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Medical Technologies

May 10, 2012

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Chief, Rules, Announcements, and Directives Branch
Office of Administration
Mail Stop TWB-05-B01M
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

SHINE Medical Technologies, Inc.
Project No. 0792
SMT-2012-016

Subject: Comments on the Draft Interim Staff Guidance Augmenting NUREG-1537, Chapters 7-18, Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors for the Production of Radioisotopes, Docket ID NRC-2011-0135

Dear Ms. Bladey:

The purpose of this letter is to provide comments on the proposed Draft Interim Staff Guidance (ISG) Augmenting NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content," for the Production of Radioisotopes.

Comments on the proposed draft Interim Staff Guidance are contained in the enclosure to this letter. SHINE appreciates the opportunity to provide comments and hopes that the Staff will consider the merits of the requested feedback during the development of final license application guidance for medical isotope production facilities.

If you have any questions regarding this letter, please contact Mr. James Freels, Licensing Project Manager, at 865.719.5061.

Sincerely,

Dr. Gregory Piefer, PhD
CEO – SHINE Medical Technologies, Inc.

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Enclosure

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Docket ID NRC-2011-0135

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General Comments:

1. NUREG-1537 was written to allow applicants to submit one Safety Analysis Report to address the needed information for both a Preliminary Safety Analysis Report (PSAR) and a Final Safety Analysis Report (FSAR) supporting both an application for a construction permit and an operating license. If well planned, the final facility design and the final SAR descriptions, analyses, and conclusions will not differ significantly from those in an initial application and a one-step licensing process can be undertaken. As stated in NUREG 1537, the regulations in 10 CFR 2.105(c) do not preclude a joint application for a construction permit and the initial operating license. When utilized, this streamlined licensing process provides benefits for both the NRC staff and the applicant. As currently written, NUREG-1537's stated purpose is to describe an acceptable format and content of the safety analysis report (SAR) to be submitted to the NRC staff by an applicant or licensee of a non-power reactor for a new license. However, not all applicants would prefer this one-step joint application for various reasons, and would prefer to follow the conventional process of the two step licensing process under 10 CFR 50. NUREG 1537 and the draft Interim Staff Guidance (ISG) for the NUREG-1537 chapters do not provide sufficient guidance for the content necessary to submit a high quality PSAR for a construction permit, followed at a later date by an FSAR for the operating license.

   The NRC staff routinely provides regulatory guidance (i.e. NUREGs, Regulatory Guides, etc.) to minimize the possibility that regulations are interpreted differently by different applicants and licensees. However, NUREG-1537 and the draft ISG do not provide the same level of differentiation needed for PSAR and FSAR scope, content and level of detail found in earlier regulatory guidance documents. For instance in Regulatory Guide 1.70, Revision 3, the NRC staff did provide information relative to the difference in scope, content and level of detail between a PSAR and FSAR.

   The NRC staff should consider guidance in NUREG-1537 that specifies the requisite information needed for scope, content and level of detail for applicants wishing to submit both a PSAR for the construction permit and an FSAR for an operating license to ensure consistency and completeness of content.

2. Part 1 of the draft ISG should provide the framework and structure for the content of chapters within the SAR, irrespective of being a PSAR or FSAR. Information related to the structure and content should be located in Part 1 of the NUREG. In

Chapter 7b of Part 2, guidance is provided for content and structure for the SAR, but the same information is not presented in Part 1. NRC staff should consider putting all necessary information related to content and structure for a SAR in Part 1 of the NUREG and not expect applicants and licensees to reference different Parts of the NUREG to determine structure and content.

Specific Comments on Part 1:

Chapter 9 Auxiliary Systems

Section 9b.3 Fire Protection Systems and Programs

The draft ISG looks for information to be included in this section related to hydrogen or other combustible gases. These issues are addressed in Chapter 13 for the fission process as well as the radioisotope production facility specific hazard analysis and are not necessary to be repeated in this section. This section need only address the systems and programs necessary to detect, alarm and suppress a fire as needed for the Chapter 13 analysis.

Chapter 10 Experimental Facilities

The draft ISG for NUREG-1537 suggests that the post-extraction radioisotope processing operations should be discussed in this section. This is only appropriate if the post-extraction radioisotope processing operations are being conducted as an experiment, one which might be used to optimize the post-extraction process. This type of operational decision would be evaluated under 10 CFR 50.59 as part of a normal change process. Clearly the intent of this section in NUREG-1537 is for experimental facilities used in conjunction with a non-power reactor. The many examples of the experiments described in NUREG-1537 do not have a nexus to post-extraction processes that are integral to the production of radioisotopes and described in other SAR chapters.

Additionally, the language regarding the "AHR case where the reactor fuel is the target, the radioisotope extraction and post-extraction process is an integral part of the reactor operation." is inconsistent with the concept of having two different processes of interest in a SAR, the fission process and the radioisotope production facility processes. If the extraction and post-extraction processes are integral to the reactor operation (or fission process) then the line of demarcation between the reactor (or fission process) and the radioisotope production facility does not exist. This suggests that all the processes are reactor- (or fission-) related and the concept of a separate radioisotope production facility is undermined by this statement. SHINE believes that there is a difference between the fission process and the radioisotope production facility process and that the regulations should recognize and accommodate this difference.

