September 15, 2015

SMT-2015-042
10 CFR 50.30

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

References: (1) SHINE Medical Technologies, Inc. letter to NRC, dated March 26, 2013, Part One of the SHINE Medical Technologies, Inc. Application for Construction Permit (ML130880226)
(2) SHINE Medical Technologies, Inc. letter to NRC, dated May 31, 2013, Part Two of the SHINE Medical Technologies, Inc. Application for Construction Permit (ML13172A324)
(3) NRC electronic mail to SHINE Medical Technologies, Inc., dated August 26, 2015, Draft Request for Additional Information Supporting SHINE Preliminary Safety Analysis Report (ML15239B051)
(4) NRC electronic mail to SHINE Medical Technologies, Inc., dated August 27, 2015, Draft Request for Additional Information Supporting SHINE Preliminary Safety Analysis Report (ML15244A501)
(5) SHINE Medical Technologies, Inc. letter to NRC, dated September 2, 2015, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information (ML15247A067)

SHINE Medical Technologies, Inc. Application for Construction Permit
Revision 1 of SHINE Response to Request for Additional Information 6b.3-34

Pursuant to 10 CFR 50.30, SHINE Medical Technologies, Inc. (SHINE) submitted an application for a construction permit to construct a medical isotope facility to be located in Janesville, WI (References 1 and 2). Via References (3) and (4), the NRC staff determined that additional information was required to enable the staff's continued review of the SHINE construction permit application. SHINE responded to the NRC staff's requests via Reference (5). SHINE has determined that the SHINE Response to Request for Additional Information (RAI) 6b.3-34, previously provided via Reference (5), requires revision.

Enclosure 1 provides Revision 1 of the SHINE Response to RAI 6b.3-34.

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

I declare under the penalty of perjury that the foregoing is true and correct.
Executed on September 15, 2015.

Very truly yours,

Gregory Piefer, Ph.D.
Chief Executive Officer
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.

SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT REVISION 1 OF SHINE RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION 6B.3-34

The NRC staff determined that additional information was required (References 1 and 2) to enable the continued review of the SHINE Medical Technologies, Inc. (SHINE) application for a construction permit to construct a medical isotope facility (References 3 and 4). SHINE responded to the NRC staff's requests via Reference (5). SHINE has determined that the SHINE Response to Request for Additional Information (RAI) 6b.3-34, previously provided via Reference (5), requires revision. The following information is provided as Revision 1 of the SHINE Response to RAI 6b.3-34.

CHAPTER 6 – ENGINEERED SAFETY FEATURES

Section 6b.3 – Nuclear Criticality Control

RAI 6b.3-34

As required by 10 CFR 50.34(a), "Contents of applications; technical information," a preliminary safety analysis report should include "[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." Additionally, the preliminary design of the facility should provide reasonable assurance to the NRC staff that the final design will conform to its design bases with adequate margin for safety.

With respect to nuclear criticality control, the Interim Staff Guidance (ISG) Augmenting NUREG-1537, Part 2, Section 6b.3, "Nuclear Criticality Safety for the Processing Facility," 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" and that "NCS [nuclear criticality safety] limits on controlled parameters will be established to ensure that all nuclear processes are subcritical, including an adequate margin of subcriticality for safety."

The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, states, in part, that the reviewer should determine "whether the margin of subcriticality for safety is sufficient to provide reasonable assurance of subcriticality."

In response to RAI 6b.3-4, SHINE states it intends to utilize a subcritical margin of 0.05 with additional considerations for uncertainty in the validation and modeling. In addition, SHINE states in multiple places in the PSAR that processes will be maintained to a keff ≤ 0.95 (assuming a subcritical margin of 0.05).

