a saline solution through the Al_2O_3 column. The saline removes the Tc-99m but leaves the Mo-99 in place. A technetium generator can be used several times a day for about a week before it needs to be replaced.

Due to its 66-hour half-life Mo-99 cannot be stockpiled for use. To ensure availability, it must be made on a weekly or more frequent basis. The processes for producing Mo-99 and technetium generators and delivering them to customers are tightly scheduled and highly time dependent. An interruption at any point in the production, transport, or delivery of Mo-99 or technetium generators can have substantial impacts on patient care.

Nearly all of the world's supply of Mo-99 is met by five aging nuclear research reactors located in the Netherlands, South Africa, Belgium, Canada, and France. Over the past few years, extended shutdowns at some of these major Mo-99 production facilities have resulted in significant shortages, both domestically and internationally, of this important medical isotope. One of the producers, the National Research Universal reactor, is responsible for over 40 percent of the global supply and will cease production in 2016. Based on recent history, additional planned and unplanned shutdowns are likely to occur in order to address

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1 "Medical Isotope Production without Highly Enriched Uranium," The National Academies Press, Washington, DC, 2009.

2 Canadian Agency for Drugs and Technologies in Health, "Clinical Uses of Technetium-99m," http://www.cadth.ca/en/publication/2866.

maintenance and aging issues. Therefore, it may be appropriate to anticipate additional shortages of Mo-99 will continue to occur until additional production capabilities are established.

1.2 Statement of the Problem and Objective

1.2.1 Problem Statement

By letters dated February 14, 2011, and May 3, 2011,[3] SHINE Medical Technologies, Inc. (SHINE) notified the U.S. Nuclear Regulatory Commission (NRC) of its intent to submit applications to construct, and operate, a medical isotope production facility. SHINE's medical isotope production facility would include an irradiation facility 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) states that the irradiation facility consists of eight irradiation units.[4] Each irradiation unit is an accelerator-driven subcritical operating assembly and would be used for the irradiation of an aqueous uranyl sulfate target solution. 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 reactors as defined in § 50.2, "Definitions," 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 SHINE irradiation units and radioisotope production facility could be jointly licensed under the third part of the production facility definition in 10 CFR 50.2.

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[6] (SNM), similar to the irradiation units proposed by SHINE, could be licensed as a production facility pursuant to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."[7] Based on the guidance provided in the ISG, on March 26, 2013, and May 31, 2013,

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3 Gregory Piefer, PhD, SHINE, letter 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 Gregory Piefer, PhD, SHINE, letter to Mr. John Kinnemann, NMSS, "Updated Request for Regulatory Interpretations," dated May 3, 2011 (ADAMS Accession No. ML11138A220), respectively.

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

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).

6 Special nuclear material (SNM) is defined to include "uranium enriched in the isotope 233 or in the isotope 235." *See* Atomic Energy Act Section 11aa, 42 U.S.C. 2014 (2005).

7 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 at iv.

SHINE submitted a two-part construction permit application for a production facility as defined in § 50.2.[8] 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. As currently defined in § 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.[9]

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.

1.2.2 Objective

The objective of this regulatory analysis is to provide the benefits and costs of alternatives for consideration that would ensure that the SHINE application is reviewed under the most cost-beneficial (i.e., cost-effective) framework.

2. IDENTIFICATION AND PRELIMINARY ANALYSIS OF ALTERNATIVE APPROACHES

The NRC has identified three alternatives, with sub-alternatives, for consideration. Under Section 11cc. of the Atomic Energy Act of 1954, as amended (AEA), 42 U.S.C. 2011 et seq., the Commission determines by rule what constitutes a utilization facility; therefore, only rulemaking alternatives were considered.

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[8] *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.

[9] *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).

2.1 Alternative 1 – Taking No Action

This alternative entails evaluating the SHINE irradiation units without modifying the 10 CFR Part 50 definition of utilization facility. Without this modification to the regulations, the SHINE irradiation units would not fall under the scope of 10 CFR Part 50 and would be licensed under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

The no action alternative would not amend the current definition of utilization facility in 10 CFR 50.2:

> *Utilization facility* means any nuclear reactor other than one designed or used primarily for the formation of plutonium or U-233.

