August 26, 2014

MEMORANDUM TO: Mark A. Satorius
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary **/RA/**

SUBJECT: STAFF REQUIREMENTS – AFFIRMATION SESSION, 10:00 A.M., TUESDAY, AUGUST 26, 2014, COMMISSIONERS' CONFERENCE ROOM, ONE WHITE FLINT NORTH, ROCKVILLE, MARYLAND (OPEN TO PUBLIC ATTENDANCE)[1]

I. COMSECY-14-0020 – Revisions to Direct Final Rule: Safeguards Information - Modified Handling Categorization Change for Materials Facilities (RIN 3150-AJ18)

The Commission approved a direct final rule and the companion proposed rule amending 10 CFR Parts 30, 37, 73, and 150 to remove the Safeguards Information – Modified Handling (SGI-M) designation of the security-related information for large irradiators, manufacturers and distributors, and for transport of category 1 quantities of radioactive material, with the changes in attachments 1 and 2.

Following incorporation of these changes, the *Federal Register* notice should be reviewed by the Rulemaking, Directives, and Editing Branch in the Office of Administration and forwarded to the Office of the Secretary for signature and publication.

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

The Commission approved a direct final rule and companion proposed rule amending 10 CFR Part 50.2 to add SHINE Medical Technologies, Inc.'s (SHINE) proposed accelerator-driven subcritical operating assemblies to the definition of a "utilization facility," subject to the changes in attachments 3 and 4. This rule will 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."

Following incorporation of these changes, the *Federal Register* notice should be reviewed by the Rulemaking, Directives, and Editing Branch in the Office of Administration and forwarded to the Office of the Secretary for signature and publication.

[1] Section 201 of the Energy Reorganization Act, 42 U.S.C. Section 5841, provides that action of the Commission shall be determined by a Amajority vote of the members present.@ Chairman Macfarlane, and Commissioners Svinicki, and Ostendorff were present in the Conference Room. Commissioner Magwood participated in the meeting via speakerphone.

III. SECY-14-0072 – Final Rule: Continued Storage of Spent Fuel (RIN 3150-AJ20)

The Commission approved a final rule and its associated generic environmental impact statement (GEIS) amending 10 CFR Part 51 to revise the generic determination on the environmental impacts of continued storage of spent nuclear fuel beyond the licensed life for operation of a reactor, with the changes in attachment 5.

The staff should revise the responses to the comments in Appendix D to reflect the possibility that the U.S. government will have to pay for the long-term storage of spent fuel.

Following incorporation of these changes, the *Federal Register* notice should be reviewed by the Rulemaking, Directives, and Editing Branch in the Office of Administration and forwarded to the Office of the Secretary for signature and publication.

In implementing the published GEIS findings into site-specific environmental analyses, the staff should utilize approaches that are transparent to the public on how these impact ranges are considered for each specific site.

IV. SECY-14-0075 – Continued Storage of Spent Nuclear Fuel - Memorandum and Order Lifting Suspension on Final Licensing Decisions and Addressing Pending Contentions

The Commission approved a Memorandum and Order lifting the suspension on final licensing decisions that the Commission imposed in CLI-12-16 as of the effective date of the Continued Storage Rule, and providing direction with respect to "continued storage" contentions that are currently held in abeyance in twenty-one adjudications before the Commission and the Atomic Safety and Licensing Boards.

(Subsequently, on August 26, 2014, the Secretary signed the Memorandum and Order.)

Attachments:
1. Changes to the *Federal Register* Notice for the Final Rule in COMSECY-14-0020
2. Changes to the *Federal Register* Notice for the Proposed Rule in COMSECY-14-0020
3. Changes to the *Federal Register* Notice for the Final Rule in SECY-14-0061
4. Changes to the *Federal Register* Notice for the Proposed Rule in SECY-14-0061
5. Changes to the *Federal Register* Notice for the Final Rule and GEIS in SECY-14-0072

cc: Chairman Macfarlane
Commissioner Svinicki
Commissioner Magwood
Commissioner Ostendorff
OGC
CFO
OCA
OPA
Office Directors, Regions, ACRS, ASLBP (via E-Mail)

PDR

Attachment 1
[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 37, 73, and 150

[NRC-2012-0140]

RIN 3150-AJ18

Safeguards Information - Modified Handling Categorization

Change for Materials Facilities

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to remove the Safeguards Information – Modified Handling (SGI-M) designation of the security-related information for large irradiators, manufacturers and distributors, and for transport of category 1 quantities of radioactive material. The rulemaking will also result in the removal of the SGI-M designation of the security-related information for the transportation of irradiated reactor fuel that weighs 100 grams or less in net weight of irradiated fuel. The security-related information for these facilities and the transportation of certain materials will no longer be designated as SGI-M and will be protected under the information protection requirements that apply to other materials licensees that possess category 1 and category 2 quantities of radioactive material.

DATES: This final rule is effective **[INSERT DATE 120 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-2012-0140 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-2012-0140. 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 direct final rule.

- **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: Vanessa Cox, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-8342, e-mail: Vanessa.Cox@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background.

The NRC has issued three sets of security orders containing SGI-M for the protection of category 1 and category 2 quantities of radioactive material. These orders were all issued under the Commission's authority for common defense and security. The first set of orders was issued to panoramic and underwater irradiator licensees that possess more than 370 Terabequerels (TBq) (10,000 curies (Ci)) of radioactive material (large irradiators) (EA-02-249; June 6, 2003) (68 FR 35458; June 13, 2003). The second set of orders was issued to manufacturing and distribution (M&D) licensees (EA-03-225; January 12, 2004) (69 FR 5375; February 4, 2004). The third set of orders was issued to licensees that transport source, byproduct, or special nuclear material in category 1 quantities of radioactive material (EA-05-006; July 19, 2005) (70 FR 44407; August 2, 2005). The third set of orders also covered transportation of irradiated reactor fuel that weighs 100 grams or less in net weight of irradiated fuel.

The orders issued to large irradiators, M&D licensees, and licensees transporting category 1 quantities of radioactive materials, require these licensees to perform specified actions within specific timeframes. The information related to these timeframes is designated SGI-M. Some licensees have developed security plans incorporating these timeframes. Therefore, information contained in these security plans has been designated as SGI-M. Furthermore, the orders to licensees transporting category 1 quantities of radioactive material require these licensees to develop transportation security plans and coordinate itinerary information with the states through which the shipment will be traveling. Portions of these transportation security plans and itinerary information are also designated as SGI-M.

A fourth set of orders, commonly called the Increased Control (IC) Orders, was issued to all other licensees that possessed greater than category 2 quantities of radioactive material (EA-05-090; November 14, 2005) (70 FR 72128; December 1, 2005). These orders were issued under the Commission's authority for protection of public health and safety. The IC Orders require licensees to immediately detect, assess, and respond to any unauthorized access to category 2 or greater quantities of radioactive material. These orders do not contain any specific response times or other SGI-M information. Because these licensees' security plans are based on the IC Orders, and these orders do not contain SGI information, the security plans for licensees subject only to the IC Orders are not designated as SGI-M.

On October 24, 2008 (73 FR 63546), the NRC published a final rule that established, among other things, the requirements for protection of SGI-M and designated categories of licensees that would be subject to the SGI-M provisions. The SGI-M requirements are located in part 73 of Title 10 of the *Code of Federal Regulations* (10 CFR), "Physical Protection of Plants and Materials." This rule~~making~~ required certain licensees to establish, implement, and maintain an information protection system that includes the applicable measures for SGI-M specified in ~~§~~ 10 CFR 73.23, "Protection of Safeguards Information – Modified Handling:

Specific requirements." This section contains specific requirements related to panoramic and underwater irradiators that possess greater than 370 TBq (10,000 Ci) of byproduct material in the form of sealed sources; manufacturers and distributors of items containing source, byproduct, or special nuclear material in greater than or equal to category 2 quantities of concern; the transportation of irradiated reactor fuel that weighs 100 grams or less in net weight of irradiated fuel; and transportation of source, byproduct, or special nuclear material in greater than or equal to category 1 quantities of concern. The rule was effective on February 23, 2009. Orders containing the requirements for protection of SGI-M were not modified or rescinded after issuance of the final rule; therefore, licensees are currently subject to both the requirements in the regulations and the orders.

On March 19, 2013 (78 FR 16922), the NRC published a final rule in the *Federal Register*, adding a new part 37 to Title 10 of the CFR, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material." NRC licensees were required to comply with 10 CFR part 37 by March 19, 2014. The final rule establishes the security requirements for the protection of category 1 and category 2 quantities of radioactive material and for transportation of irradiated reactor fuel that weighs 100 grams or less in net weight of irradiated fuel. The rule also contains information protection requirements for the security plan, procedures, and other information.

