SHINE™
Medical Technologies

July 28, 2011

Ms. Cindy K. Bladey
Chief, Rules, Announcements, and Directives Branch
Division of Administrative Services
Office of Administration
Mail Stop TWB-05-B01M
U.S. Nuclear Regulatory Commission
Washington, DC 20555-001

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SHINE Medical Technologies, Inc.
Project No. 0792
SMT-2011-011

Subject: Comments on Interim Staff Guidance Regarding the Environmental Report for Applications to Construct and/or Operate Medical Isotope Production Facilities, 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), NPR-ISG-2011-001, "Staff Guidance Regarding the Environmental Report for Applications to Construct and/or Operate Medical Isotope Production Facilities".

Comments on the proposed draft Interim Staff Guidance are contained in the enclosure to this letter. The enclosure includes both general and specific comments for identified sections. 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 Environmental Report 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,

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

Enclosure: As stated

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Enclosure

Comments on Interim Staff Guidance Regarding the Environmental Report for Applications to Construct and/or Operate Medical Isotope Production Facilities

Docket ID NRC-2011-0135

Comments on Interim Staff Guidance Regarding the Environmental Report for Applications to Construct and/or Operate Medical Isotope Production Facilities

Docket ID NRC-2011-0135

General Comments:

Not all medical isotope facilities will be based on the same technology. While some medical isotope facilities may employ reactor-based technologies, others may be based on less environmentally impactful technologies, such as particle accelerators or other non-reactor based technologies. The use of NUREG-1537, Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, for all medical isotope facilities' licensing framework, including Environmental Reports is a sub-optimal licensing framework. This premise is supported by the recognition of the Staff that Interim Staff Guidance is needed to supplement NUREG-1537 for both the Environmental Report and the Safety Analysis Report. While there is no generic licensing framework for individual medical isotope production technologies, the Staff should be agile and responsive to the various medical isotope technologies' differing needs for regulatory interpretations while potential applicants are working to follow the licensing guidance for non-power reactors. The Staff should implement an expeditious internal process for assessing licensing issues and providing NRC policy and interpretation findings for the potential applicant's licensing process.

Medical isotope facilities based on these non-reactor technologies will be significantly smaller in physical size, have a much smaller plant footprint, represent a much lower hazard to the public and most importantly, have far less impact on the human environment than nuclear power reactors. In the proposed Interim Staff Guidance, there are numerous examples where the draft ISG requests information that is in excess of what is requested for nuclear power reactors in NUREG-1555: Standard Review Plans for Environmental Reviews for Nuclear Power Plants. The Staff should not request more information from medical isotope production facility Environmental Reports than it requests from the initial licensing of nuclear power reactors, as identified in many of the Specific Comments. It also appears that in numerous areas, the Staff has referenced NUREG-1555, Supplement 1, for the proposed language. NUREG-1555, Supplement 1, provides the Staff guidance in reviewing Environmental Reports for nuclear power plant license renewal, not their initial licensing, and is inappropriate for providing guidance related to medical isotope facility initial licensing.

Throughout the draft ISG, the radial distance to be considered in specific Environmental Report sections is identified as 50 miles (80 km). The 50 mile (80 km) radial distance for Environmental Report considerations is excessive for medical isotope production facilities. For nuclear power reactors, a radial distance of 50 miles (80 km) is appropriate as that distance is driven by the Ingestion Pathway distance identified in 10 CFR 50.47(c)(2). Therefore, for power reactors consideration of demographic considerations and socioeconomic impacts at a 50 mile radial distance is appropriate. However, for non-power reactors, as previously evaluated by the NRC and specified in NUREG-1537, Section 2.1.2, the radial distance needed for population distribution consideration in the Safety Analysis Report is identified as 8 kilometers. For non-power reactors accident considerations, the emergency planning zone guidance is provided in

NUREG-0849, Standard Review Plan for the Review and Evaluation of Emergency plans for Research and Test Reactors, Appendix II, as referenced by NUREG-1537. Emergency planning zones are based on the hazard presented by research and test reactors and do not exceed 800 meters, unless thermal power is greater than 50 MW. For non-reactor based medical isotope facilities, there is no accident-driven need for consideration of a radius of 50 miles (80 km) and the socioeconomic impacts and demographic considerations from construction and operation are significantly smaller (approximately 10 to 100 times smaller) than for nuclear power reactors. The information requested in the draft ISG related to a 50 mile (80 km) radius is not warranted for non-reactor based medical isotope production facilities.

There are numerous examples where the distinction between the Safety Analysis Report and the Environmental Report become confused. The Environmental Report does not need to contain information regarding the impact of the environment on the facility; rather the Environmental Report should evaluate the impact of the facility on the environment. The former information will be found in the Safety Analysis Report and does not need to be included in the Environmental Report.