2.2 Alternative 2 – Rule of Particular Applicability

This alternative amends the definition of utilization facility found in 10 CFR 50.2 through either a direct final rule (DFR)[10] or a proposed and final rule to include only the irradiation units proposed under docket number 50-608. Amending the definition of utilization facility will allow for the SHINE application to be licensed under 10 CFR Part 50 instead of under 10 CFR Part 70. The DFR will amend the definition of utilization facility to state:

> *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.

2.2.1 Alternative 2.1 – Direct Final Rule

For the DFR rulemaking alternative, the DFR would amend the definition of utilization facility in 10 CFR 50.2 as stated above in Section 2.2. The benefits and costs of this alternative are detailed in the following sections.

2.2.2 Alternative 2.2 – Proposed and Final Rule

For the proposed and final rule sub-alternative, the rule language provided above would be provided as a proposed rule for public comment. The proposed rule would allow for a 75-day comment period. The NRC would respond to any comments received on the proposed rulemaking and provide a final rule to the Commission for vote. The time between issuing the proposed rule and the final rule is expected to be one year. Therefore, assuming the DFR does not receive any significant adverse comments, this proposed rule alternative would require one extra year before implementation.

This sub-alternative is similar to a DFR that has received significant adverse comments. Therefore, this sub-alternative is not described in detail below. However, one can surmise the potential benefits and costs from a proposed and final rule by the benefits and costs from a DFR

[10] A DFR provides both the DFR and a proposed rule package. If any significant adverse comments are received, then the DFR would be withdrawn, and the comments would be addressed in the publication of a final rule.

that has received significant adverse comments (i.e., the benefits would not change, but the costs would increase).

2.3 Alternative 3 – Rule of Generic Applicability

This alternative amends the definition of utilization facility found in 10 CFR 50.2 to allow for technology similar to that proposed by SHINE to be licensed under 10 CFR Part 50. A generic rulemaking can be implemented by developing a DFR or through issuing a proposed and final rule. In both sub-alternatives, the DFR or proposed rule would amend the definition of utilization facility in 10 CFR 50.2 to state a more generic definition.

2.3.1 Alternative 3.1 – Direct Final Rule

For the DFR rulemaking alternative, the DFR would amend the definition of utilization facility in 10 CFR 50.2 as stated above in Section 2.3. The benefits and costs of this alternative are detailed in the following sections.

2.3.2 Alternative 3.2 – Proposed and Final Rule

For the proposed and final rule sub-alternative, the language above would be provided, as a proposed rule requesting public comment, to the Commission for a vote. If approved by Commission vote, the proposed rule would be published in the *Federal Register* and allow for a 75-day comment period. The NRC would respond to any comments received on the rulemaking and provide a final rule to the Commission for a vote. The time between issuing the proposed rule and the final rule is expected to be one year. Therefore, assuming the DFR does not receive any significant adverse comments, the notice and comment rulemaking alternative would require one extra year before implementation.

This sub-alternative is similar to a DFR that has received significant adverse comments. Therefore, the benefits and costs of this sub-alternative are not described in detail below. However, one can surmise the potential benefits and costs from a proposed and final rule by the benefits and costs from a DFR that has received significant adverse comments (i.e., the benefits would not change, but the costs would increase).

3. ESTIMATION AND EVALUATION OF COSTS AND BENEFITS/PRESENTATION OF RESULTS

3.1 Methodology

The methodology for a regulatory analysis is specified by various guidance documents. The two documents that govern the NRC's voluntary regulatory analysis process are NUREG/BR-0058, "Regulatory Analysis [RA] Guidelines of the U.S. Nuclear Regulatory Commission," Revision 4, September 2004 (RA Guidelines), and NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook," January 1997 (RA Handbook). The regulatory analysis identifies all attributes related to the regulatory action and analyzes them either quantitatively or qualitatively.