II. Discussion.

A. What Action is the NRC Taking?

The NRC is amending its regulations to remove the SGI-M designation of the security-related information for large irradiators, M&Ds, and transport of category 1 quantities of radioactive material. The rulemaking will also result in the removal of the SGI-M designation of

the security-related information for the transportation of irradiated reactor fuel that weighs 100 grams or less in net weight of irradiated fuel. The security-related information will instead be protected under the new 10 CFR part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."

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

The purpose of the direct final rule is to remove the SGI-M designation of the security-related information for large irradiators, M&Ds, and for transport of category 1 quantities of radioactive material. The rulemaking will also result in the removal of the SGI-M designation of the security-related information for the transportation of irradiated reactor fuel that weighs 100 grams or less in net weight of irradiated fuel.

C. Whom Will This Action Affect?

The direct final rule will apply to any panoramic and underwater irradiator licensee that possesses more than 370 TBq (10,000 Ci) of radioactive material, M&D licensees, and any licensee that transports small quantities of irradiated reactor fuel that weighs 100 grams or less in net weight of irradiated fuel or category 1 quantities of radioactive material whether the facility is licensed by the NRC or an Agreement State. There are 85 Agreement State licensees and 27 NRC licensees that will be impacted by this rule. These are the materials licensees that received orders under the Commission's authority to protect the common defense and security.

D. With the Redesignation of the Security-related Information, Will the Security Plans Become Public Information?

No, the security-related information will not be made public. The change in the designation of the security-related information does not result in public disclosure of the

information as the information will still be protected under 10 CFR part 37. Access to this information will be based upon a trustworthiness and reliability determination and on a need-to-know determination.

E. Will Documents Now Designated SGI-M Still Have to be Protected as SGI-M?

Yes, documents marked as SGI-M must be protected as SGI-M until they are removed from the SGI-M category (destroyed or decontrolled). Once Part 37 or the equivalent Agreement State regulations are in place and the NRC security orders are rescinded, the SGI-M security Orders and security plans required by the Orders must be destroyed in accordance with 10 CFR 73.23(i). Additionally, if a panoramic irradiator or M&D licensee develops a part 37 security plan in preparation for compliance with part 37 or the equivalent Agreement State regulation before § 73.23 is revised, the licensee must decontrol the part 37 security plan in accordance with § 73.23(h) once § 73.23 is revised.

The NRC does not expect licensees who were subject to the NRC security orders to find all stored documents designated as SGI-M solely for the purpose of destroying the documents. Instead, as those documents are removed from storage, the licensee must either destroy or decontrol the document(s) at that time. Documents marked as SGI-M must continue to be protected as SGI-M until they are destroyed or decontrolled. Additional information on the destruction or decontrolling of SGI is available in Section 9 of Regulatory Guide 5.79, "Protection of Safeguards Information."

~~The SGI-M security Orders, security plans required by the orders, and any other SGI-M information must be destroyed in accordance with 10 CFR 73.23(i) once the rule is effective and the orders are rescinded. The Documents must be marked and protected as SGI-M until they are destroyed. Additionally, if a panoramic irradiator or M&D licensee develops a 10 CFR part 37 security plan in preparation for compliance with 10 CFR part 37, before § 73.23 is revised,~~

~~the licensee may decontrol the 10 CFR part 37 security plan in accordance with § 73.23(h). To decontrol the 10 CFR part 37 security-related information that is currently designated as SGI-M, the licensee should draw a horizontal line through the SGI designation on each page of the document and initial adjacent to the horizontal line.~~

~~Agreement State licensees will continue to be subject to the SGI-M provisions of the orders until the NRC rescinds the orders after the Agreement State adopts the provisions of 10 CFR part 37. Once an Agreement State adopts 10 CFR part 37 and the provisions are effective in the State, the NRC will rescind relevant security orders for the licensees in that State. At that time the licensees may destroy SGI-M in their possession.~~

~~The NRC does not expect a licensee to find all documents designated as SGI-M that may be in storage solely for the purpose of destroying the documents. Instead, as those documents are removed from storage for use, the licensee can destroy the document at that time. Additional information on the decontrol and destruction of SGI is available in Section 9 of Regulatory Guide 5.79, "Protection of Safeguards Information" (ADAMS Accession No. ML103270219).~~

F. What are the Information Protection Requirements under 10 CFR Part 37? How Does This Compare to the Information Protection Requirements Prescribed for SGI-M?

The 10 CFR part 37 rulemaking requires that a need-to-know determination be made before an individual is allowed to have access to the security-related information. The 10 CFR part 37 rulemaking requires licensees to limit access to and prevent unauthorized disclosure of their security plans and implementing procedures. When not in use, the security plan and implementing procedures must be stored in a manner that will prevent the unauthorized removal of those documents. Information stored in non-removable electronic form must be password-protected. These requirements are similar to the storage requirements for SGI-M.

The regulations in 10 CFR part 37 also require a background investigation to determine the trustworthiness and reliability of an individual seeking access to protected information. This determination must be conducted by a reviewing official who has also been determined to be trustworthy and reliable. The background investigation for access to information under 10 CFR part 37 is similar to that required by § 73.23, with the exception that fingerprints are not submitted and a Federal Bureau of Investigation (FBI) criminal history records check is not required. However, many of the individuals needing access to protected information would also require access to radioactive material. Unescorted access to radioactive material requires fingerprinting and an FBI criminal history records check as part of the background investigation required under 10 CFR part 37. Therefore, the NRC anticipates that most individuals requiring access to security-related information would already have undergone fingerprinting and an FBI criminal history records check.

The regulations in 10 CFR part 37 do not have requirements for the transmission of information or for marking the material. However, with the exception of routing information, licensees do not routinely transmit security-related information and the routing information is not transmitted as SGI-M, but is protected as SGI-M once received. Licensees are not required to submit the security plan or implementing procedures to the NRC.

The NRC concludes that 10 CFR part 37 provides adequate protection of the security-related information without unduly burdening licensees with the additional requirements for protection of SGI-M.

G. What is the Reason for the Designation Change?

The NRC considers that this re-designation is appropriate based on the following: 1) large irradiators have a lower risk of theft, and M&D licensees have a similar risk of theft when compared to other licensees possessing category 1 and category 2 quantities of

radioactive material; 2) the information protection requirements in 10 CFR part 37 provide adequate protection of the security-related information; 3) the security requirements under 10 CFR part 37 are the same for all licensees; 4) information security requirements should be consistent across all areas that are regulated under NRC authority for public health and safety; 5) the change will ease ~~of~~ communication between regulator and licensee; and 6) under 10 CFR part 73, the NRC would continue to inspect Agreement State licensee programs for the protection of SGI-M until the ~~compatible~~ Agreement State requirements become ~~becomes~~ effective. Additionally, several commenters on the proposed 10 CFR part 37 rule, including several Agreement States, indicated that the security-related information for large irradiators, M&Ds, and licensees that transport category 1 quantities of radioactive material should not be considered SGI-M.

Sandia National Laboratories (SNL) performed vulnerability assessments on a variety of materials licensees before the ICs were developed. The ICs and 10 CFR part 37 incorporate security measures that were identified in the draft vulnerability assessments (ADAMS Accession No. ML082130714) as being effective in providing reasonable assurance that public health and safety and the common defense and security will be adequately protected. The SNL study also indicates that certain licensees are less vulnerable to theft than other licensees. Large irradiators have a lower risk of theft, and M&D licensees have a similar risk of theft when compared to other licensees subject to the security requirements in 10 CFR part 37. The NRC, therefore, concludes that licensee security plans for M&D and large irradiator licensees need not be protected at a higher level than the security plans of other licensees subject to 10 CFR part 37.

As noted in the response to Question F, 10 CFR part 37 will provide adequate protection of the security-related information that is currently designated as SGI-M for these licensees. The actual security requirements in 10 CFR part 37 are the same for all licensees. These

security requirements do not contain any of the information from the security orders that was designated as SGI-M. The SGI-M timeframes that were in the orders are replaced in the 10 CFR part 37 rule by terms such as prompt, immediate, and without delay. Therefore, disclosure of one licensee's response times will not compromise another licensees' security-related information because the response time designated in the rule is already public knowledge, *i.e.*, immediate.

Currently, itinerary information for the transportation of category 1 quantities of material and for the transportation of irradiated reactor fuel that weighs 100 grams or less in net weight of irradiated fuel is designated as SGI-M under 10 CFR part 73 and the orders. Licensees are required to coordinate this information with states through which the shipment will pass. Shipment information is shared on a need-to-know basis for pre-planning, coordination, and advance notification purposes. Although the information is considered to be SGI-M, the information is not handled as SGI-M for the purposes of communication (telephone and facsimile) with the States and other licensees; however, once the shipment information is received, it must be handled as SGI-M. If the SGI-M designation for these licensees is revised, the licensees will be able to communicate freely with the States and transportation companies possessing a need-to-know and will not need to deal with the inconsistency in transmitting the SGI-M shipment information as non-SGI-M.