Specific Comments:

12.12.1.2 Applicable Regulatory Requirements, Permits and Required Consultations

Language used in this section is inconsistent with the language in 10 CFR 51.45(d). This ISG section identifies that the status of all Federal, State, local and other regulatory requirements, permits, and consultations be provided in accordance with 10 CFR 51.45(d). 10 CFR 51.45(d) requires that the Environmental Report list all *Federal* [emphasis added] permits, licenses, approvals and other entitlements along with their status of compliance (i.e., in compliance or not yet in compliance). Status of compliance is also required for applicable environmental quality standards and requirements such as zoning and land-use, thermal and other water pollution limitations or requirements which have been imposed by Federal, State, regional, and local agencies. The information requested in Section 12.12.1.2 exceeds what is required by 10 CFR 51.45(d) and should not create information needs beyond those required by regulations. (10 CFR 51.45(d); NUREG-1555, Section 1.2, Status of Reviews, Approvals and Consultations)

12.12.3.1 Land Use and Visual Resources

There is inconsistent use of the terms "region" and "vicinity" regarding the "site". These terms are not defined in the ISG, as they are in NUREG-1555 which specifies distinct differences between "site", "vicinity" and "region". For example, Section 12.12.3.1 asks for descriptions of land use conditions on and in the vicinity of the site, but the bulleted items ask for information related to the "region". Additionally, the same section introduces a new term, "area" which is also undefined. The inconsistent use of these terms should be modified based on a specific definition being created for the terms in a similar manner as in NUREG-1555. The site vicinity, as defined in NUREG-1555, should be utilized as the scope of off-site land use and visual resource impact studies. The 50 mile (80 km) radius around non-reactor based medical isotope production facilities is excessive and is not warranted. (NUREG-1555, Section 2.2.1, The Site and Vicinity)

12.12.3.2 Meteorology, Climatology
This section states that the most recent 5 years of on-site or near-on-site meteorological data needs to be provided. This data need is excessive as only one year of onsite meteorological data is needed for nuclear reactor power plants. (NUREG-1555, Section 2.7, Meteorology and Air Quality)

12.12.3.3 Geology, Soils and Seismology
This section differs greatly from the same topical section in NUREG-1555 for nuclear power reactors. In NUREG-1555, there is little to no information requested relative to geology for power reactors, due to the extensive discussion in the Safety Analysis Report and the small potential for geological impacts by the construction, operation and decommissioning of a nuclear power reactor. This section appears to confuse the safety analysis impact from the geological setting on the plant, and the environmental impact from the plant on the geologic setting. This information request is excessive and should not request additional information over that needed for a nuclear power reactor for this section. In fact, medical isotope facilities will have a substantially lesser effect on the geological setting than power reactors due to their smaller size and weight, and the Staff should consider this when preparing the Interim Staff Guidance. (NUREG-1555, Section 2.6, Geology)

12.12.3.5 Ecological Resources
This section requests information related to the historical description of the ecological environment. The history of the ecological environment is not relevant to the impact of the proposed facility on the current and future environment, which is the intent of the Environmental Report. This information is not requested for nuclear power reactors and is considered extraneous for licensing a medical isotope production facility. (NUREG-1555, Section 2.4, Ecology)

12.12.3.8 Human Health
This section requests the following information:

- Historical exposures to radioactive materials to both workers and members of the public

It is not clear what is being requested for this line item, if there is no previous or currently operating nuclear facility at the proposed site location. The information request cannot be satisfied with a reasonable effort and is not relevant to the potential impact on the environment and the population from the proposed facility. This line item should be deleted from this section for new facilities, since, in many cases, it will be impossible to satisfy and no similar information request can be found in NUREG-1555 for new nuclear power plants. The information request should be limited to medical isotope facilities located near existing nuclear facilities or sites that once contained nuclear facilities. (NUREG-1555)

12.12.4.2 Meteorology, Climatology, and Air Quality
This section requests the following information:

- Description of design considerations for severe weather events

The design considerations for severe weather events are not related to the impact of the facility on the environment; rather they are related to the facility design specifications in Chapter 3 of the Safety Analysis Report. This duplicative information should not be included in the Environmental Report. Design considerations related to the potential impact of severe weather events are not requested for nuclear power reactor Environmental Reports. (NUREG-1555, Section 2.7, Meteorology)

12.12.7 List of Preparers

This section states that the applicant or licensee should list the name, educational background, and summary or work experience for all personnel who have a role in preparing the Environmental Report. NUREG-1555 was reviewed for a similar statement; none was found during the review. This information is extraneous, is not requested for power reactors and need not be identified for medical isotope production facilities. (NUREG-1555)

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