

September 24, 2015

Gregory Piefer, Ph.D.
Chief Executive Officer
SHINE Medical Technologies, Inc.
2555 Industrial Drive
Monona, WI 53713

SUBJECT: SHINE MEDICAL TECHNOLOGIES, INC. – REQUEST FOR ADDITIONAL
INFORMATION REGARDING APPLICATION FOR CONSTRUCTION PERMIT
(TAC NOS. MF2305 AND MF2307)

Dear Dr. Piefer:

By letters dated July 23, 2015, and August 7, 2015 (Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML15222A201 and ML15236A127, respectively), SHINE Medical Technologies, Inc. (SHINE) responded to the U.S. Nuclear Regulatory Commission (NRC) staff's March 25, 2015, request for additional information (RAI) (ADAMS Accession No. ML15055A116) to complete the review of SHINE's preliminary safety analysis report (PSAR) supporting a construction permit application.

In the course of reviewing SHINE's RAI responses submitted on July 23, 2015, and August 7, 2015, the NRC staff has determined that additional information is required to complete the review of SHINE's PSAR in order to prepare a safety evaluation report.

This RAI supplements the NRC's previous RAI related to SHINE's construction permit application dated September 19, 2014, January 6, 2015, March 25, 2015, and April 15, 2015 (ADAMS Accession Nos. ML14195A159, ML15005A407, ML15055A116, and ML15099A607, respectively). The specific information requested is addressed in the enclosure to this letter. A draft of this RAI was provided to SHINE via e-mail on August 26, 2015, and August 27, 2015 (ADAMS Accession Nos. ML15239A101 and ML15244A506, respectively), to ensure that the requests are understandable and the regulatory basis is clear. By letters dated September 2, 2015, and September 15, 2015 (ADAMS Accession Nos. ML15247A067 and ML15259A024), SHINE submitted responses to the draft request for information. If information is needed to supplement the September 2, 2015, and September 15, 2015, responses and complete the NRC's review of SHINE's PSAR, additional RAIs will be issued.

G. Piefer

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In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.30(b), SHINE must execute its response in a signed original document under oath or affirmation. SHINE's response must be submitted in accordance with 10 CFR 50.4, "Written communications." Information included in this response that SHINE considers sensitive or proprietary must be marked in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." Any information related to security should be submitted in accordance with 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements."

If you have any questions, please contact Steven Lynch at 301-415-1524, or by e-mail at Steven.Lynch@nrc.gov.

Sincerely,

/RA/

Alexander Adams, Jr., Chief
Research and Test Reactors Licensing Branch
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Docket No. 50-608

Enclosure:
Request for Additional Information

cc: See next page

cc:

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If you have any questions, please contact Steven Lynch at 301-415-1524, or by e-mail at Steven.Lynch@nrc.gov.

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ADAMS Accession No.: ML15259A164

NRR-088

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REQUEST FOR ADDITIONAL INFORMATION

SHINE MEDICAL TECHNOLOGIES, INC.

REGARDING THE PRELIMINARY SAFETY ANALYSIS REPORT

SUPPORTING A CONSTRUCTION PERMIT APPLICATION

DOCKET NO. 50-608

TAC NOS. MF2305 AND MF2307

By letter dated May 31, 2013 (SMT-2013-023, Agencywide Documents Access and Management System (ADAMS) Accession No. ML13172A361), SHINE Medical Technologies, Inc. (SHINE) submitted the second and final part of its two-part application for a construction permit. Part one of SHINE's construction permit application, primarily consisting of SHINE's environmental report, was submitted by letter dated March 26, 2013 (SMT-2013-012, ADAMS Accession No. ML13088A192). By letter dated September 25, 2013 (SMT-2013-033, ADAMS Accession No. ML13269A378), SHINE supplemented this submission with a discussion of preliminary plans for coping with emergencies, as required by Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.34(a)(10), completing its application for a construction permit.

In the course of reviewing SHINE's construction permit application, the U.S. Nuclear Regulatory Commission (NRC) staff has determined that additional information is required to complete the review of the SHINE preliminary safety analysis report (PSAR) submitted on May 31, 2013 (ADAMS Package No. ML13172A324), in support of the development of its safety evaluation report.

By letter dated March 25, 2015 (ADAMS Accession No. ML15055A116), NRC staff issued a request for additional information (RAI). SHINE responded to the NRC staff's request by letters dated July 23, 2015, and August 7, 2015 (ADAMS Accession Nos. ML15222A201 and ML15236A127, respectively).

In the course of reviewing SHINE's RAI responses submitted on July 23, 2015, and August 7, 2015, the NRC staff has determined that additional information is required to complete the review of SHINE's PSAR in order to prepare a safety evaluation report. It is requested that SHINE respond to this request within 30 days of the date of this letter. Timely responses to RAIs contribute toward an efficient and effective review of the submitted application.