The security orders for the transportation of category 1 quantities of radioactive material, large irradiator licensees, and M&D licensees were issued under the NRC's common defense and security authority. The new 10 CFR part 37 security requirements, however, were issued under the NRC's authority to protect the public health and safety. The NRC has determined that the information protection requirements set forth in the new 10 CFR part 37 are adequate to protect the security information associated with large irradiators, M&Ds, and licensees that transport category 1 quantities of radioactive material. Therefore, once this direct final rule is

effective, the security information associated with these licensees is no longer required to be handled as SGI-M. Furthermore, this will ensure that all the information security requirements are consistent across all areas that are regulated under public health and safety.

Protection of information at a level less than SGI-M will allow licensees to communicate more easily with regulators regarding implementation of the 10 CFR part 37 requirements, but still requires licensees to limit access to specific security plans and procedures. For example, licensees will be required to limit access to the plans to those employees who need access to perform a job function. Licensees also will be required to store their security plans in locked cabinets while not in use, but could use normal lines of communication with the NRC or an Agreement State to discuss security-related questions or concerns. This approach achieves meaningful information protection without unduly burdening licensees' and regulators' ability to achieve effective implementation of the 10 CFR part 37 requirements.

If the security-related information for these facilities remains designated as SGI-M, the NRC will be responsible for inspection and enforcement of the SGI-M programs at those facilities regulated by an Agreement State. This can result in confusion for licensees. Results of many aspects of the security inspections would be SGI-M and could not be discussed in an open environment. Because only some security-related information at these facilities would be SGI-M, licensees would need to maintain two systems to protect security-related information, which needlessly increases the burden on the licensee.

H. Will the Orders be Rescinded?

Yes, the orders will be rescinded once 10 CFR part 37 is implemented for NRC licensees. For Agreement State licenses, the orders will be rescinded when the Agreement State adopts program element requirements ~~compatible with~~ based on those elements that

embody the essential objectives of the 10 CFR part 37 requirements. Agreement States have until March 2016 to ~~adopt requirements compatible with the 10 CFR part 37~~ comply.

I. Will the NRC Issue Guidance for This Rule?

No, the NRC does not plan to issue guidance specific to this rule. Existing guidance on SGI does not contain references to these types of facilities and, therefore, does not need to be revised. The guidance on 10 CFR part 37, NUREG-2155, Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material" (ADAMS Accession No. ML13053A061), will be revised to remove references to SGI-M. Only the revised pages will be issued for the 10 CFR part 37 guidance document. The changes will be included in the next update to NUREG-2155.

J. Are Individuals Transporting Category 1 Radioactive Material Subject to the Background Investigation Requirements?

No. Under this final rule, the Commission is revising the listing of categories of individuals relieved from the background investigation requirements to include employees of carriers that transport category 1 quantities of radioactive material. Additionally, information related to the physical protection of shipments of source and byproduct material in category 1 quantities of radioactive material is no longer designated as SGI-M. For these reasons, t~~T~~he NRC will rely on the background investigations required by the U.S. Department of Transportation (DOT) and the Transportation Security Administration (TSA) programs for background investigations of these personnel. While the background investigation may not be identical to one required under 10 CFR part 37, the potential risk that a commercial driver or package handler may pose due to any difference in the background investigation is acceptably small.

As part of this rulemaking, the NRC considered the level of responsibility to place on its licensees regarding fingerprinting and criminal history records checks for persons involved in the transportation of category 1 radioactive material. Licensees covered by the fingerprinting and criminal history records check requirements of 10 CFR part 37 may decide to transfer radioactive material away from the site or may receive radioactive material from another entity.

Such transfers or receipts may occur either as part of a shipment to or from a domestic ~~company~~ or an international company. Individuals involved in the shipment, in particular those employed by carriers or other organizations handling shipments, may have unescorted access to the material during the shipment process. These persons may not be employees of the licensee and therefore may not be under the licensee's direct control. Section 37.29(a) grants relief from the background investigation for those individuals who are commercial vehicle drivers for category 2 road shipments and package handlers at transportation facilities such as freight terminals and railroad yards.

~~Under this final rule, the Commission is revising the listing of categories of individuals relieved from the background investigation requirements with the following modification: employees of carriers that transport category 1 quantities of radioactive material as are also relieved.~~ These individuals would typically be outside the control of the licensee ~~and the licensee would have no way of knowing or influencing who those individuals might be~~. ~~Additionally, information related to the physical protection of shipments of source and byproduct material in category 1 quantities of radioactive material is no longer designated as SGI-M. The NRC will rely on U.S. Department of Transportation (DOT) and the Transportation Security Administration (TSA) programs for background investigations of these personnel. While the background investigation may not be identical to one required under 10 CFR part 37, the NRC believes that the potential risk posed by any difference in the background investigation is acceptably small.~~

III. Summary of Changes.

Section 30.4 Definitions.

The definition for “Quantities of ~~c~~Concern” is removed from the regulations as it is no longer needed.

Section 30.32 Application for specific licenses.

Paragraph (k) is removed from the regulations to remove the reference to the SGI requirements in 10 CFR part 73.

Section 30.34 Terms and conditions of licenses.

Paragraph (l) is removed from the regulations to remove the reference to the SGI requirements in 10 CFR part 73.

Section 37.29 Relief from fingerprinting, identification, and criminal history records checks and other elements of background investigations for designated categories of individuals permitted unescorted access to certain radioactive materials.

Paragraph (a)(10) is revised to include category 1 drivers.

Section 37.43 General security program requirements.

Paragraph (d)(1) is revised to remove reference to § 37.43(d)(9).

Paragraph (d)(9) is removed from the regulations to remove the reference to the SGI requirements in 10 CFR part 73.

Section 37.77 Advance notification of shipment of category 1 quantities of radioactive material.

Paragraph (f) is revised to change the reference for protection of the information from § 73.21 to § 37.43(d).

Section 73.2 Definitions.

The definition for “Quantities of ~~c~~Concern” is removed from the regulations as it is no longer needed.

Section 73.21 Protection of Safeguards Information: Performance Requirements.

Paragraph (a)(1)(ii) is revised to remove panoramic and underwater irradiators that possess greater than 370 TBq (10,000 Ci) of byproduct material in the form of sealed sources; manufacturers and distributors of items containing source, byproduct, or special nuclear material in greater than or equal to category 2 quantities of radioactive material; and transportation of source, byproduct, or special nuclear material in greater than or equal to category 1 quantities of radioactive material from the list of categories of licensees subject to the provisions of 10 CFR part 73 for the protection of SGI-M.

Section 73.23 Protection of Safeguards Information-Modified Handling: Specific Requirements.

The introductory text in this section is revised to remove panoramic and underwater irradiators that possess greater than 370 TBq (10,000 Ci) of byproduct material in the form of sealed sources; manufacturers and distributors of items containing source, byproduct, or special nuclear material in greater than or equal to category 2 quantities of concern; transportation of more than 1000 TBq (27,000 Ci) but less than or equal to 100 grams of spent nuclear fuel; and

transportation of source, byproduct, or special nuclear material in greater than or equal to category 1 quantities of radioactive material from the list of categories of licensees subject to the provisions of 10 CFR part 73 for the protection of SGI-M.

Paragraph (a)(2) is revised to remove the security-related information that is associated with the physical protection of shipments of more than 1000 TBq (27,000 Ci) but less than or equal to 100 grams of spent nuclear fuel, source material and byproduct material in category 1 quantities of concern from the SGI-M category.

Appendix I to Part 73 - Category 1 and 2 Radioactive Materials.

Appendix I, Table I-1-Quantities of Concern Threshold Limits, is removed from the regulations as it is no longer needed.

Section 150.15 Persons not exempt.

Paragraph (a)(9) is removed from the regulations to remove the reference to the SGI requirements in 10 CFR part 73.

IV. 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 120 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. However, if the NRC receives a significant adverse comment by **[INSERT 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]** then the NRC will publish a document that withdraws this action and will address the comments received in a final rule as a response to

the companion proposed rule. 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 staff to make a change (other than editorial) to the rule.

For detailed instructions on submitting a comment, please see the companion proposed rule published elsewhere in this issue of the *Federal Register*.

