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.

TABLE OF CONTENTS

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.