For the quantified regulatory analysis, the NRC staff develops expected values for each cost and benefit. The expected value is the product of the probability of the cost or benefit occurring

and the consequences that would occur assuming the event actually happens. First, for each alternative, the staff determines the probabilities and consequences for each cost and benefit, including the year the consequence is incurred. The NRC staff then discounts the consequences in future years to the current year of the regulatory action. Finally, the NRC staff sums the costs and the benefits for each alternative and compares them.

After performing a quantitative regulatory analysis, the NRC staff will add attributes that could only be qualified. Based on the qualification of each attribute, uncertainties, sensitivities, and the quantified costs and benefits, the staff will make a recommendation for each alternative. If the benefits, both quantified and qualified, are judged to be greater than the quantified and qualified costs, then the staff will recommend the alternative should be implemented. If the benefits, both quantified and qualified, are judged to be less than the quantified and qualified costs, then the staff will recommend the alternative not be implemented.

3.2 Assumptions

The assumptions provided in this section are used to develop this regulatory analysis.

3.2.1 Affected Entities

The NRC assumes that alternative 2 will only affect one current entity (SHINE) and alternative 3 may affect multiple entities outside of SHINE. This is based on the eight letters of intent to construct and operate medical radioisotope production facilities that the NRC has received, to date. The NRC also assumes that SHINE may need to supplement its current application if there is a change to the definition of utilization facility.

3.2.2 Time-frames for Alternatives

The NRC assumes that a DFR (alternatives 2.1 and 3.1) would be completed in FY 2014. The NRC also assumes that a proposed and final rulemaking (alternative 2.2 and 3.2) would be completed in FY 2015, prior to the completion of the staff's review of the SHINE construction permit.

3.2.3 Base Year of Analysis

The NRC assumes that the base year of the analysis is FY 2014. Therefore, all quantified benefits and costs will be escalated or discounted to FY 2014.

3.2.4 Labor Costs

A year's worth of labor effort is known as a full-time equivalent (FTE). The NRC assumes that one FTE for the NRC is $166,000. This labor cost is based on the FY 2012 incomes, benefits, and other expenses and the methodology provided in NUREG/CR-4627, "Generic Cost Estimates," Revision 2, February 1992.

The NRC assumes that one FTE for industry for the administrative supplement to the SHINE construction permit application is $200,000.

3.2.5 Present Value Calculations

The present value calculations determine how much society would need to invest today to ensure that the designated dollar amount is available in a given year in the future. By using discount factors for the costs and benefits, it allows for future costs and benefits to be valued equally. Based on the Office of Management and Budget's (OMB) guidance, Circular No. A-4, dated September 17, 2003, present value calculations are presented using both 3 percent and 7 percent real discount rates where the decision rationale is based on the 7 percent real discount rate. Although the NRC is not bound to follow OMB guidance, historically the NRC has voluntarily complied with the present value calculations developed in OMB Circular No. A-4 and has stated such in RA Guidelines and the RA Handbook.

3.3 Alternative 2 – Rule of Particular Applicability

3.3.1 Industry Implementation

The current application was submitted under 10 CFR Part 50. SHINE is requesting a construction permit to build a single production facility as defined in 10 CFR 50.2, which would consist of an irradiation facility and a radioisotope production facility. The alternative would designate the irradiation units as utilization facilities, as defined in 10 CFR 50.2. The radioisotope production facility would remain a production facility. Modifying the definition of utilization facility would require SHINE to meet some of the requirements found in 10 CFR 50.55a, "Codes and standards" and 10 CFR Part 55, "Operator's Licenses." Therefore, SHINE may need to supplement its existing construction permit application and add additional information to any future operating license application. The NRC estimates that it would take 0.05 FTE in FY 2014 for SHINE to supplement its construction permit application and 0.05 FTE in FY 2015 to add information to any future operating license application. Therefore, the industry implementation cost is estimated to be $10,000 for a DFR and ranges from $9,700 (3 percent net present value) to $9,300 (7 percent net present value) for a rule of particular applicability with a proposed and final rule.

