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SMT-2016-022

10 CFR 73.5

10 CFR 73.21

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

Request for Exemption Related to Specific 10 CFR 73 Requirements

Pursuant to 10 CFR 73.5, "Specific exemptions," SHINE Medical Technologies, Inc. (SHINE) is submitting a request for exemption related to certain requirements of 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements." Specifically, the requested exemption would allow SHINE to establish, implement, and maintain an information protection system for the SHINE medical isotope production facility to be constructed in Janesville, Wisconsin that includes the applicable measures for Safeguards Information specified in 10 CFR 73.23, rather than those specified in 10 CFR 73.22. SHINE's activities would be consistent with those required for protection of Safeguards Information for research and test reactors that, similar to the SHINE facility, possess special nuclear material of moderate strategic significance.

Enclosure 1 provides the SHINE exemption request related to 10 CFR 73.21(a)(1). SHINE requests approval of the exemption request by May 27, 2016.

If you have any questions, please contact me at 608/210-1735.

Very truly yours,

A handwritten signature in black ink, appearing to read "Jeff M. Bartelme".

Jeff Bartelme
Licensing Manager
SHINE Medical Technologies, Inc.
Docket No. 50-608

Enclosure

cc: Administrator, Region III, USNRC
Project Manager, USNRC
Environmental Project Manager, USNRC
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health

ENCLOSURE 1

SHINE MEDICAL TECHNOLOGIES, INC.

REQUEST FOR EXEMPTION RELATED TO SPECIFIC 10 CFR 73 REQUIREMENTS

1.0 INTRODUCTION

Pursuant to 10 CFR 73.5, "Specific exemptions," SHINE Medical Technologies, Inc. (SHINE) is submitting a request for exemption related to certain requirements of 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements." Specifically, the requested exemption would allow SHINE to establish, implement, and maintain an information protection system for the SHINE medical isotope production facility to be constructed in Janesville, Wisconsin that includes the applicable measures for Safeguards Information (SGI) specified in 10 CFR 73.23, "Protection of Safeguards Information-Modified Handling: Specific Requirements," rather than those specified in 10 CFR 73.22, "Protection of Safeguards Information: Specific Requirements." As discussed below, the SHINE facility is more similar to the research and test reactors that possess special nuclear material of moderate strategic significance, and which must follow 10 CFR 73.23 requirements, rather than those facilities which must follow 10 CFR 73.22 requirements.

As discussed in Section 3.0 below, SHINE meets the requirements of 10 CFR 73.5 because the requested exemption is authorized by law, does not endanger life or property or the common defense and security, and is otherwise in the public interest. Additionally, as discussed in Section 4.0 below, this exemption request is subject to a categorical exclusion in 10 CFR 51.22 from the need to prepare an environmental assessment or an environmental impact statement.

Accordingly, the NRC should approve this exemption request.

2.0 BACKGROUND

SHINE has developed a new method for the manufacture of medical isotopes and plans to construct and operate a facility for the purpose of producing molybdenum-99. The decay product of molybdenum-99 (technetium-99m) is used to perform approximately 40 million imaging procedures worldwide each year, and accounts for approximately 80% of all nuclear medicine procedures. SHINE's technology involves the use of a non-reactor based, subcritical fission process that utilizes low enriched uranium. The U.S. Nuclear Regulatory Commission (NRC) issued a 10 CFR 50 Construction Permit (No. CPMIF-001) to SHINE on February 29, 2016, authorizing construction of the SHINE facility in the City of Janesville, Rock County, Wisconsin.

As part of its activities to construct and operate the SHINE facility, SHINE may need to produce, receive, or acquire SGI. 10 CFR 73, "Physical Protection of Plants and Materials," contains requirements for the protection of SGI. SGI is a special category of sensitive unclassified information to be protected from unauthorized disclosure under Section 147 of the Atomic Energy Act of 1954, as amended. Information designated as SGI must be withheld from public

disclosure and must be physically controlled and protected. Protection requirements include: (1) secure storage; (2) document marking; (3) restriction of access; (4) limited reproduction; (5) protected transmission; and (6) controls for information processing and on electronic systems.