V. 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 direct final rule will be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among the Agreement States and the NRC requirements. The NRC staff and Agreement State representation analyzed the rule in accordance with the procedure established within Part III, "Categorization Process for NRC Program Elements," of Handbook 5.9 to Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs" (a copy of which may be viewed at http://www.nrc.gov/reading-rm/doc-collections/management-directives/).

The NRC program elements (including regulations) are placed into four compatibility categories (see the Compatibility Table in this section). In addition, the NRC program elements can also be identified as having particular health and safety significance or as being reserved solely to the NRC. Compatibility Category A ~~are those~~ consists of program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State should adopt Category A program elements in an essentially identical manner to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B consists of ~~are those~~ program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Category B program elements in an essentially identical manner. Compatibility Category C consists of ~~are those~~ program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. An Agreement State should adopt the essential objectives of the Category C program elements. Compatibility Category D consists of ~~are those~~ program elements that do not meet any of the criteria of Category A, B, or C, and, therefore, do not need to be adopted by Agreement States for purposes of compatibility.

Health and Safety (H&S) are program elements that are not required for compatibility but are identified as having a particular health and safety role (*i.e.*, adequacy) in the regulation of agreement material within the State. Although not required for compatibility, the State should adopt program elements in this H&S category based on those of the NRC that embody the essential objectives of the NRC program elements because of particular health and safety considerations. Compatibility Category NRC consists of ~~are those~~ program elements that address areas of regulation that cannot be relinquished to Agreement States under the Atomic Energy Act of 1954, as amended, or provisions of 10 CFR. These program elements are not adopted by Agreement States. The following table lists the parts and sections that will be revised and their corresponding categorization under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs."

Compatibility Table for Direct Final Rule.

Section	Change	Subject	Compatibility	
			Existing	New
		10 CFR Part 30		
30.4	Remove	Definition of "Quantities of Concern."	NRC	-
30.32(k)	Remove	Application for specific licenses.	NRC	-
30.34(l)	Remove	Terms and conditions of licenses.	NRC	-
		10 CFR Part 37		
37.29(a)(10)	Amend	Relief from fingerprinting, identification, and criminal history records checks and other elements of background investigations for designated categories of individuals permitted unescorted access to certain radioactive materials.	B	B
37.43(d)(1)	Amend	Remove reference to § 37.43(d)(9).	NRC	-
37.43(d)(9)	Remove	General security program requirements.	NRC	-
37.77(f)	Revise	Advance notification of shipment of category 1 quantities of radioactive material.	NRC	C

		10 CFR Part 73		
73.2	Remove	Definition of “Quantities of Concern.”	NRC	-
73.21	Amend	Protection of Safeguards Information: Performance Requirements.	NRC	NRC
73.23	Amend	Protection of Safeguards Information-Modified Handling: Specific Requirements.	NRC	NRC
Appendix I	Remove	Category 1 and Category 2 Radioactive Materials.	NRC	-
		10 CFR Part 150		
150.15(a)(9)	Remove	Persons not exempt.	NRC	-

VI. 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).

VII. 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 categories of licensees subject to the provision of 10 CFR part 73 for the protection of SGI-M by removing panoramic and underwater irradiator licensees that possess more than 370 TBq (10,000 Ci) of radioactive material, M&D licensees, licensees that transport category 1

quantities of radioactive material, and licensees that transport irradiated reactor fuel that weighs 100 grams or less in net weight of irradiated fuel from the listing. This action does not constitute the establishment of a standard that establishes generally applicable requirements.

VIII. Finding of No Significant Environmental Impact: Availability.

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 is not 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 information protection requirements for 112 licensees. The rule will ~~not~~ affect neither radiological or nonradiological releases nor occupational or public exposure. The NRC has determined that there is no significant environmental impact associated with the rulemaking action

The environmental assessment (ADAMS Accession No. ML13046A330) is available for inspection at the NRC's PDR, 11555 Rockville Pike, Rockville, MD 20852.

IX. Paperwork Reduction Act Statement.

This direct final rule decreases the burden on record-keepers to mark documents containing Safeguards Information designated as SGI-M as specified in 10 CFR 73.23 (b), (d), and (f). The burden reduction for this information collection is estimated to average 5.5 hours per record-keeper. Further information about information collection requirements associated with this direct final rule can be found in the companion proposed rule published elsewhere in this issue of the *Federal Register*.

This direct final rule is being issued prior to approval by the Office of Management and Budget (OMB) of these information collection requirements, which were submitted under OMB control number 3150-0002. When OMB notifies us of its decision, we will publish a document in the *Federal Register* providing notice of the effective date of the information collections or, if approval is denied, providing notice of what action we plan to take.

Send comments on any aspect of these information collections, including suggestions for reducing the burden, to the Information Services Branch, Mail Stop T-5 F53, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@NRC.gov and to the Desk Officer, Danielle Jones, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0002), Office of Management and Budget, Washington, DC 20503.

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 request unless the requesting document displays a currently valid OMB control number.

X. Regulatory Analysis.

The Commission has prepared a regulatory analysis (ADAMS Accession No. ML13046A332) for this direct final rule. The regulatory analysis examines the costs and benefits of the alternatives considered by the Commission. The rule will reduce the burden on affected licensees as they will no longer be required to protect security-related information as

SGI-M. The analysis is available for inspection in the NRC's PDR, 11555 Rockville Pike, Rockville, MD 20852.

XI. Regulatory Flexibility Certification.

In accordance with the Regulatory Flexibility Act of 1980 (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 112 licensees, 27 are licensed by the NRC and 85 are licensed by Agreement States. These licensees include large irradiators, M&Ds, any licensee that ships category 1 quantities of radioactive material, and any licensee that transports irradiated reactor fuel that weighs 100 grams or less in net weight of irradiated fuel. Most of the companies that own these facilities do not fall 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). However, some of the licensees may. The rule will reduce the burden on affected licensees as they will no longer be required to protect security-related information as SGI-M.

XII. Backfitting and Issue Finality.

The NRC has determined that the backfit rules (§§ 50.109, 70.76, 72.62, or 76.76) and the issue finality provisions in 10 CFR part 52 do not apply to this direct final rule because this amendment does not involve any provisions that will either impose backfits as defined in 10 CFR chapter I, or represent non-compliance with the issue finality of provisions in 10 CFR part 52. Therefore, a backfit analysis is not required for this direct final rule, and the NRC did not prepare a backfit analysis for this direct final rule.

XIII. Congressional Review Act

In accordance with the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 37

Byproduct material, Criminal penalties, Export, Hazardous materials transportation, Import, Licensed material, Nuclear materials, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 73

Criminal penalties, Export, Hazardous materials transportation, Import, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 150

Criminal penalties, Hazardous materials transportation, Intergovernmental relations, Nuclear materials, Reporting and recordkeeping requirements, Security measures, Source material, Special nuclear material.

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 parts 30, 37, 73, and 150.

PART 30 -- RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

1. The authority citation for part 30 continues to read as follows:

AUTHORITY: Atomic Energy Act secs. 81, 82, 161, 181, 182, 183, 186, 223, 234 (42 U.S.C. 2111, 2112, 2201, 2231, 2232, 2233, 2236, 2273, 2282); Energy Reorganization Act secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. 109-58, 119 Stat. 549 (2005).

Section 30.7 also issued under Energy Reorganization Act sec. 211, Pub. L. 95-601, sec. 10, as amended by Pub. L. 102-486, sec. 2902 (42 U.S.C. 5851). Section 30.34(b) also issued under Atomic Energy Act sec. 184 (42 U.S.C. 2234). Section 30.61 also issued under Atomic Energy Act sec. 187 (42 U.S.C. 2237).

§ 30.4 [Amended]

2. In § 30.4, remove the definition for “Quantities of Concern.”

§ 30.32 [Amended]

3. In § 30.32, remove paragraph (k).

§ 30.34 [Amended]

4. In § 30.34, remove paragraph (l).

PART 37 -- PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

5. The authority citation for part 37 continues to read as follows:

AUTHORITY: Atomic Energy Act secs. 53, 81, 103, 104, 147, 148, 149, 161, 182, 183, 223, 234 (42 U.S.C. 2073, 2111, 2133, 2134, 2167, 2168, 2169, 2201a., 2232, 2233, 2273, 2282).

6. In § 37.29, revise paragraph (a)(10) to read as follows:

§ 37.29 Relief from fingerprinting, identification, and criminal history records checks and other elements of background investigations for designated categories of individuals permitted unescorted access to certain radioactive materials.

(a) * * *

(10) Commercial vehicle drivers for road shipments of category 1 and category 2 quantities of radioactive material;

*** * * * ***

7. In § 37.43, revise paragraph (d)(1) and remove paragraph (d)(9) to read as follows:

§37.43 General security program requirements.