Relative to alternative 3, if an entity similar to SHINE submits an application to the NRC in the future, the costs provided above would be incurred by the entity. However, as an entity similar to SHINE is unknown at this time, a discounted cost cannot be provided within this regulatory analysis.

3.3.2 NRC Implementation

The NRC would incur costs for implementing the rule of particular applicability as a DFR. The NRC estimates that the rule of particular applicability would require 0.4 FTE in FY 2014 to develop the DFR and assuming no significant adverse comments. If any significant adverse comments are received, then the DFR would be withdrawn, and the comments would be addressed in the publication of a final rule. In this scenario, the NRC estimates that the rule of particular applicability would require 1 FTE in FY 2014 and 0.4 FTE in FY 2015. Therefore, the NRC estimates that the NRC cost of implementing the rule of particular applicability as a DFR is $66,400 (0.4 FTE X $166,000) and the NRC estimates that the cost to the NRC of implementing the rule of particular applicability with a proposed and final rule ranges from $230,000 (3 percent net present value) to $228,000 (7 percent net present value).

As any supplement to the SHINE construction permit application would likely be minimal, the NRC's review of any such supplement would also likely require minimal resources; therefore, the NRC estimates that it would require 0.05 FTE in FY 2014 for a DFR and 0.05 FTE in FY 2015 for a rule of particular applicability with a proposed and final rule. The NRC estimates the cost for the review of the supplement to be $8,300 for a DFR and an estimated range from $8,100 (3 percent net present value) to $7,800 (7 percent net present value) for a rule of particular applicability with a proposed and final rule.

The overall estimated quantified cost for the NRC implementation of the rule of particular applicability as a DFR is $74,700 and an estimated range for a rule of particular applicability with a proposed and final rule from $238,000 (3 percent net present value) to $236,000 (7 percent net present value).

If any future entities similar to SHINE submit an application to the NRC, then the NRC would incur this cost, which would be similar, but likely less than the above cost. This cost would also need to be discounted back to the current year; therefore, the further in the future an entity applies to the NRC, the less cost it would be to the NRC in current dollars. Also, as mentioned previously, the NRC does not expect any other entity similar to SHINE to submit an application to the NRC.

3.3.3 Regulatory Efficiency

There would be several forms of regulatory efficiency by implementing alternative 2.

The first efficiency would be consistency with the American Medical Isotope Production Act of 2012 (AMIPA). Specifically, the AMIPA instructs the Secretary of Energy to carry out a program to evaluate and support projects for the production of significant quantities of Mo-99 for medical uses in the United States, without the use of highly enriched uranium. Therefore, by amending the definition of utilization facility, a well-established and existing regulatory framework can be applied toward the licensing of a domestic isotope production facility.

Another regulatory efficiency comes from expanding the 10 CFR 50.2 definition of utilization facility. This creates a more efficient and technically justified means for licensing an isotope production facility under existing regulations. The rule change does not impose any new or different regulatory requirements nor does it impose any new reporting or recordkeeping requirements.

Relative to a generic rulemaking, this alternative may be more efficient. By having a rule of particular applicability, it will ensure that there is no over-inclusion. Specifically, there would be no 10 CFR Part 70 entities that may be accidentally redefined as a utilization facility and then fall under the regulations of 10 CFR Part 50. If an entity were to be accidently included within the definition of utilization facility, it would create a situation where an entity would need to be regulated under a different part than it is currently licensed under and may raise safety concerns.

3.3.4 Other Government

By redefining the SHINE irradiation units as utilization facilities, no part of the facility would be regulated by the state of Wisconsin, an Agreement State. This poses no regulatory burden on the Agreement State.

3.3.5 Attributes Not Affected

The following attributes are not affected by this alternative: (1) public health (accident), (2) public health (routine), (3) occupational health (accident), (4) occupational health (routine), (5) offsite property, (6) onsite property, (7) industry operation, (8) NRC operation, (9) improvements in knowledge, (10) antitrust considerations, (11) safeguards and security considerations, (12) general public, (13) environmental considerations, and (14) other considerations.

