SHINE™
Medical Technologies

February 18, 2013

SMT-2013-010
10 CFR 50.12

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

References: (1) NRC letter to SHINE Medical Technologies, dated December 7, 2012, SHINE Medical Technologies, Inc. – Clarification on the Applicability of 10 CFR 2.101(a)(5) to Proposed Medical Isotope Production Facilities Regarding Two-Part Construction Permit Application Submittals (ML12319A258)

Request for Exemption to Submit Application for Construction Permit in Two Parts

In response to Reference (1), and pursuant to 10 CFR 50.12, "Specific Exemptions," SHINE Medical Technologies, Inc. (SHINE) is submitting a request for exemption from certain requirements of 10 CFR 2.101, "Filing of an application." The requested exemption would allow SHINE to submit an application for a Construction Permit for a medical isotope production facility in two parts in accordance with the provisions of 10 CFR 2.101(a)(5).

Enclosure 1 provides the Exemption Request to portions of 10 CFR 2.101. Approval of the Exemption Request is requested by March 15, 2013.

This letter contains no new Regulatory Commitments and no revisions to existing Regulatory Commitments.

If you have any questions, please contact Mr. Jim Costedio, Licensing Manager, at 608/210-1730

Very truly yours,

R. V. Bynum

R. Vann Bynum, PhD
Chief Operating Officer
SHINE Medical Technologies, Inc.
Project No.: PROJ0792

Enclosure

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

ENCLOSURE 1

SHINE MEDICAL TECHNOLOGIES, INC.

REQUEST FOR EXEMPTION TO SUBMIT APPLICATION FOR CONSTRUCTION PERMIT IN TWO PARTS

1.0 INTRODUCTION

Pursuant to 10 CFR 50.12, "Specific Exemptions," SHINE Medical Technologies, Inc. (SHINE) is submitting a request for exemption from certain requirements of 10 CFR 2.101, "Filing of an application." The requested exemption would allow SHINE to submit an application for a Construction Permit for a medical isotope production facility in two parts in accordance with the provisions of 10 CFR 2.101(a)(5).

As demonstrated below, SHINE meets the requirements of 10 CFR 50.12 because the requested exemption is authorized by law, does not present an undue risk to the public health and safety, will not endanger the common defense and security, and because special circumstances are present such that the exemption should be granted.

2.0 BACKGROUND

SHINE seeks to construct and operate a medical isotope production facility able to produce molybdenum-99 (Mo-99). Mo-99's decay product, technetium-99m (Tc-99m), is used to perform approximately 16 million imaging procedures in the U.S. each year, and accounts for 80% of all nuclear medicine procedures. Tc-99m is used in a wide variety of imaging procedures, including cardiac perfusion imaging (used in the detection and treatment of heart disease) and bone scans (to detect cancer metastases). Despite being the world's largest consumer of Tc-99m, the U.S. has no domestic production of Mo-99. Approximately 95% of the world's supply of Mo-99 comes from only five nuclear reactors, all of which are greater than 45 years old.

As these reactors age, they must be shut down for repairs and maintenance with increasing frequency. Mo-99, with a half-life of just 66 hours, cannot be stockpiled, and must be produced continuously. In May 2009, the National Research Universal (NRU) reactor in Chalk River, Ontario, shut down to repair a coolant leak, and the world lost approximately one-third of its Mo-99 supply capacity. While other reactors were able to increase production to partially cover the shortfall, when the High-Flux Reactor (HFR) reactor in Petten, the Netherlands, shut down for scheduled maintenance in February 2010, the world saw another third of its capacity taken off-line. With more than half of its normal supply capacity out of service, the world experienced a Tc-99m shortage. The U.S., which normally receives almost all of its Mo-99 from the NRU and HFR, was especially impacted. Around the country, radiologists were forced to postpone and cancel procedures.

As the five reactors continue to age, unless new, reliable production capacity is brought on-line, supply disruptions like these will become more and more frequent. In addition, the Canadian government has announced its intention to permanently shut down the NRU reactor when its license expires in 2016. Without new production capacity, the U.S. will certainly face another Mo-99 shortage in 2016, potentially impacting the health of hundreds of thousands of patients every week. SHINE is currently on schedule to help avert this health crisis by meeting its milestone to produce Mo-99 by 2016.

Per the NRC (Reference 1), SHINE must apply for an exemption under 10 CFR 50.12 in order to submit its application for a Construction Permit in two parts, as described in 10 CFR 2.101(a)(5). In order for an applicant for a Construction Permit under 10 CFR Part 50 to submit an application in two parts, under 10 CFR 2.101(a)(5), the proposed facility must be subject to 10 CFR 51.20(b). The regulation identifies those types of actions that require an environmental impact statement (EIS). Construction and operation of a medical isotope production facility does not require an EIS under 10 CFR 51.20(b), therefore, 10 CFR 2.101(a)(5) does not apply to such facilities (Reference 1).