***** ***** ***** ***** *****

(d) *Protection of information.* (1) Licensees authorized to possess category 1 or category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

***** ***** ***** ***** *****

8. In § 37.77, revise paragraph (f) to read as follows:

§ 37.77 Advance notification of shipment of category 1 quantities of radioactive material.

* * * * *

(f) *Protection of information*. State officials, State employees, and other individuals, whether or not licensees of the Commission or an Agreement State, who receive schedule information of the kind specified in § 37.77(b) shall protect that information against unauthorized disclosure as specified in § 37.43(d) of this part.

PART 73 -- PHYSICAL PROTECTION OF PLANTS AND MATERIALS

9. The authority citation for part 73 continues to read as follows:

AUTHORITY: Atomic Energy Act secs. 53, 147, 161, 223, 234, 1701 (42 U.S.C. 2073, 2167, 2169, 2201, 2273, 2282, 2297(f), 2210(e)); Energy Reorganization Act sec. 201, 204

(42 U.S.C. 5841, 5844); Government Paperwork Elimination Act sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. 109-58, 119 Stat. 594 (2005).

Section 73.1 also issued under Nuclear Waste Policy Act secs. 135, 141 (42 U.S.C, 10155, 10161).

Section 73.37(f) also issued under sec. 301, Pub. L. 96-295, 94 Stat. 789 (42 U.S.C. 5841 note).

§ 73.2 [Amended]

10. In § 73.2, remove the definition for “Quantities of Concern.”

11. In § 73.21, revise paragraph (a)(1)(ii) to read as follows:

§ 73.21 Protection of Safeguards Information: Performance Requirements.

(a) * * *

(1) * * *

(ii) Establish, implement, and maintain an information protection system that includes the applicable measures for Safeguards Information specified in § 73.23 related to: research and test reactors that possess special nuclear material of moderate strategic significance or special nuclear material of low strategic significance.

* * * * *

12. In § 73.23, revise the introductory text and paragraph (a)(2) to read as follows:

§ 73.23 Protection of Safeguards Information-Modified Handling: Specific Requirements.

This section contains specific requirements for the protection of Safeguards Information in the hands of any person subject to the requirements of § 73.21(a)(1)(ii) and research and test reactors that possess special nuclear material of moderate strategic significance or special nuclear material of low strategic significance. The requirements of this section distinguish Safeguards Information requiring modified handling requirements (SGI–M) from the specific Safeguards Information handling requirements applicable to facilities and materials needing a higher level of protection, as set forth in § 73.22.

(a) * * *

(2) *Physical protection in transit*. Information not classified as Restricted Data or National Security Information related to the physical protection of shipments of special nuclear material in less than a formula quantity (except for those materials covered under § 73.22), including:

* * * * *

Appendix I to Part 73 -- Category 1 and 2 Radioactive Materials [Removed]

13. Remove Appendix I to part 73, Table of Quantities of Concern Threshold Limits.

PART 150 -- EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

14. The authority citation for part 150 continues to read as follows:

AUTHORITY: Atomic Energy Act secs. 161, 181, 223, 234 (42 U.S.C. 2201, 2021, 2231, 2273, 2282); Energy Reorganization Act sec. 201 (42 U.S.C. 5841); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. 109-58, 119 Stat. 594 (2005).

Sections 150.3, 150.15, 150.15a, 150.31, 150.32 also issued under Atomic Energy Act secs. 11e(2), 81, 83, 84 (42 U.S.C. 2014e(2), 2111, 2113, 2114).

Section 150.14 also issued under Atomic Energy Act sec. 53 (42 U.S.C. 2073).

Section 150.15 also issued under Nuclear Waste Policy Act secs. 135 (42 U.S.C. 10155, 10161).

Section 150.17a also issued under Atomic Energy Act sec. 122 (42 U.S.C. 2152).

Section 150.30 also issued under Atomic Energy Act sec. 234 (42 U.S.C. 2282).

§ 150.15 [Amended]

15. In § 150.15, remove paragraph (a)(9).

Dated at Rockville, Maryland, this_____ day of_____, 2014.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

Attachment 2

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 37, 73, and 150

[NRC-2012-0140]

RIN 3150-AJ18

Safeguards Information - Modified Handling Categorization

Change for Materials Facilities

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to remove the Safeguards Information – Modified Handling (SGI-M) designation of the security-related information for large irradiators, manufacturers and distributors, and for transport of category 1 quantities of radioactive material. The rulemaking would also result in the removal of the SGI-M designation of the security-related information for the transportation of irradiated reactor fuel that weighs 100 grams or less in net weight of irradiated fuel. The security-related information for these facilities and the transportation of certain materials would no longer be designated as SGI-M and would be protected under the information protection requirements that apply to other materials licensees that possess category 1 and category 2 quantities of radioactive material.

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DATES: Submit comments on the proposed rule by **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. Submit comments specific to the information collections aspects of this proposed rule 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 assure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments related to this proposed rule 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-2012-0140. Address questions about NRC dockets to Carol Gallagher; telephone: 301-492-3668; 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.

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: Vanessa Cox, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-8342; e-mail: Vanessa.Cox@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments.

A. Obtaining Information.

Please refer to Docket ID NRC-2012-0140 when contacting the NRC about the availability of information for this proposed rule. You may obtain publicly-available information related to this proposed rule by any of the following methods:

- **Federal Rulemaking Web Site:** Go to http://www.regulations.gov and search for Docket ID NRC-2012-0140.
- **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.

B. Submitting Comments.

Please include Docket ID NRC-2012-0140 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 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. 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 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 120 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. However, if the NRC receives a significant adverse comment 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 for this action if 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 rules 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 staff to make a change (other than editorial) to the rule.

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

This proposed rule decreases the burden on recordkeepers to mark documents containing Safeguards Information designated as SGI-M as specified in § 73.23 (b), (d), and (f). The NRC is requesting comment on this decrease in recordkeepers' burden in Section III, Paperwork Reduction Act Statement, of this proposed rule.

III. Paperwork Reduction Act Statement.

This proposed rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). This proposed rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

Type of submission, new or revision: Revision.

The title of the information collection: Parts 30, 37, 73, and 150 of Title 10 of the *Code of Federal Regulations* (10 CFR), Safeguards Information - Modified Handling Categorization Change for Materials Facilities.

The form number if applicable: Not applicable.

How often the collection is required: The proposed rule would reduce annual recordkeeping requirements.

Who will be required or asked to report: The proposed rule would affect panoramic and underwater irradiators that possess greater than 370 TBq of byproduct materials; manufacturers and distributors of items containing source, byproduct, or special nuclear material in greater than or equal to category 2 quantities of concern; and transportation of source, byproduct, or special nuclear material in greater than or equal to category 1 quantities of concern.

An estimate of the number of annual responses: A reduction of 112 recordkeeping responses.

The estimated number of annual respondents: A reduction of 112 recordkeepers subject to 10 CFR part 73, Physical Protection of Plants and Materials.

An estimate of the total number of hours needed annually to complete the requirement or request: A reduction of 616 recordkeeping hours.

Abstract: The proposed rule would decrease burden on 112 recordkeepers to mark documents containing Safeguards Information designated as SGI-M as specified in § 73.23 (b), (d), and (f). These 112 licensees include panoramic and underwater irradiators that possess greater than 370 TBq of byproduct materials; manufacturers and distributors of items containing source, byproduct, or special nuclear material in greater than or equal to category 2 quantities of concern; and transportation of source, byproduct, or special nuclear material in greater than or equal to category 1 quantities of concern.

The NRC is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

A copy of the OMB clearance package may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O-1 F21, Rockville, MD 20852. The OMB clearance package and proposed rule will be available on the NRC's Web site, http://www.nrc.gov/public-involve/doc-comment/omb/index.html, for 60 days after the signature date of this document.

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the previously stated issues, by **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]** to the FOIA, Privacy, and Information Collections Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to INFOCOLLECTS.RESOURCE@NRC.GOV and to the Desk Officer, Danielle Y. Jones, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0002), Office of Management and Budget, Washington, DC 20503. You may also e-mail comments to Danielle_Y_Jones@omb.eop.gov or comment by telephone at 202-395-1741. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

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 OMB control number.

IV. 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

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 37

Byproduct material, Criminal penalties, Export, Hazardous materials transportation, Import, Licensed material, Nuclear materials, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 73

Criminal penalties, Export, Hazardous materials transportation, Import, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 150

Criminal penalties, Hazardous materials transportation, Intergovernmental relations, Nuclear materials, Reporting and recordkeeping requirements, Security measures, Source material, Special nuclear material.

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 proposing to adopt the following amendments to 10 CFR parts 30, 37, 73, and 150.