Following the terrorist attacks of September 11, 2001, the NRC issued orders which increased the number of licensees whose security measures were to be protected as SGI, and added types of security information to be protected as SGI. The NRC issued orders to power reactor licensees, fuel cycle facility licensees, certain source material licensees, and certain byproduct material licensees. Some of the orders expanded the types of information to be protected by licensees who already have an SGI protection program, such as nuclear power reactor licensees. Other orders were issued to licensees that had not previously been subject to SGI protection requirements in the regulations.

Some orders imposed a new designation: Safeguards Information-Modified Handling (SGI-M). SGI-M refers to SGI with handling requirements that are modified somewhat due to the lower risk posed by unauthorized disclosure of the information. The SGI-M protection requirements apply to certain security-related information regarding quantities of source, byproduct, and special nuclear materials for which the harm caused by unauthorized disclosure of information would be less than that for other SGI.

The NRC subsequently amended its regulations to protect SGI from inadvertent release and unauthorized disclosure which might compromise the security of nuclear facilities and materials via Reference (1). The purpose of the rulemaking was, in part, to include a new category of protected material (i.e., SGI-M) and to expand the scope of 10 CFR 73 to include additional categories of licensees (e.g., research and test reactors not previously covered and fuel cycle facilities not previously covered). In the development of the rule, the NRC used a graded approach to determine which category of licensee or type of information would be subject to certain protection requirements, based on the risks and consequences of information disclosure.

10 CFR 73.21 provides general performance requirements for each licensee, certificate holder, applicant, or other person who produces, receives, or acquires SGI (including SGI-M). Via the Reference (1) Final Rule, the NRC revised 10 CFR 73.21 to explicitly include research and test reactors that possess special nuclear material of moderate or low strategic significance as a licensee category subject to the specific requirements for protection of SGI-M described in 10 CFR 73.23. Although the rulemaking described in Reference (1) included other categories of licensees (e.g., certain irradiators), those were subsequently removed through the Direct Final Rule described in Reference (2).

10 CFR 73.21(a)(1) currently states:

“Each licensee, certificate holder, applicant, or other person who produces, receives, or acquires Safeguards Information (including Safeguards Information with the designation or marking: Safeguards Information—Modified Handling) shall ensure that it is protected against unauthorized disclosure. To meet this general performance requirement, such licensees, certificate holders, applicants, or other persons subject to this section shall:

(i) Establish, implement, and maintain an information protection system that includes the applicable measures for Safeguards Information specified in § 73.22 related to: Power reactors; a formula quantity of strategic special nuclear material; transportation of or delivery to a carrier for transportation of a formula quantity of strategic special nuclear

material or more than 100 grams of irradiated reactor fuel; uranium hexafluoride production or conversion facilities; fuel fabrication facilities; uranium enrichment facilities; independent spent fuel storage installations; and geologic repository operations areas.

(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.

(iii) Protect the information in accordance with the requirements of § 73.22 if the Safeguards Information is not described in paragraphs (a)(1)(i) and (a)(1)(ii) of this section.”

In summary, 10 CFR 73.21(a)(1)(i) describes the facility types required to establish, implement, and maintain an information protection system that includes the applicable measures for SGI specified in 10 CFR 73.22. 10 CFR 73.21(a)(1)(ii) describes the facility types required to establish, implement, and maintain an information protection system that includes the applicable measures for SGI-M specified in 10 CFR 73.23. 10 CFR 73.21(a)(1)(iii) was added, as described in Reference (1), to ensure that if the SGI was not described in paragraphs (a)(1)(i) and (a)(1)(ii), it would be protected in accordance with the requirements of 10 CFR 73.22.

Because the SHINE facility is not explicitly described in 10 CFR 73.21(a)(1)(i) or 10 CFR 73.21(a)(1)(ii), it falls within 10 CFR 73.21(a)(1)(iii), requiring SHINE to protect SGI in accordance with 10 CFR 73.22. If applicable, SHINE would need to establish, implement, and maintain SGI requirements similar to those required for power reactors and facilities possessing a formula quantity of strategic special nuclear material. The SHINE facility, however, is a medical isotope production facility that intends to possess special nuclear material of only moderate strategic significance (i.e., 10,000 grams or more of uranium-235 (contained in uranium enriched to 10 percent or more but less than 20 percent in the U-235 isotope)).