Although construction and operation of a medical isotope production facility does not require an EIS under 10 CFR 51.20(b), the Commission could determine the SHINE's proposed action should be covered by an EIS. Early review of the Environmental Report would enable the Commission to make an earlier determination if an EIS, in accordance with 10 CFR 51.20(a)(2), is required. This early determination should be performed as soon as possible, which will allow SHINE to realign resources and mitigate the schedule impacts as a result of the expected longer review timeframe associated with an EIS. If no EIS is required, a two part application would facilitate potential earlier completion of the environmental review and ultimate issuance of the Construction Permit and construction of the SHINE medical isotope facility.

Therefore, in accordance with the provisions of 10 CFR 50.12, SHINE requests an exemption to allow submittal of an application for a Construction Permit for a medical isotope facility in two parts in accordance with the provisions of 10 CFR 2.101(a)(5). Part one of SHINE's application for a Construction Permit for a medical isotope production facility is expected to be submitted in March 2013, and will include the following:

- Environmental Report (Preliminary Safety Analysis Report (PSAR), Chapter 19) in accordance with 10 CFR 50.30(f);
- Description and safety assessment of site (PSAR, Chapter 2) in accordance with 10 CFR 50.34(a)(1);
- Fee information in accordance with 10 CFR 50.30(e) and 10 CFR 170.21;
- General information in accordance with 10 CFR 50.33; and,
- Classified information agreement in accordance with 10 CFR 50.37.

Part two of SHINE's application for a Construction Permit for a medical isotope production facility will include the PSAR, in accordance with 10 CFR 50.34(a).

3.0 PROPOSED EXEMPTION

As noted above, an exemption from 10 CFR 2.101(a)(5) would allow SHINE to submit an application for a Construction Permit for a medical isotope production facility in two parts. Submitting an application in two parts would allow the Commission to commence the environmental review of the SHINE application for a Construction Permit at an earlier date, thereby allowing for an earlier decision on whether an EIS is required, and, if no EIS is required, allowing a potential earlier completion of the environmental review and ultimate issuance of the Construction Permit and construction of the SHINE medical isotope facility.

10 CFR 50.12 states that the Commission may grant an exemption from requirements of the regulations provided that: 1) the exemption is authorized by law; 2) the exemption will not result in an undue risk to public health and safety; 3) the exemption is consistent with the common defense and security; and, 4) special circumstances, as defined in 10 CFR 50.12(a)(2) are present.

As pertinent here, special circumstances are defined to include either: a) application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule; or b) the exemption would result in benefit to the public health and safety that compensates for any decrease in safety that may result from the grant of the exemption.

The requested exemption to allow SHINE to submit an application for a Construction Permit in two parts satisfies these requirements, as described below, including the two special circumstances listed above.

1. The requested exemption is authorized by law.

No law exists which precludes the activities covered by this exemption request. The medical isotope production facility will be licensed under Section 103 of the Atomic Energy Act of 1954 (AEA), 42 U.S.C. § 2133, as amended. Nothing in AEA § 103 prohibits the submittal of a Construction Permit application for a Class 103 facility in multiple parts, nor does any other statute.

The NRC has promulgated 10 CFR 2.101(a)(5) to authorize certain types of Construction Permit applicants to submit their application in multiple parts, including Class 103 facilities under 10 CFR 50.22, confirming that this process is not prohibited by statute. As explained in Section 4.a below, the regulatory history of 10 CFR 2.101(a)(5) suggests that the reason medical isotope production facilities have been omitted from this authorization is because the need for such an option has not previously arisen.

This exemption request does not change the quality or content of the Environmental Report or the PSAR, and is administrative in nature. Therefore, the requested exemption is authorized by law.

2. The requested exemption does not present an undue risk to the public health and safety.

No risk to public health and safety is presented by the requested exemption. SHINE will satisfy all of the substantive licensing criteria in 10 CFR Parts 50 and 51 in its Construction Permit application for the medical isotope production facility. The

Commission will have a full opportunity to conduct a complete safety and environmental review of the application, and the full right of public participation in the licensing process will be afforded in accordance with the Commission's regulations. The NRC will not issue the Construction Permit until it makes the requisite findings under 10 CFR Parts 50 and 51. Accordingly, granting the exemption will not interfere with the licensing or public participation process in any respect.

As explained in Section 4.b below, if the exemption is approved and the Construction Permit ultimately granted, there will be significant benefits to the public health and safety.

3. The requested exemption will not endanger the common defense and security.

The NRC's substantive requirements for a Construction Permit will be fully met in SHINE's application. The submittal of the application for a Construction Permit in two parts will in no way affect the security or safeguards features or programs at the facility at any point during construction or operation. Accordingly, the granting of the requested exemption is consistent with the common defense and security.

4. Special circumstances are present, such that the exemption request should be granted.

a. <u>The application of 10 CFR 2.101(a)(5) to prevent the submittal of this application for a Construction Permit in two parts would not serve the underlying purpose of the rule.</u>

The requested exemption meets the special circumstances of 10 CFR 50.12(a)(2)(ii), since a strict application of 10 CFR 2.101(a)(5) would not serve the underlying purpose of the rule.