PART 30 -- RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

1. The authority citation for part 30 continues to read as follows:

AUTHORITY: Atomic Energy Act secs. 81, 82, 161, 181, 182, 183, 186, 223, 234 (42 U.S.C. 2111, 2112, 2201, 2231, 2232, 2233, 2236, 2273, 2282); Energy Reorganization Act

secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. 109-58, 119 Stat. 549 (2005).

Section 30.7 also issued under Energy Reorganization Act sec. 211, Pub. L. 95-601, sec. 10, as amended by Pub. L. 102-486, sec. 2902 (42 U.S.C. 5851). Section 30.34(b) also issued under Atomic Energy Act sec. 184 (42 U.S.C. 2234). Section 30.61 also issued under Atomic Energy Act sec. 187 (42 U.S.C. 2237).

§ 30.4 [Amended]

2. In § 30.4, remove the definition for “Quantities of Concern.”

§ 30.32 [Amended]

3. In § 30.32, remove paragraph (k).

§ 30.34 [Amended]

4. In § 30.34, remove paragraph (l).

PART 37 -- PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

5. The authority citation for part 37 continues to read as follows:

AUTHORITY: Atomic Energy Act secs. 53, 81, 103, 104, 147, 148, 149, 161, 182, 183, 223, 234 (42 U.S.C. 2073, 2111, 2133, 2134, 2167, 2168, 2169, 2201a., 2232, 2233, 2273, 2282).

6. In § 37.29, revise paragraph (a)(10) to read as follows:

§ 37.29 Relief from fingerprinting, identification, and criminal history records checks and other elements of background investigations for designated categories of individuals permitted unescorted access to certain radioactive materials.

(a) * * *

(10) Commercial vehicle drivers for road shipments of category 1 and category 2 quantities of radioactive material;

* * * * *

7. In § 37.43, revise paragraph (d)(1) and remove paragraph (d)(9) to read as follows:

§37.43 General security program requirements.

* * * * *

(a) * * *

(d) *Protection of information.* (1) Licensees authorized to possess category 1 or category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

* * * * *

8. In § 37.77, revise paragraph (f) to read as follows:

§ 37.77 Advance notification of shipment of category 1 quantities of radioactive material.

* * * * *

(f) *Protection of information*. State officials, State employees, and other individuals, whether or not licensees of the Commission or an Agreement State, who receive schedule information of the kind specified in § 37.77(b) shall protect that information against unauthorized disclosure as specified in § 37.43(d) of this part.

PART 73 -- PHYSICAL PROTECTION OF PLANTS AND MATERIALS

9. The authority citation for part 73 continues to read as follows:

AUTHORITY: Atomic Energy Act secs. 53, 147, 161, 223, 234, 1701 (42 U.S.C. 2073, 2167, 2169, 2201, 2273, 2282, 2297(f), 2210(e)); Energy Reorganization Act sec. 201, 204 (42 U.S.C. 5841, 5844); Government Paperwork Elimination Act sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. 109-58, 119 Stat. 594 (2005). Section 73.1 also issued under Nuclear Waste Policy Act secs. 135, 141 (42 U.S.C, 10155, 10161).

Section 73.37(f) also issued under sec. 301, Pub. L. 96-295, 94 Stat. 789 (42 U.S.C. 5841 note).

§ 73.2 [Amended]

10. In § 73.2, remove the definition for “Quantities of Concern.”

11. In § 73.21, revise paragraph (a)(1)(ii) to read as follows:

§ 73.21 Protection of Safeguards Information: Performance Requirements.

(a) * * *

(1) * * *

(ii) Establish, implement, and maintain an information protection system that includes the applicable measures for Safeguards Information specified in § 73.23 related to: research and test reactors that possess special nuclear material of moderate strategic significance or special nuclear material of low strategic significance.

* * * * *

12. In § 73.23, revise the introductory text and paragraph (a)(2) to read as follows:

§ 73.23 Protection of Safeguards Information-Modified Handling: Specific Requirements.

This section contains specific requirements for the protection of Safeguards Information in the hands of any person subject to the requirements of § 73.21(a)(1)(ii) and research and test reactors that possess special nuclear material of moderate strategic significance or special nuclear material of low strategic significance. The requirements of this section distinguish Safeguards Information requiring modified handling requirements (SGI–M) from the specific Safeguards Information handling requirements applicable to facilities and materials needing a higher level of protection, as set forth in § 73.22.

(a) * * *

(2) *Physical protection in transit*. Information not classified as Restricted Data or National Security Information related to the physical protection of shipments of special nuclear material in less than a formula quantity (except for those materials covered under § 73.22), including:

* * * * *

Appendix I to Part 73 -- Category 1 and 2 Radioactive Materials [Removed]

13. Remove appendix I to part 73.

PART 150 -- EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

14. The authority citation for part 150 continues to read as follows:

AUTHORITY: Atomic Energy Act secs. 161, 181, 223, 234 (42 U.S.C. 2201, 2021, 2231, 2273, 2282); Energy Reorganization Act sec. 201 (42 U.S.C. 5841); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. 109-58, 119 Stat. 594 (2005).

Sections 150.3, 150.15, 150.15a, 150.31, 150.32 also issued under Atomic Energy Act secs. 11e(2), 81, 83, 84 (42 U.S.C. 2014e(2), 2111, 2113, 2114).

Section 150.14 also issued under Atomic Energy Act sec. 53 (42 U.S.C. 2073).

Section 150.15 also issued under Nuclear Waste Policy Act secs. 135 (42 U.S.C. 10155, 10161).

Section 150.17a also issued under Atomic Energy Act sec. 122 (42 U.S.C. 2152).

Section 150.30 also issued under Atomic Energy Act sec. 234 (42 U.S.C. 2282).

§ 150.15 [Amended]

15. In § 150.15, remove paragraph (a)(9).

Dated at Rockville, Maryland, this_____ day of_____, 2014.

For the Nuclear Regulatory Commission.

_____
Annette Vietti-Cook,
Secretary of the Commission.

Attachment 3

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[NRC-2013-0053]

RIN 3150-AJ18

Definition of a Utilization Facility

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule.

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

DATES: This final rule is effective **[INSERT DATE 75 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**, unless a significant adverse comment is received by **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. If the rule is withdrawn as a

result of such comments, timely notice of the withdrawal will be published in the *Federal Register*. Comments received after this date will be considered if it is practical to do so, but the NRC staff is able to ensure consideration only for comments received on or before this date.

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

- **Federal Rulemaking Web Site:** Go to http://www.regulations.gov and search for Docket ID NRC-2013-0053. Address questions about NRC dockets to Carol Gallagher; telephone: 301-287-3422; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.
- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at http://www.nrc.gov/reading-rm/adams.html. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by e-mail to **pdr.resource@nrc.gov**. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the SUPPLEMENTARY INFORMATION section.
- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Steven Lynch, Office of Nuclear Reactor Regulation; telephone: 301-415-1524; e-mail: Steven.Lynch@nrc.gov; U.S. Nuclear

Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

TABLE OF CONTENTS:

I. Procedural Background.

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

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

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

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

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

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

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

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

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

II. Background.

By letters dated February 14, 2011, and May 3, 2011,2 SHINE notified the NRC of its intent to submit applications to construct, and operate, a medical isotope production ~~system~~ facility. SHINE's medical isotope production facility would include an irradiation facility and a radioisotope production facility housed in a single building~~,~~ and is proposed to be built in

2 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.

Wisconsin, an Agreement State.

The SHINE preliminary safety analysis report (PSAR)[3] 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.[4] 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.[5]

In 2012, the NRC staff published interim staff guidance (ISG)[6] 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

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

4 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).

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

6 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.[7] 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.[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 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.[9]

However, the NRC staff maintains its initial position that SHINE's radioisotope

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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 page iv.

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).

production facility ~~should be considered~~ is analogous to a "production facility~~.~~" and therefore should be licensed under part 50. Specifically, the radioisotope production facility is a facility designed or used for the processing of irradiated materials containing SNM and does not meet any of the exceptions found in the definition of production facility in 10 CFR 50.2.

III. Discussion.

A. What Action is the NRC Taking?

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

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

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

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

Section 11cc. of the Atomic Energy Act of 1954, as amended (AEA), specifies that the Commission may determine by rule what constitutes a utilization facility. The licensing requirements for utilization facilities are in 10 CFR part 50. This rulemaking will resolve any licensing uncertainty concerning the applicable regulations for licensing the construction and potential operation of the SHINE irradiation units, as well as expedite the NRC staff's technical review of the SHINE construction permit application.