3.4 Alternative 3 – Rule of Generic Applicability

As the general rulemaking sub-alternative will not be evaluated, as mentioned in Section 2.3, this alternative will only provide the costs and benefits of a generic DFR.

3.4.1 Industry Implementation

The generic rulemaking alternative would expand the definition of utilization facility in 10 CFR 50.2 to include technologies similar to the irradiation units proposed by SHINE. As in alternative 2, this alternative would designate SHINE's irradiation units as utilization facilities as defined in 10 CFR 50.2 and would require SHINE to meet some of the requirements found in 10 CFR 50.55a, "Codes and standards" and 10 CFR Part 55, "Operator's Licenses." Therefore, SHINE may need to supplement its existing construction permit application and add additional information to any future operating license application. Additionally, expansion of the definition of utilization facility generically under this alternative could result in the inclusion of existing or future technologies appropriately regulated by Agreement States or 10 CFR Part 70 under the regulatory scope of 10 CFR Part 50. This could result in additional regulatory burdens or unintended consequences for existing or future licensees subject to the regulatory requirements for utilization facilities as a result of this generic rulemaking, including the application of the requirements of 10 CFR 50.55a and 10 CFR Part 55. The NRC estimates that it would take 0.05 FTE in FY 2014 for SHINE to supplement its construction permit application and 0.05 FTE in FY 2015 to add information to any future operating license application. However, the NRC considers the impact of a generic rulemaking on existing or future facilities to be too speculative and unknown to assign industry implementation costs for the purposes of this regulatory analysis. Therefore, the total industry implementation cost for this alternative is estimated to be $10,000 for a DFR and ranges from $9,700 (3 percent net present value) to $9,300 (7 percent net present value) for a rule of generic applicability with a proposed and final rule.

3.4.2 NRC Implementation

The NRC would incur costs for implementing the rule of generic applicability as a DFR. The NRC estimates that the rule of generic applicability would require 0.6 FTE in FY 2014 to develop the DFR, assuming no significant adverse comments. The difference in effort is due to the increased time in development of the technical basis for the rule of generic applicability and to

ensure that no entities are inadvertently included within 10 CFR Part 50 that should remain in other parts of the NRC's regulations. If any significant adverse comments are received, then the DFR would be withdrawn, and the comments would be addressed in the publication of the final rule. In this scenario, the NRC estimates that the rule of generic applicability would require 1.2 FTE in FY 2014 and 0.4 FTE in FY 2015. Therefore, the NRC estimates that the NRC's cost of implementing the rule of generic applicability as a DFR is $99,600 (0.6 FTE X $166,000), and the NRC estimates that the NRC's cost of implementing the rule of generic applicability with a proposed and final rule ranges from $264,000 (3 percent net present value) to $261,000 (7 percent net present value).

As any supplement to the SHINE construction application or additional information provided in support of any future operating license application would likely be minimal, the NRC's review of such a supplement would likely also require minimal resources; therefore, the NRC estimates that it would require 0.05 FTE in FY 2014 for a DFR and 0.05 FTE in FY 2015 for a rule of generic applicability with a proposed and final rule. The NRC estimates the cost for the review of any supplement or additional information to be $8,300 for a DFR and an estimated range from $8,100 (3 percent net present value) to $7,800 (7 percent net present value) for a rule of generic applicability with a proposed and final rule.

The overall estimated quantified cost for the NRC to implement the rule of generic applicability as a DFR is $108,000 and an estimated range for a rule of generic applicability with a proposed and final rule from $272,000 (3 percent net present value) to $269,000 (7 percent net present value).

3.4.3 Regulatory Efficiency

There would be several forms of regulatory efficiency by implementing alternative 3.