10 CFR 73.2 defines special nuclear material of moderate strategic significance as:

“Special nuclear material of moderate strategic significance means:

(1) Less than a formula quantity of strategic special nuclear material but more than 1,000 grams of uranium-235 (contained in uranium enriched to 20 percent or more in the U-235 isotope) or more than 500 grams of uranium-233 or plutonium, or in a combined quantity of more than 1,000 grams when computed by the equation, grams = (grams contained U-235) + 2 (grams U-233 + grams plutonium); or

(2) 10,000 grams or more of uranium-235 (contained in uranium enriched to 10 percent or more but less than 20 percent in the U-235 isotope).

This class of material is sometimes referred to as a Category II quantity of material.”

Therefore, the facility is more similar to the research and test reactors that possess special nuclear material of moderate strategic significance, and which must follow 10 CFR 73.23 requirements, rather than those facilities which must follow 10 CFR 73.22 requirements. Consistent with research and test reactors that possess special nuclear material of moderate strategic significance, the potential harm caused by unauthorized disclosure of SHINE SGI also would be less than the harm caused by unauthorized disclosure of SGI for those categories of

licensees described in 10 CFR 73.21(a)(1)(i) given the types and amount of radioactive material present. Due to the lower risk posed by unauthorized disclosure of SGI related to the SHINE facility, modified handling requirements, as described in 10 CFR 73.23 and applied to research and test reactors that possess special nuclear material of moderate strategic significance, should be applied to SHINE SGI.

Therefore, in accordance with the provisions of 10 CFR 73.5, SHINE requests an exemption related to 10 CFR 73.21(a)(1) to subject the SHINE facility to the requirements of 10 CFR 73.21(a)(1)(ii), rather than 10 CFR 73.21(a)(1)(iii). This would allow SHINE to establish, implement, and maintain an information protection system that includes the applicable measures for SGI-M specified in 10 CFR 73.23, consistent with research and test reactors that possess special nuclear material of moderate strategic significance.

The requested exemption also will be consistent with previous licensing actions. As described in Section 12.8 of the SHINE Preliminary Safety Analysis Report (PSAR) (Reference 3), the SHINE Security Plan will be developed using the guidance provided in Revision 1 of Regulatory Guide 5.59, "Standard Format and Content for a Licensee Physical Security Plan for the Protection of Special Nuclear Material of Moderate or Low Strategic Significance" (Reference 4). The NRC Staff discussed this plan in Section 12.4.8 of the Safety Evaluation Report (SER) related to the SHINE Construction Permit (Reference 5), and did not identify any concerns.

SHINE does not believe that it needs exemptions from 10 CFR 73.22 or 10 CFR 73.23 themselves. The introductory paragraphs to those regulations base their applicability on whether a facility is "subject to the requirements of" 10 CFR 73.21(a)(1)(i), (ii), or (iii). The requested exemption described above would result in the SHINE facility being subject to 10 CFR 73.21(a)(1)(ii), resulting in the applicability of 10 CFR 73.23.

3.0 PROPOSED EXEMPTION

As noted above, an exemption related to 10 CFR 73.21(a)(1) would allow SHINE to establish, implement, and maintain an information protection system that includes the applicable measures for SGI-M specified in 10 CFR 73.23, consistent with research and test reactors that possess special nuclear material of moderate strategic significance.

10 CFR 73.5 states that the Commission may grant an exemption from the requirements of the regulations, provided that: (1) the requested exemption is authorized by law; (2) the requested exemption will not endanger life or property or the common defense and security; and (3) the requested exemption is in the public interest.

The requested exemption to allow SHINE to establish, implement, and maintain an information protection system that includes the applicable measures for SGI-M specified in 10 CFR 73.23 satisfies these requirements, as described below.

1) The requested exemption is authorized by law

Section 147 of the Atomic Energy Act of 1954 (AEA), as amended, provides the Commission the authority to prescribe such regulations or issue such orders, as necessary, to prohibit the unauthorized disclosure of SGI. Nothing in Section 147 of the AEA, as amended, or any other law, prohibits the NRC from

allowing SHINE to establish, implement, and maintain an information protection system that includes the applicable measures for SGI-M specified in 10 CFR 73.23, rather than those specified in 10 CFR 73.22.

This exemption request would not eliminate the requirement to protect against unauthorized disclosure of SGI. Instead, the requested exemption would allow SHINE to establish, implement, and maintain an information protection system that includes the applicable measures for SGI-M specified in 10 CFR 73.23, consistent with research and test reactors that possess special nuclear material of moderate strategic significance. Therefore, the requested exemption is authorized by law.