The NRC staff's review of SHINE's responses to RAIs 6b.3-1 and 6b.3-26 found that there was insufficient benchmarking of the code against experiments utilizing the materials and enrichments expected in SHINE's processes. For this reason, the proposed subcritical margin of 0.05 is not sufficient to adequately address the uncertainty associated with the neutron interactions of these process materials. The subcritical margin of 0.05, which SHINE quoted from NUREG-1520, was intended for facilities with enrichment less than five percent utilizing well established processes and for which there is significant experience and data. In contrast, the SHINE facility will be a first-of-a-kind facility using materials not normally utilized and of an enrichment up to 20 percent.

Provide additional information describing how SHINE has or will sufficiently benchmark against experiments utilizing the materials and enrichments expected to be used in SHINE facility processes for its proposed margin of subcriticality, or propose a new margin of subcriticality that appropriately takes into account materials and enrichment.

SHINE Response

In the previous SHINE Response to RAI 6b.3-34 (Reference 5), SHINE stated that the calculated uranyl sulfate volumes from the modeling information in the IEU-SOL-THERM-001 benchmark were approximately 3% less than the critical uranyl sulfate volumes specified in the benchmark description. Since the submittal of that RAI response, SHINE has determined that an error exists in the computer model that was created to match the benchmark. This model error led to the apparent low volume found in the cases, which led to Monte Carlo N-Particle Transport Code (MCNP) k_{eff} values being significantly below (-1.6% to -2.7%) the experimental k_{eff} values. An Issues Management Report (IMR) has been initiated to resolve this issue.

Based on the above, SHINE has determined that there is not an inconsistency of the data in the International Criticality Safety Benchmark Evaluation Project (ICSBEP) Handbook description of IEU-SOL-THERM-001. Based on current modeling, the IEU-SOL-THERM-001 cases result in k_{eff} values of approximately 0.99 to 1.0, which may decrease the Upper Subcritical Limit (USL) calculated in the validation report if these cases were included.

The SHINE criticality safety validation report, Atkins-NS-DAC-SHN-15-03, Revision 2, provided as Attachment 4 to Enclosure 1 of Reference (6), sufficiently benchmarks against experiments using materials and enrichments expected to be used in the SHINE facility processes. However, given that this benchmark is applicable to the SHINE design, that the benchmark is not inconsistent, and that including these four IEU-SOL-THERM-001 cases could decrease the USL, SHINE plans to include this benchmark in the SHINE criticality safety validation report in a future revision. An IMR has been initiated to track the inclusion of these four IEU-SOL-THERM-001 cases in a future revision to the SHINE criticality safety validation report.

Since the four IEU-SOL-THERM-001 cases are not included in the criticality safety validation report, SHINE proposes a new Margin of Subcriticality (MOS) of 0.06 to bound expected changes in the USL from the inclusion of these cases.

Therefore, SHINE shall apply a minimum margin of subcriticality of 0.06 to demonstrate that the radioisotope production facility (RPF) is subcritical under normal and credible abnormal conditions. A margin of subcriticality of 0.05 may be applied if it is technically justified in a validation report accepted by the NRC.

In accordance with 10 CFR 50.34(a)(8), SHINE will provide a schedule with milestones to resolve this issue at or before the latest date stated in the application for completion of construction of the facility. Following resolution of this issue, SHINE will provide the NRC-accepted MOS in the Final Safety Analysis Report (FSAR). An IMR has been initiated to track the inclusion of the NRC-accepted MOS in the FSAR.

References

(1) NRC electronic mail to SHINE Medical Technologies, Inc., dated August 26, 2015, Draft Request for Additional Information Supporting SHINE Preliminary Safety Analysis Report (ML15239B051)

(2) NRC electronic mail to SHINE Medical Technologies, Inc., dated August 27, 2015, Draft Request for Additional Information Supporting SHINE Preliminary Safety Analysis Report (ML15244A501)

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(5) SHINE Medical Technologies, Inc. letter to NRC, dated September 2, 2015, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information (ML15247A067)

(6) SHINE Medical Technologies, Inc. letter to NRC, dated July 23, 2015, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information 6b.3-30 (ML15222A231)