Chapter 11 Radiation Protection and Waste Management

Section 11.3 Respiratory Protection Program

The draft ISG states:

> *Under 10 CFR 20.1703(c)(4), the applicant must describe the installation of the ventilation and containment systems and how these will protect personnel from inhaling airborne concentrations of radionuclides that are above the SLs. The applicant should also describe the surveillance requirements that will be imposed on the ventilation and containment systems and the respiratory protection equipment. This information should be sufficient to support an understanding of how the worker will be protected and how a safe working environment will be maintained.*

10 CFR 20.1703(c)(4) addresses the scope and content of written procedures necessary to implement the regulations related to implementing and maintaining a respiratory protection program and does not address what the draft ISG states. The NRC staff should consider whether to cite a different regulation or instead remove the statements.

Chapter 12 Conduct of Operations

Section 12.1.6 Production Facility Safety Program

The draft ISG states:

> *The radioisotope production facility must have an established safety program, as required by 10 CFR 70.61, "Performance Requirements" and 10 CFR 70.62, "Safety Program and Integrated Safety Analysis."*

Based on the draft ISG language, it is presumed that 10 CFR 70 Subpart H applies to all radioisotope production facilities using NUREG-1537 as its licensing model. However, 10 CFR 70.60, in part, states the applicants or licensees to which 10 CFR 70 Subpart H applies:

> ***§ 70.60 Applicability.***
>
> *The regulations in § 70.61 through § 70.76 apply, in addition to other applicable Commission regulations, to each applicant or licensee that is or plans to be authorized to possess greater than a critical mass of special nuclear material, and engaged in enriched uranium processing, fabrication of uranium fuel or fuel assemblies, uranium enrichment, enriched uranium hexafluoride conversion, plutonium processing, fabrication of mixed-oxide fuel or fuel assemblies, scrap recovery of special nuclear material, or any other activity that the Commission determines could significantly affect public health and safety.*

While most radioisotope production facilities may possess greater than a critical mass of special nuclear material, they may not satisfy any of the other identified applicability criteria in 10 CFR 70.60. Unless the Commission determines that the radioisotope production facility could significantly affect public health and safety, then an additional criterion must be satisfied for Subpart H to be legally binding. Many of the additional criteria are not defined, such as enriched uranium processing and plutonium processing.

The staff should note a distinction between "processing" special nuclear material (enriched uranium and plutonium) and "separation" of radioisotopes from special nuclear material (enriched uranium and plutonium). This distinction is reflected in the Atomic Energy Act of 1954 (as amended) Section 161(m), and Section 161(t).

The staff should consider clarifying which criteria apply to radioisotope production facilities with appropriate definitions or instead specify that a Commission determination that makes all radioisotope production facilities subject to this regulation.

Section 12.7 Emergency Planning

The second sentence in the second paragraph of Part 1 states that Section 12.7 of Part 2 specifies the portions of NUREG-1520 that should be addressed. Section 12.7 of Part 2 has no direct references to NUREG-1520 but has included some of its suggested information in the text. Please clarify.

Section 12.10b Production Facility Operator Training and Requalification

The last sentence of the first paragraph states that the NRC will be imposing applicable Part 55 requirements to production facility operators. The corresponding paragraph in Part 2 seems to indicate that all the requirements of Part 55 will be imposed. Please clarify.

The Atomic Energy Act of 1954, as amended, provides a definition of the term "production facility" in Chapter 2, Section 11,"Definitions". 10 CFR 50.2, "Definitions" also provides a definition of the term "production facility". These two definitions appear to be different. The draft Interim Staff Guidance (ISG) references the Atomic Energy Act in this section when discussing radioisotope production facilities. However, the Atomic Energy Act's use of the term "production facility" in Section 107 of the AEA is based on the AEA's definition of the term, not the definition provided in 10 CFR 50.2. Using the AEA definition for a production facility when the 10 CFR 50.2 definition differs can create difficult issues of interpretation and compliance.

Section 12.14 References

The referenced version of ANSI/ANS 15.11 is given as 2004. The latest version of this standard is 2009, and should be referenced instead.

Chapter 13 Accident Analysis

Section 13a.2.1.1 Maximum Hypothetical Accident

The first listed MHA is the dispersal of the contents of the primary boundary with bypass of any scrubbing capacity. If the vessel forming the primary boundary is located in a relatively deep pool, then the requirement of bypassing scrubbing is going to eliminate the principal means for reducing the iodine inventory released from the pool. Scrubbing of iodine by the pool water is a physical process and should not be eliminated as part of an accident. This scenario of breaking the primary boundary and bypassing scrubbing is similar to a postulated double failure with the second "failure" being the elimination of a

physical process. This first MHA should be re-defined without the "bypass of any scrubbing capacity" restriction.

Chapter 13b Radioisotope Production Facility Accident Analysis

In this section of the draft ISG, the Staff states:

> *The regulations in Subpart H of 10 CFR Part 70 require licensees possessing and processing SNM in quantities that are greater than a critical mass to conduct integrated safety analyses (ISAs) of all such operations.*
>
> *In 10 CFR 70.62, the NRC requires that, through a well-defined safety program (refer to Section 12.1.6 of this ISG), all processes involving licensed material be examined through an ISA.*

As previously identified in comments for Section 12.1.6, these statements are incomplete as they are only reflective of a portion of the regulations. At least one of the additional criteria is required to be satisfied to make this regulation applicable.

Chapter 14 Technical Specifications

Chapter 14b Technical Specifications for Radioisotope and Special Nuclear Material Processing Outside of the Reactor

As identified in comments for Chapters 12.1.6 and 13b, the staff prescribes adherence to 10 CFR 70 Subpart H in this section, even though the criteria to follow this regulation is assumed without additional clarification. The staff should modify the wording to reflect the use of Subpart H, as applicable, unless other 10 CFR 70.60 criteria are specified or defined by the Commission.