2) The requested exemption will not endanger life or property or the common defense and security

The requested exemption does not pertain to the design, construction, or operation of the SHINE facility; instead, it applies to requirements for protection of SGI. It does not present any risk to life or property, or the common defense and security.

The SHINE facility intends to possess special nuclear material of moderate strategic significance (i.e., 10,000 grams or more of uranium-235 (contained in uranium enriched to 10 percent or more but less than 20 percent in the U-235 isotope)). As discussed above in Section 2.0, the SHINE facility is more similar to the research and test reactors that possess special nuclear material of moderate strategic significance, which must follow 10 CFR 73.23 requirements, rather than those facilities which must follow 10 CFR 73.22 requirements.

Allowing SHINE to establish, implement, and maintain an information protection system that includes the applicable measures for SGI-M specified in 10 CFR 73.23 ensures SHINE's SGI is protected commensurate with the risks and consequences of unauthorized disclosure, and similar to other facilities that may possess this type and amount of special nuclear material. SHINE would still be subject to SGI protection requirements related to (1) secure storage; (2) document marking; (3) restriction of access; (4) limited reproduction; (5) protected transmission; and (6) controls for information processing and on electronic systems. Accordingly, the granting of the requested exemption will not endanger life or property, or the common defense and security.

3) The requested exemption is in the public interest

The requested exemption is in the public interest because it would align the SGI protections for the SHINE facility with those of facilities with similar types and quantity of radiological material and provide commensurate levels of security. As discussed above, the SHINE facility intends to possess special nuclear material of moderate strategic significance (i.e., 10,000 grams or more of uranium-235 (contained in uranium enriched to 10 percent or more but less than 20 percent in the U-235 isotope)). Granting the requested exemption would allow SHINE to

protect SGI-M in accordance with the specific requirements described in 10 CFR 73.23, consistent with the specific protection requirements applied to research and test reactors that also possess special nuclear material of moderate strategic significance.

Additionally, the requested exemption would reduce the cost and burden for complying with the SGI requirements. For example, 10 CFR 73.22(c)(2) requires unattended information to be locked in costlier security storage containers, while 10 CFR 73.23(c)(2) only requires unattended information to be locked in a file drawer or cabinet. Similarly, the requirements for processing of SGI on electronic systems described in 10 CFR 73.22(g) are more burdensome than those requirements for processing of SGI-M on electronic systems described in 10 CFR 73.23(g). Any delay, additional cost, and additional burden has the potential to impact the ability of the SHINE facility to produce molybdenum-99, which has a direct public health benefit.

For these reasons, the requested exemption is in the public interest.

4.0 ENVIRONMENTAL ASSESSMENT

The requested exemption meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(25), as the requested exemption involves: (i) no significant hazards consideration; (ii) no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; (iii) no significant increase in individual or cumulative public or occupational radiation exposure; (iv) no significant construction impact; (v) no significant increase in the potential for or consequences from radiological accidents; and (vi) the requirements from which an exemption is sought involve: safeguard plans, and materials control and accounting inventory scheduling requirements (10 CFR 51.22(c)(25)(vi)(F)); or other requirements of an administrative, managerial, or organizational nature (10 CFR 51.22(c)(25)(vi)(I)). Therefore, pursuant to 10 CFR 51.22(b), no environmental assessment or environmental impact statement is required to be prepared in connection with the requested exemption.

(i) No Significant Hazards Consideration Determination

SHINE has evaluated the requested exemption to determine whether or not a significant hazards consideration is involved by focusing on the three standards set forth in 10 CFR 50.92, "Issuance of amendment," as discussed below:

1. Does the requested exemption involve a significant increase in the probability or consequences of an accident previously evaluated?

The requested exemption would allow SHINE to establish, implement, and maintain an information protection system that includes the applicable measures for SGI-M specified in 10 CFR 73.23, consistent with research and test reactors that possess special nuclear material of moderate strategic significance. The requested exemption is administrative in nature, and has no effect on the design of any SHINE system, structure, or component. The requested exemption does not

alter any assumptions or any methodology associated with the accidents analyzed in the PSAR, nor does it affect the probability of occurrence of analyzed accidents.