The first efficiency would be consistency with the AMIPA. Specifically, the AMIPA instructs the Secretary of Energy to carry out a program to evaluate and support projects for the production of significant quantities of Mo-99 for medical uses in the United States, without the use of highly enriched uranium. Therefore, by amending the definition of utilization facility, a well-established and existing regulatory framework can be applied toward the licensing of SHINE's irradiation units.

Another regulatory efficiency comes from expanding the 10 CFR 50.2 definition of utilization facility, creating a more efficient and technically justified means for licensing SHINE's irradiation units.

This alternative would be less efficient than the rule of particular applicability rulemaking alternative (alternative 2). 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 10 CFR Part 70 under the regulatory scope of 10 CFR Part 50. Additionally, while a generic rule would not impose any new or different requirements, including reporting or recordkeeping requirements, on existing 10 CFR Part 50 facilities, any existing or future facilities that meet the expanded definition of utilization facility would be subject to all applicable regulatory requirements for utilization facilities, including reporting or recordkeeping requirements. Also, a generic rulemaking may need to be cleared by OMB under the Paperwork Reduction Act. This

imposition of additional licensing and oversight requirements as a result of a generic rulemaking could reduce the NRC's regulatory efficiency.

The generic rulemaking could provide a regulatory efficiency should the NRC receive another application for a medical radioisotope production facility proposing a technology similar to SHINE's irradiation units. In that circumstance an additional rulemaking would not be necessary. However, there is no regulatory efficiency to be gained from this approach at this time as the staff does not anticipate receiving any other applications for medical radioisotope production facilities that would propose a technology similar to SHINE's irradiation units.

3.4.4 Other Government

As a result of this rule change, the accelerators integrated into the SHINE irradiation units would be considered part of the utilization facilities. This would give the NRC exclusive jurisdiction over the SHINE facility, including the licensing and oversight of the accelerators associated with the irradiation units. This decreases the regulatory burden on the Agreement State and eliminates any potential jurisdictional issues and inefficiencies associated with dual regulation.

3.4.5 Attributes Not Affected

The following attributes are not affected by this alternative: (1) public health (accident), (2) public health (routine), (3) occupational health (accident), (4) occupational health (routine), (5) offsite property, (6) onsite property, (7) industry operation, (8) NRC operation, (9) improvements in knowledge, (10) antitrust considerations, (11) safeguards and security considerations, (12) general public, (13) environmental considerations, and (14) other considerations.

3.5 Totals

This section provides the totals both quantitatively and qualitatively for each of the alternatives.

3.5.1 Summary Tables

Table 1 – Summary of Totals for Alternatives

Net Monetary Savings (or Costs) – Total Present Value	**Non-Monetary Benefits/Costs**
Alternative 1 – No Action $0	**Qualitative Benefits and Costs:** None
Alternative 2 – Rule of Particular Applicability <u>Industry Implementation</u> *Direct Final Rule (DFR):* ($10,000) – 3 and 7 percent net present value *Proposed and Final Rule:* ($9,300) – 7 percent net present value ($9,700) – 3 percent net present value	**Qualitative Costs:** Industry Implementation NRC Implementation Other Government Regulatory Efficiency **Qualitative Benefits:** Regulatory Efficiency

NRC Implementation: *Direct Final Rule (DFR):* ($74,700) – 3 and 7 percent net present value *Proposed and Final Rule:* ($236,000) – 7 percent net present value ($238,000) – 3 percent net present value Total Quantified Benefit (or Cost): *Direct Final Rule (DFR):* ($84,700) – 3 and 7 percent net present value *Proposed and Final Rule:* ($245,000) – 7 percent net present value ($248,000) – 3 percent net present value	Total Qualitative Benefit (or Cost): Positive net benefit
Alternative 3 – Rule of Generic Applicability Industry Implementation *Direct Final Rule (DFR):* ($10,000) – 3 and 7 percent net present value *Proposed and Final Rule:* ($9,300) – 7 percent net present value ($9,700) – 3 percent net present value NRC Implementation *Direct Final Rule (DFR):* ($108,000) – 3 and 7 percent net present value *Proposed and Final Rule:* ($269,000) – 7 percent net present value ($272,000) – 3 percent net present value Total Quantified Benefit (or Cost): *Direct Final Rule (DFR):* ($118,000) – 3 and 7 percent net present value *Proposed and Final Rule:* ($278,000) – 7 percent net present value ($282,000) – 3 percent net present value	**Qualitative Costs:** Other Government Regulatory Efficiency **Qualitative Benefits:** Regulatory Efficiency Total Qualitative Benefit (or Cost): Positive net benefit

3.6 Disaggregation

A disaggregation was not performed for this regulatory analysis as this rule has only one part.