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

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

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

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

Third, "production facility" is defined as any facility designed or used for the processing of irradiated materials containing SNM. While "processing," as used in the definition of production facility, is not defined in the regulations, the NRC staff does not consider processing to include the irradiation and fission of materials, whether the material was irradiated previously ~~irradiated~~ or not, containing SNM. Given the similarities between the treatment of SHINE's target solution and the fuel in existing power and non-power reactors, the NRC staff does not

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

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.[10] Given this fission power, the irradiation units also have many safety considerations similar to those of non-power reactors, including the following:

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

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 (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.

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

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

The NRC staff believes, however, that based on the safety considerations associated with operation of the irradiation units, the NRC should define and license each of the irradiation units as a utilization facility. Section 11cc. of the AEA provides that the Commission may determine what a utilization facility is by rule.[11] 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?*

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

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).

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.[12] 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?*

The rulemaking will allow the NRC staff to conduct its licensing review of the proposed

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

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

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

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

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

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

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

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

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

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

The NRC staff is using a direct final rule because it considers this rulemaking to be non-controversial, it does not expect to receive significant adverse comments, and using the direct final rule process would allow the rulemaking to proceed in the most efficient manner.

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

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

~~The NRC staff is using a direct final rule because it considers this rulemaking to be non-controversial, it does not expect to receive significant adverse comments, and using the direct final rule process would allow the rulemaking to proceed in the most efficient manner.~~

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

~~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,[14] that application would be considered on a case-by-case basis, and a distinct docket number would be assigned to each application. Should SHINE propose a technology other than the irradiation units currently described in its PSAR, the rule would no longer apply to SHINE, and the NRC staff would pursue an alternative licensing approach.~~

By identifying 10 CFR part 50 as the licensing framework to review and evaluate the irradiation units in the SHINE construction permit application, this rulemaking would clarify the appropriate regulatory requirements governing SHINE's requested licensing action ~~to SHINE~~ for the applicant; interested members of the public; federal, state, Tribal, 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, if approved, licensing SHINE's proposed irradiation units and will support the national effort to establish a reliable domestic supply of Mo-99 utilizing low enriched uranium technologies.

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

14 ~~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.~~

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

IV. Discussion of Amendments by Section.

§ 50.2 Definitions.

The definition for utilization facility will be changed to add: an accelerator-driven subcritical operating assembly used for the irradiation of materials containing special nuclear material and described in the application assigned docket number 50-608.

Authority Citation.

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

V. Regulatory Flexibility Certification.

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. The

direct final rule will impact one applicant for a construction permit, who may subsequently apply for an ~~and potential~~ operating license. Although this company falls within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810), the rule is intended to facilitate NRC staff review of the company's construction permit application and subsequent operating license application.

VI. Regulatory Analysis.

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

VII. Backfitting and Issue Finality.

The NRC has determined that the backfit rule, 10 CFR 50.109, ~~and~~ the issue finality provisions in 10 CFR part 52, and the backfitting provisions in 10 CFR 70.76, 72.62, or 76.76 do not apply to this direct final rule because the only affected entity, SHINE, is currently an applicant for a construction permit. ~~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.~~ These backfitting and issue finality provisions, with exceptions not applicable here, do not apply to applicants. ~~The NRC has also determined that the backfitting provisions in 10 CFR 70.76, 72.62, or 76.76 do not apply to this direct final rule because this rulemaking does not affect entities who are accorded backfitting protection under these backfit rules.~~ For these reasons, the NRC did not prepare either a backfit analysis or documentation addressing issue finality provisions in 10 CFR part 52 for this direct final rule.

VIII. Plain Writing.

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, "Plain Language in Government Writing," published June 10, 1998 (63 FR 31883).

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

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

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

X. Paperwork Reduction Act Statement.

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

Public Protection Notification.

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

XI. Congressional Review Act.

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

XII. Compatibility of Agreement State Regulations.

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

XIII. Voluntary Consensus Standards.

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

List of Subjects in 10 CFR Part 50

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

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR part 50.

PART 50 -- DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for 10 CFR part 50 is revised to read as follows:

Authority: Atomic Energy Act secs. 11, 102, 103, 104, 105, 147, 149, 161, 181, 182, 183, 186, 189, 223, 234 (42 U.S.C. 2014, 2132, 2133, 2134, 2135, 2167, 2169, 2201, 2231,

2232, 2233, 2236, 2239, 2273, 2282); Energy Reorganization Act secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); Nuclear Waste Policy Act sec. 306 (42 U.S.C. 10226); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. 109–58, 119 Stat. 194 (2005). Section 50.7 also issued under Pub. L. 95–601, sec. 10, as amended by Pub. L. 102–486, sec. 2902 (42 U.S.C. 5851). Section 50.10 also issued under Atomic Energy Act secs. 101, 185 (42 U.S.C. 2131, 2235); National Environmental Policy Act sec. 102 (42 U.S.C. 4332). Sections 50.13, 50.54(d), and 50.103 also issued under Atomic Energy Act sec. 108 (42 U.S.C. 2138).

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

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

§ 50.2 Definitions.

***** ***** ***** ***** *****

Utilization facility means: (1) any nuclear reactor other than one designed or used primarily for the formation of plutonium or U-233; or (2) an accelerator-driven subcritical operating assembly used for the irradiation of materials containing special nuclear material and described in the application assigned docket number 50-608.

Dated at Rockville, Maryland, this _____ day of _____, 2014.

For the Nuclear Regulatory Commission,

_____
Annette Vietti-Cook,
Secretary of the Commission.

Attachment 4

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[NRC-2013-0053]

RIN 3150-AJ18

Definition of a Utilization Facility

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

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

DATES: Submit comments by **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to

do so, but the NRC staff is able to ensure consideration only for comments received on or before this date.

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

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

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

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

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments.

A. Obtaining Information

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

- **Federal Rulemaking Web Site:** Go to http://www.regulations.gov and search for Docket ID NRC-2013-0053.
- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at http://www.nrc.gov/reading-rm/adams.html. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the SUPPLEMENTARY INFORMATION section. SHINE's construction permit application, submitted May 31, 2014, is publicly available in ADAMS, Accession No. ML13172A324.
- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC-2013-0053 in the subject line of your comment

submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

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

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

II. Procedural Background.

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

initiate a second comment period on this action in the event the direct final rule is withdrawn.

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

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

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

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

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

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

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

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

III. Plain Writing.

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

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

List of Subjects in 10 CFR Part 50

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

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

PART 50 -- DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

3. 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).

4. 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.

Attachment 5

Changes to the Federal Register Notice in SECY-14-0072

1. As appropriate, c~~C~~hange references to "NUREG-2157" throughout the FRN to "the GEIS."

2. In § 51.23(a) delete the words "and conclusively" and make conforming changes where appropriate in the preamble materials in the FRN.

3. On page 2, 1st bullet, revise line 4 to read ' ... individual ~~(~~listed ....'

4. On page 2, 2nd bullet, revise line 5 to read ' ... 1-800-397-4209, at ....'

5. On page 3, paragraph A., revise line 1 to read ' ... is to ~~improve~~ preserve ....' Revise line 9 to read ' … for operation~~s~~ of ….'

6. On page 5, revise line 1 from the top to read ' ... clarify that the ....'

7. On page 6, item C., revise to read 'Repository and ~~Safety~~ Continued Storage Conclusions'

8. On page 8, revise line 7 from the top to read ' ... sub nom., ~~NRDC v. NRC~~ *NRDC v. NRC*, 582 ....'

9. On page 8, 1st full paragraph, revise line 4 to read ' ... in ~~Minnesota v. NRC~~ *Minnesota v. NRC*, 602 ....'

10. On page 8, last paragraph, revise line 2 to read ' ... in ~~Minnesota v. NRC~~ *Minnesota v. NRC*.'

11. On page 10, 1st full paragraph, revise line 5 to read ' ... 30 years ~~under a revised or renewed license~~ (which may include the term of a revised or renewed license).'

12. On page 12, 1st full paragraph, revise line 6 to read ' ... (~~New York v. NRC~~ *New York v. NRC*, 681 ....'

13. On page 15, paragraph A5., revise line 7 to read ' ... In ~~New York v. NRC~~ *New York v. NRC*, the ....'

14. On page 16, 1st full paragraph, revise line 10 to read ' ... applications. ~~These~~ Site-specific analyses ....'

15. On page 17, 1st full paragraph, revise line 3 to read ' ... spent fuel pools ....'

16. On page 18, paragraph A7., revise line 5 to read ' ... fuel, ~~and~~ or the ....'

17. On page 18, paragraph A7., revise line 5 to read ' ... nuclear power (see also question A9).'

18. On page 19, paragraph A10., revise line 6 to read ' ... license term at a specific site, as distinct ....'

19. On page 20, 1st full paragraph, revise line 5 to read ' ... 2.335,~~;~~ ....'

20. On page 21, revise line 1 from the top to read '~~Because a GEIS has been developed, "Findings" are no longer necessary.~~ The relationship between the prior "Findings" and the technical feasibility analyses in the current GEIS is discussed in greater detail in Section D.2.4.1. As noted in the GEIS, the former "Findings" were outputs of previous Waste Confidence proceedings, which included an environmental assessment and finding of no significant impact. In contrast, the current GEIS provides a detailed analysis under NEPA and provides an analysis of specific impacts.'