Therefore, the requested exemption does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the requested exemption create the possibility of a new or different kind of accident from any accident previously evaluated?

The requested exemption is administrative in nature, and has no effect on the design of any SHINE system, structure, or component. No new initiators or precursors of a new or different kind of accident than those previously analyzed in the PSAR are created.

Therefore, the requested exemption does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the requested exemption involve a significant reduction in a margin of safety?

The requested exemption is administrative in nature, and does not involve a change to the design bases of the SHINE facility. The requested exemption does not impact any SHINE system, structure, or component relied upon for accident mitigation.

Therefore, the requested exemption does not involve a significant reduction in a margin of safety.

Based on the above, SHINE concludes that a finding of “no significant hazards consideration” is justified for the requested exemption.

(ii) No significant change in the types or significant increase in the amounts of any effluents that may be released offsite

The requested exemption is administrative in nature, and has no effect on the types or amounts of effluents released from the SHINE facility. There are no materials or chemicals introduced to the SHINE facility as a result of this requested exemption that could affect the types or amounts of effluents released offsite. Additionally, the requested exemption has no effect on the design basis of structures, systems, and components that function to monitor or limit the release of effluents.

Therefore, the requested exemption does not involve a significant change in the types or significant increase in the amounts of any effluents that may be released offsite.

(iii) No significant increase in individual or cumulative public or occupational radiation exposure

The requested exemption is administrative in nature, and would result in no expected increases in individual or cumulative public or occupational radiation exposure. Additionally, the requested exemption has no effect on the radiological dose consequence analyses associated with the accidents analyzed in the PSAR.

Therefore, the requested exemption does not involve a significant increase in individual or cumulative public or occupational radiation exposure.

(iv) No significant construction impact

The requested exemption is administrative in nature, and has no effect on the construction of any SHINE system, structure, or component. There are no construction activities associated with the requested exemption.

Therefore, the requested exemption does not involve a significant construction impact.

(v) No significant increase in the potential for or consequences from radiological accidents

The requested exemption would allow SHINE to establish, implement, and maintain an information protection system that includes the applicable measures for SGI-M specified in 10 CFR 73.23, consistent with research and test reactors that possess special nuclear material of moderate strategic significance. The requested exemption is administrative in nature, and has no effect on the design of any SHINE system, structure, or component. The requested exemption does not alter any assumptions or any methodology associated with the accidents analyzed in the PSAR, nor does it affect the potential for or consequences from radiological accidents.

Therefore, the requested exemption does not involve a significant increase in the potential for or consequences from radiological accidents.

(vi) The requirements from which an exemption is sought involve: safeguard plans, and materials control and accounting inventory scheduling requirements; or other requirements of an administrative, managerial, or organizational nature.

Granting the requested exemption would allow SHINE to establish, implement, and maintain an information protection system that includes the applicable measures for SGI-M specified in 10 CFR 73.23, consistent with research and test reactors that possess special nuclear material of moderate strategic significance.

Therefore, the requirements from which the exemption is sought involve safeguards plans (10 CFR 51.22(c)(25)(vi)(F)), and are administrative in nature (10 CFR 51.22(c)(25)(vi)(I)).

5.0 REFERENCES

- (1) U.S. Nuclear Regulatory Commission, "10 CFR Parts 2, 30, 40, et. al., Protection of Safeguards Information; Final Rule," *Federal Register*, Vol. 73, No. 207, October 24, 2008, pp. 63546-63582
- (2) U.S. Nuclear Regulatory Commission, "Safeguards Information—Modified Handling Categorization; Change for Materials Facilities," *Federal Register*, Vol. 79, No. 189, September 30, 2014, pp. 58664-58672
- (3) SHINE Medical Technologies, Inc., "Preliminary Safety Analysis Report," August 27, 2015 (ML15258A431)
- (4) U.S. Nuclear Regulatory Commission, "Standard Format and Content for a Licensee Physical Security Plan for the Protection of Special Nuclear Material of Moderate or Low Strategic Significance," Regulatory Guide 5.59, Revision 1, February 1983 (ML100341301)
- (5) U.S. Nuclear Regulatory Commission, "Safety Evaluation Report Related to the SHINE Medical Technologies, Inc. Construction Permit Application for a Medical Radioisotope Production Facility," October 2015 (ML15288A076)