ENCLOSURE 2

SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION 6B.3-30

PUBLIC VERSION

The NRC staff determined that additional information was required (Reference 1) to enable the continued review of the SHINE Medical Technologies, Inc. (SHINE) application for a construction permit to construct a medical isotope facility (References 2 and 3). The following information is provided by SHINE in response to RAI 6b.3-30 (Reference 1).

CHAPTER 6 – ENGINEERED SAFETY FEATURES

Section 6b.3 – Nuclear Criticality Control

(Applies to RAIs 6b.3-23 through 30)

> *As required by 10 CFR 50.34(a)(4), an applicant needs to submit "[a] preliminary analysis and evaluation of the design and performance of structures, systems, and components of the facility with the objective of assessing the risk to public health and safety resulting from operation of the facility…, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents."*
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> *As stated in the ISG Augmenting NUREG-1537, Chapter 13, the NRC staff has determined that the use of integrated safety analysis (ISA) methodologies as described in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," and NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," Revision 1, May 2010, application of the radiological and chemical consequence and likelihood criteria contained in the performance requirements of 10 CFR Section 70.61, designation of IROFS, and establishment of management measures are acceptable ways of demonstrating adequate safety for the medical isotopes production facility.*
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> *Applicants may propose alternate accident analysis methodologies, alternate radiological and chemical consequence and likelihood criteria, alternate safety features, and alternate methods of assuring the availability and reliability of the safety features. As used in this ISG, the term "performance requirements," when referencing 10 CFR Part 70, Subpart H, is not intended to mean that the performance requirements of Subpart H are required for a radioisotope production facility license, only that their use as accident consequence and likelihood criteria may be found acceptable by NRC staff.*

RAI 6b.3-30

The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, states, in part, that "[c]riticality process safety controls should be provided for criticality safety, and a description of their safety function should be described. The applicant should use enough safety controls to demonstrate that, under normal and abnormal credible conditions, all nuclear processes remain subcritical."

While SHINE states in response to RAIs 6b.3-1 and 6b.3-22, that the NCS reference manual and formal NCSEs have yet to be generated, the NRC staff need additional information to determine that enough safety controls have been considered to demonstrate that, under normal and abnormal credible conditions, all nuclear processes remain subcritical.

Provide additional information discussing the methodologies and assumptions that will be used to develop SHINE's NCS reference manual and provide a representative sample of nuclear criticality safety evaluations to demonstrate the methods used to demonstrate that under normal and abnormal credible conditions, all nuclear processes remain subcritical.

SHINE Response

Via Reference (4), SHINE stated that the following information would be provided to the NRC, to show the methods that will be used to demonstrate that under normal and abnormal credible conditions, all nuclear processes remain subcritical:

1. The nuclear criticality safety reference manual;
2. Two nuclear criticality safety calculations; and
3. A nuclear criticality safety evaluation (NCSE) covering criticality safety in the uranyl sulfate preparation tank (1-TSPS-01T).

Attachment 1 provides the SHINE Medical Technologies Nuclear Criticality Safety Reference Manual. Calculation Atkins-NS-DAC-SHN-15-04, "Single Parameter Subcritical Limits for Homogeneous 21 wt% ^{235}U Uranyl Sulfate, Uranium Oxide, and Uranium Metal," is provided as Attachment 2. Calculation Atkins-NS-DAC-SHN-15-02, "Criticality Safety Calculations for the Preliminary Design of Annular Tanks for the SHINE Medical Isotope Facility," is provided as Attachment 3.

SHINE will provide an NCSE covering criticality safety in the uranyl sulfate preparation tank to the NRC by July 31, 2015.

In addition, SHINE determined that the equation for the calculation of the Upper Subcritical Limit (USL) in the facility-specific validation report, provided via Reference (5), contained an error. The error is administrative in nature, and did not affect the results of the evaluation. SHINE has revised the facility-specific validation report to correct the error. Revision 2 of Atkins-NS-DAC-SHN-15-03, "MCNP 6.1 Validation with Continuous Energy ENDF/B-VII.1 Cross Sections for SHINE Medical Technologies," is provided as Attachment 4.

References

(1) NRC letter to SHINE Medical Technologies, Inc., dated March 25, 2015, SHINE Medical Technologies, Inc. – Request for Additional Information Regarding Application for Construction Permit (TAC Nos. MF2305, MF2307, and MF2308) (ML15055A116)

(2) SHINE Medical Technologies, Inc. letter to NRC, dated March 26, 2013, Part One of the SHINE Medical Technologies, Inc. Application for Construction Permit (ML130880226)

(3) SHINE Medical Technologies, Inc. letter to NRC, dated May 31, 2013, Part Two of the SHINE Medical Technologies, Inc. Application for Construction Permit (ML13172A324)

(4) SHINE Medical Technologies, Inc. letter to NRC, dated May 1, 2015, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information (ML15131A464)

(5) SHINE Medical Technologies, Inc. letter to NRC, dated June 19, 2015, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information (ML15183A292)