4. DECISION RATIONALE FOR SELECTION OF PROPOSED ACTION

The decision rationale for the selection of the alternative is based on quantitative and qualitative factors. Specifically, the costs of the rule are provided quantitatively and qualitatively and the benefits are provided only qualitatively.

In general, the rule of particular applicability alternative (alternative 2) and the generic rulemaking alternative (alternative 3), both of which are DFRs, are considered to be cost-beneficial alternatives relative to the no-action alternative (alternative 1) as the qualitative benefits outweigh the quantitative and qualitative costs for each of the alternatives. Specifically, the qualitative benefits from the gains in regulatory efficiency through these rulemakings outweigh the costs of developing the rule that are mostly incurred by the NRC.

4.1 Cost-Beneficial Alternatives

As stated above, both alternative 2 and alternative 3 are cost-beneficial alternatives. Therefore, to provide the Commission the staff's recommended alternative, the cost-beneficial alternatives are analyzed relative to each other.

4.1.1 Quantitative Comparison

As the costs are the only attributes that have been quantified, this will be the only attribute compared between the two alternatives. Assuming that both alternatives are a DFR, then alternative 2 is estimated to cost $33,300 less than alternative 3. If both of the alternatives receive significant adverse comments, then alternative 2 is estimated to cost $106,000 less than alternative 3 assuming a 7 percent discount rate. Also to note, the probability of receiving significant adverse comments is higher in alternative 3 than in alternative 2, so there is a probability that alternative 2 would not receive an adverse comment that alternative 3 would. If a significant adverse comment is provided in alternative 3, but not in alternative 2, then alternative 2 is estimated to cost $195,000 less than alternative 3.

4.1.2 Qualitative Comparison

There are various qualitative benefits and costs in relation to alternative 2 and alternative 3. The main qualitative benefit and cost for each alternative relates to the regulatory efficiency gained from the development of the rules. The benefits for alternative 2 from the regulatory efficiency are greater than those of alternative 3 as the possibility of over inclusion from alternative 3 negates any regulatory efficiency gained and costs averted from a future entity similar to SHINE requiring a rulemaking. Essentially, the risk of over inclusion of other entities is greater than the risk from an entity similar to SHINE submitting an application.

4.2 Decision Rationale for Selection of Cost-Beneficial Alternative

The staff recommends alternative 2 over alternative 3, as it provides the greatest cost-benefit. As mentioned in Section 4.1, the quantitative costs of alternative 2 are less than alternative 3. Also, the qualitative benefits for alternative 2 are greater to those of alternative 3. Because the qualitative benefits of alternative 2 are equal to or greater than the qualitative benefits of alternative 3 and equal to or greater than the cost savings from alternative 2 relative to alternative 3, alternative 2 should be implemented.

APPENDIX A – REFERENCES

1. U.S. Nuclear Regulatory Commission, “Regulatory Analysis Technical Evaluation Handbook,” NUREG/BR-0184, January 1997 (ADAMS Accession No. ML050190193).

2. U.S. Nuclear Regulatory Commission “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” NUREG/BR-0058, Revision 4, September 2004 (ADAMS Accession No. ML042820192).

3. U.S. Nuclear Regulatory Commission, “Generic Cost Estimates,” NUREG/CR-4627, Revision 1 and 2, February 1992 (ADAMS Accession No. ML13137A259).

4. Office of Management of the Budget, “Regulatory Analysis,” Circular A-4, issued September 2003.