The authorization to submit certain Construction Permit applications in two parts, up to six months apart, dates to 1974, when the Atomic Energy Commission (AEC or Commission) authorized the separate submittal of the PSAR and Environmental Report for nuclear power reactors under 10 CFR 2.101(a). This rule was later changed to link the authorization to submit a Construction Permit application in multiple parts to facilities for which an EIS must be prepared, and this link was carried forward when 10 CFR 2.101(a)(5) was first promulgated in 1976. The current 10 CFR 2.101(a)(5) allows Construction Permit applicants to submit their application in two parts, but only when the application is for certain facilities where an EIS is required.

In publishing the original 1974 rule authorizing, in 10 CFR 2.101(a), the submittal of Construction Permit applications for nuclear power reactors in two parts, the Commission noted that at that time, there was "deep national concern over energy sources and supply," and that the amendments were intended to "reduce the time required to bring on line nuclear power plants which satisfy all environmental and safety requirements." Further, there was a public interest in "removing unnecessary obstacles" to the construction of needed power plants. Thus, as relevant here, the underlying purpose of allowing multi-part Construction Permit applications under 10 CFR 2.101(a)(5) is to remove unnecessary obstacles to the timely and efficient licensing and construction of nuclear facilities that are in the national interest.

That underlying purpose fully supports the granting of an exemption here. As previously noted, the demand for medical isotopes is a significant national public health and safety concern. This concern is similar to the Commission's concerns regarding the need for nuclear power reactors at the time the two-part process was established. In addition, SHINE's proposed medical isotope production facility will be a Class 103 facility, so it meets the other prerequisite for the use of the two-part submittal process in 10 CFR 2.101(a)(5), other than the EIS requirement. No purpose is served by foreclosing SHINE from the opportunity to use this process simply because the NRC is not required by regulation to prepare an EIS for the licensing of its facility.

Finally, nothing in the regulatory history suggests that the Commission intended to foreclose other types of Class 103 applicants who could similarly benefit from the submittal of a Construction Permit application in two parts from doing so. In fact, in 2007, when the NRC extended the two-part application option to combined licenses under 10 CFR Part 52, it stated that there "are no considerations unique to combined licenses which would weigh against allowing a combined license applicant to submit a two part application..." Similarly, there are no considerations unique to medical isotope production facilities that weigh against such an option.

The NRC should, therefore, take reasonable steps to remove unnecessary obstacles to the timely licensing of such facilities. In this case, requiring SHINE to delay the first part of its Construction Permit application, and the corresponding NRC application review, until the remainder of the application is ready is an unnecessary obstacle because it will prevent an earlier review and determination of environmental issues relevant to the application. Such a determination would allow SHINE to more efficiently align its resources as necessary to address NRC decisions on such matters to better ensure timely licensing of the facility.

The application of 10 CFR 2.101(a)(5) to prevent SHINE from submitting its Construction Permit application in two parts, therefore, would not serve the underlying purpose of the rule. Instead, granting the requested exemption would meet that underlying purpose, and would facilitate an efficient and thorough review of the SHINE application.

b. <u>The exemption would result in benefit to the public health and safety.</u>

The requested exemption also meets the special circumstances of 10 CFR 50.12(a)(2)(iv), since an exemption from 10 CFR 2.101(a)(5) would result in benefit to the public health and safety, and there will be no decrease in safety as a result of the exemption.

SHINE seeks to construct and operate a medical isotope production facility able to produce Mo-99. Mo-99's decay product, Tc-99m, is used to perform approximately 16 million imaging procedures in the U.S. each year, and accounts for 80% of all nuclear medicine procedures. Tc-99m is used in a wide variety of imaging procedures, including cardiac perfusion imaging (used in the detection and treatment of heart disease) and bone scans (to detect cancer metastases). Despite being the world's largest consumer of Tc-99m, the U.S. has no domestic production of Mo-99. Approximately 95% of the world's supply of Mo-99 comes from only five nuclear reactors, all of which are greater than 45 years old.

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As the five reactors continue to age, unless new, reliable production capacity is brought on-line, supply disruptions like these will become more and more frequent. In addition, the Canadian government has announced its intention to permanently shut down the NRU reactor when its license expires in 2016. Without new production capacity, the U.S. will certainly face another Mo-99 shortage in 2016, potentially impacting the health of hundreds of thousands of patients every week. SHINE is currently on schedule to avert this crisis by meeting its milestone to produce Mo-99 by 2016.

There would be no decrease in safety as a result of granting the exemption. The Commission will have a full opportunity to conduct a complete safety and environmental review of the application, and the full right of public participation in the licensing process will be afforded. Granting this exemption and removing unnecessary obstacles to the licensing and ultimate construction and operation of this facility will provide substantial benefits to the public health and safety.

Based on the above, special circumstances are present which fully support the request for this exemption to the regulations.

4.0 REFERENCES

1. NRC letter to SHINE Medical Technologies, dated December 7, 2012, SHINE Medical Technologies, Inc. – Clarification on the Applicability of 10 CFR 2.101(a)(5) to Proposed Medical Isotope Production Facilities Regarding Two-Part Construction Permit Application Submittals (ML12319A258)