21. On page 25, footnote 3, revise lines 2 and 3 to read ' ... GEIS assumes two renewals ~~as a conservative assumption~~ in ....'

22. On page 26, 1st full paragraph, revise line 2 to read ' ... includes the following: ....'

23. On page 26, last paragraph, revise the last line to read ' ... include the following: ....'

24. On page 27, paragraph B4., revise line 3 to read ' ... limited to the following: ....'

25. On page 28, revise line 9 from the top to read ' ... rule, the ~~Commission~~ NRC will ....'

26. On page 33, revise line 16 from the top to read ' ... properties, identify adverse effects, ...'

27. On page 37, revise line 2 from the bottom to read ' ... 51.75(b), 51.75(~~b~~c), 51.80(b), ...'

28. On page 39, revise line 5 from the top to read ' ... fully implement~~ing~~ the ....'

29. On page 43, 1st full paragraph, revise lines 1 and 2 to read '~~The Commission has concluded in the GEIS that deep geologic disposal remains technically feasible,~~wWhile the ....' Revise lines 4 and 5 to read ' … final GEIS), the Commission has concluded in this GEIS that deep geologic disposal remains technically feasible. This ….'

30. On page 43, revise heading C. to read 'Repository and ~~Safety~~ Continued Storage Conclusions'

31. On page 45, revise line 1 from the top to read ' ... experience ~~have made it~~ clearly demonstrate that ....'

32. On page 45, revise lines 9 through 11 from the top to read ' ... available. ~~The~~ This analysis ~~of the long term and indefinite timeframes~~ does not constitute an endorsement of ~~an~~ extended ~~timeframe for~~ onsite storage of spent fuel as the appropriate long-term solution for disposition of spent fuel and high-level waste.'

33. On page 45, paragraph C3., revise line 5 to read ' ... discussion of ~~on~~ the ....'

34. On page 48, paragraph C6., revise line 7 to read ' ... upgrades ....'

35. On page 52, last paragraph, in line 5, correct the years to read 2013. (2 places) The staff should verify that the dates and regulatory citations are correctly noted throughout the *Federal Register* notice.

36. On page 54, 3rd full paragraph, revise line 3 to read ' ... ~~agreement~~ "contract" the ....'

37. On page 55, 1st full paragraph, move the final period outside the parentheses.

38. On page 56, 1st full paragraph, revise line 4 to read ' ... transparency~~,~~ or supported the language because ....'

39. On page 57, revise line 2 from the top to read ' ... fuel. AEA s~~S~~afety determinations ....'

40. On page 57, revise lines 6 through 8 from the top to read ' ... does not ~~mean to~~ imply that spent fuel cannot be stored safely. ~~Rather, the conclusion that~~ To the contrary, the analysis documented in the GEIS is predicated on the ability to store spent fuel safely ~~can be stored safely for~~ over the short-term, long-term, and indefinite timeframes ~~supports the analysis in the GEIS and is~~. This understanding is based upon ....'

41. On page 57, revise lines 13 and 14 from the top to read ' ... NRC's ~~belief~~ conclusion that it is feasible for ~~that~~ spent fuel ~~can continue~~ to be ....'

42. On page 59, 1st full paragraph, revise line 4 to read ' ... description of the revised rule's ....'

43. On page 61, last paragraph, revise lines 2 and 3 to read ' ... that the applicants' environmental ....'

44. On page 62, 1st full paragraph, revise line 1 to read ' ... clarify that applicants' postconstruction ....'

45. On page 62, 2nd full paragraph, revise line 2 to read ' ... clarify that ~~the~~ an applicant's ISFSI ....'

46. On page 62, 3rd full paragraph, revise line 4 to read ' ... 5 is ~~laid out~~ included in the ....'

47. On page 64, revise line 2 from the top to read ' ... are ~~laid out~~ included in the ....'

48. On page 64, in the table, 1st column, row 1, revise line 3 to read ' ... 2013 ~~2014~~)'

49. On page 66, column 1 under "Non-NRC Documents," row 1, revise to read '~~NRDC v. NRC~~ *NRDC v. NRC*, 582 …'

50. On page 66, column 1 under “Non-NRC Documents,” row 2, revise to read ‘~~Minnesota v. NRC~~ *Minnesota v. NRC*, 602 …’

51. On page 67, column 1, row 4, revise to read ‘~~New York v. NRC~~ *New York v. NRC*, 681 ...’

52. On page 69, 1st full paragraph, revise line 2 to read ‘ ... detail in the following sections of NUREG-2157: ....’

53. On page 69, 2nd full paragraph, revise line 2 to read ‘ ... storage, ~~in line~~ consistent with ....’

Changes to the GEIS in SECY 14-0072

54. On page xxx, 2nd full paragraph, revise line 7 to read ‘ ... storage for an additional 100 years after the short-term timeframe for a total ....’

55. On page xlvii, paragraph ES.16.1.19, revise lines 6 and 7 to read ‘ ... NRC finds that ~~both~~ the environmental risk ~~probability and consequences~~ of a successful radiological sabotage attack ~~are low, and therefore, the environmental risk~~ is ....’

56. On page 1-9, last paragraph, revise line 16 to read ‘ ... NRC has no ~~other~~ reason to ....’

57. On page 1-16, the staff should provide justification as noted in Appendix B that states “the most reasonably foreseeable assumption is that institutional controls will continue” as well as a cross reference to the supporting analysis in Section B.3.4 of Appendix B (page B-25)

58. On page 4-51, 1st paragraph in section 4.12.2, the second half of the paragraph discussing license termination should be deleted.

59. On page 4-96, the staff should augment the IND-related discussion to include additional context and information similar to that provided on pages D-366 and D-367 in response to a comment, clarifying that, in addition to the NRC considering the theft of SNF to be remote and speculative, the NRC considers the potential for the creation of an IND after a successful attack even more remote because of certain impediments, including that the manufacture of even a crude IND would require major chemical and metallurgical processing steps.

60. On page 6-57, revise line 1 from the top to read ‘ ... from an at-reactor ISFSI or an away-from-reactor ISFSI ~~storage facility~~ would be ....’

61. On page 7-8, the staff should add a statement noting that the adoption of the proposed action is in keeping with the Commission’s long-standing preference for resolving generic issues generically. Restructuring of Facility License Application Review and Hearing Process, 37 Fed. Reg. 15,127, 15,129 (July 28, 1972). The staff should also reflect this edit elsewhere in chapter 7, as appropriate.

62. On page B-1, 2nd full paragraph, revise lines 1 and 2 to read ' ... storage and a repository ~~availability~~ continue to ....'

63. On page B-4, 2nd full paragraph, revise line 5 to read ' ... Pilot Plant (WIPP) is ....'

64. On page B-4, insert a new paragraph after the 2nd paragraph to read: 'The NRC recognizes the incident at WIPP on February 14, 2014, which resulted in the release of americium and plutonium from one or more transuranic (TRU) waste containers into the environment. Trace amounts of americium and plutonium are believed to have leaked through unfiltered exhaust ducts and escaped aboveground. No personnel were determined to have received external contamination; however, 21 individuals were identified through bioassay to have initially tested positive for low level amounts of internal contamination. No adverse health impacts have been reported. The U.S. Department of Energy has issued a Phase 1 accident report on the incident (DOE 2014a). Despite the event, the NRC continues to conclude that a repository is technically feasible.'

    Add the following reference, as appropriate: DOE (U.S. Department of Energy). 2014a. *Accident Investigation Report, Phase I – Radiological Release Event at the Waste Isolation Plant on February 14, 2014.* Washington, D.C. Available at:http:// www.energy.gov/sites/prod/files/2014/04/f15/Final%20WIPP%20Rad%20Release% 20Phase%201%2004%2022% 202014_0.pdf
    DOE (U.S. Department of Energy).

65. On page B-5, Section B.2.2, the staff should update the summary paragraphs of international repository efforts to reflect current status and activities. For example, the status of programs in France, Canada, Sweden, and Finland have changed in the past two years.

66. On page B-29, paragraph 4., revise the heading to read '~~A permanent loss~~ Impacts of loss of institutional control~~s could have "catastrophic" impacts~~'

67. On page E-14, 1st full paragraph, revise line 1 to read 'Given the ~~need to locate~~ typical location of nuclear power plants …."