

**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

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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,<sup>1</sup> 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),<sup>2</sup> 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.<sup>3</sup>

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

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<sup>1</sup> 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.

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

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

<sup>4</sup> 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<sup>5</sup> (SNM), similar to the irradiation units proposed by SHINE, could be licensed as a production facility pursuant to 10 CFR Part 50.<sup>6</sup> 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.<sup>7</sup> 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.<sup>8</sup>

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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<sup>5</sup> 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).

<sup>6</sup> 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.

<sup>7</sup> 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).

<sup>8</sup> 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,<sup>9</sup> 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 ( $k_{\text{eff}}$ ) 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  $k_{\text{eff}}$ . 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

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<sup>9</sup> 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.<sup>10</sup> 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.<sup>11</sup> 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*

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<sup>10</sup> 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.

<sup>11</sup> 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<sup>12</sup>

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.<sup>13</sup>

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<sup>14</sup>). 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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<sup>12</sup> 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.

<sup>13</sup> 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.

<sup>14</sup> 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.<sup>15</sup> 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.

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<sup>15</sup> 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,<sup>16</sup> 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.<sup>17</sup> 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.<sup>18</sup>

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<sup>16</sup> 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.

<sup>17</sup> AMIPA, Sec. 3173.(f) Improving the Reliability of Domestic Medical Isotope Supply (page 582).

<sup>18</sup> 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<sup>19</sup>. 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<sup>20</sup>), 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

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<sup>19</sup> 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).

<sup>20</sup> 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.

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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

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.

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ADAMS Accession Nos. ML14052A149 (Pkg); ML14052A123 (SECY Paper); Enclosure 1 ML14052A105 (Direct Final Rule); Enclosure 2 ML14052A114 (Proposed Rule); Enclosure 3 ML14115A462 (Margin of Subcriticality); Enclosure 4 ML14098A315 (Proposed Tech. Review Schedule); Enclosure 5 ML14052A097 (EA); Enclosure 6 ML14052A115 (Regulatory Analysis)

\* - Concurrence by e-mail

<b>OFFICE</b>	NRR/DPR/PRLB/PM	NRR/DPR/PRLB/LA	TechEditor*	NRR/DPR/PRLB/BC	NRR/DPR/D
<b>NAME</b>	SLynch	PBlechman	CHsu	AAdams	LKokajko
<b>DATE</b>	2/26/2014	4/8/2014	3/5/2014	4/11/2014	4/15/2014
<b>OFFICE</b>	NMSS	NSIR	FSME	OIS	ADM*
<b>NAME</b>	CHaney	JWiggins	BHolian (MShaffer for)	JFlanagan	CBladey
<b>DATE</b>	4/18/2014	4/16/2014	4/22/2014	4/17/2014	5/23/2014
<b>OFFICE</b>	OGC*	NRR	EDO		
<b>NAME</b>	BJones	ELeeds (JUhle for)	MSatorius		
<b>DATE</b>	5/29/2014	5/30/14	06/16/14		

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