The SHINE irradiation facility, including the irradiation units, and radioisotope production facility, as described in the SHINE PSAR, are primarily evaluated using the appropriate 10 CFR regulations, the guidance contained in NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content," issued February 1996 (ADAMS Accession No. ML042430055), and NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria," issued February 1996 (ADAMS Accession No. ML042430048), as well as the "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537,

Part 1, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ADAMS Accession No. ML12156A069), and "Final Interim Staff Guidance [ISG] Augmenting NUREG-1537, Part 2, 'Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria,' for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," dated October 17, 2012 (ADAMS Accession No. ML12156A075). As applicable, additional guidance referenced in NUREG-1537, Parts 1 and 2, as well as the ISG Augmenting NUREG-1537, Parts 1 and 2, has been utilized in the review of the SHINE PSAR.

For the purposes of this review, the term "reactor," as it appears in the relevant guidance listed above, can be interpreted to mean "irradiation unit," "irradiation facility," or "radioisotope production facility," as appropriate. Similarly, for the purposes of this review, the term "reactor fuel," as it appears in the relevant guidance listed above, may be interpreted to mean SHINE's "target solution."

In order to avoid repeating reference numbers for specific information requests, the reference numbers used in this request for additional information are a continuation of the numbering used in the previous RAI issued on March 25, 2015.

This RAI supplements the NRC's previous RAIs related to SHINE's construction permit application dated September 19, 2014, January 6, 2015, March 25, 2015, and April 15, 2015 (ADAMS Accession Nos. ML14195A159, ML15005A407, ML15055A116, and ML15099A607, respectively).

Responses to the following RAIs are needed to continue the review of the SHINE construction permit application.

CHAPTER 6 – ENGINEERED SAFETY FEATURES

The following requests for information are based on a review of Chapter 6 of the SHINE PSAR (ADAMS Accession No. ML15175A213) using NUREG-1537, Parts 1 and 2 in conjunction with the Final ISG Augmenting NUREG-1537, Parts 1 and 2, as supplemented by SHINE's responses to RAIs.

Section 6b.3 – Nuclear Criticality Control

(Applies to RAIs 6b.3-31 through 34)

As required by 10 CFR Section 50.34, "Contents of applications; technical information," paragraph (a) which states, in part, a PSAR 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," which 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."

RAI 6b.3-31 The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, contains criteria for the use of mass, geometry, density, enrichment, reflection, moderation, concentration, interaction, neutron absorbers, and volume as controlled parameters. Additional information is needed in order for NRC staff to determine the adequacy of SHINE's treatment of controlled parameters in order to ensure that all nuclear processes are subcritical, including an adequate margin of subcriticality for safety. Specifically, SHINE's construction permit application does not contain the necessary commitments to following technical practices for the use of each controlled parameter in order to demonstrate a sufficient design basis in its preliminary design.

In order to provide reasonable assurance that SHINE's final design will conform to its design bases with adequate margin for safety, as required by 10 CFR Section 50.34, commit to following technical practices for the use of each controlled parameter described in the ISG Augmenting NUREG-1537, Part 2,

Section 6b.3, "Nuclear Criticality Safety for the Processing Facility," or state that reliance on particular parameters will not be used. For those parameters that are not controlled, commit to assuming the most reactive credible conditions. Additionally, describe any conservatism in the calculated k_{eff} resulting from the use of these technical practices.

RAI 6b3-32 The NRC staff recalculated SHINE's upper safety limit (USL) using the USLSTATS code issued with the SCALE criticality code package. This recalculation produced a lower USL than that determined in Table 8 of SHINE's Validation Report. This difference in USL calculations appears to be the result of SHINE's use of a smaller single-sided lower tolerance limit factor, K^* , and pooled standard deviation, S_t , than those determined by USLSTATS. SHINE's tolerance limits factor is also smaller than the value listed in Table 2.1 of NUREG/CR-6698.

Additional information is needed in order for the NRC staff to determine the adequacy of SHINE's USL calculation to resolve the discrepancy with NRC staff calculations. This information is necessary to demonstrate reasonable assurance that SHINE's final design will conform to its design bases with adequate margin for safety, as required by 10 CFR Section 50.34.

Provide details of the USL calculations in Tables 6, 7, and 8 of SHINE's MNCP 6.1 Validation Report, Rev. 2, including the formulas used and references justifying them.

RAI 6b.3-33 While Table 9, "Area of Applicability Summary," of the SHINE Validation Report, Rev. 2, includes cadmium, this material is not mentioned as present in Table 2, "Critical Benchmark Experiments Summary." Additionally, the discussion of some of the benchmark experiment sets mentions cadmium, but it is not clear if it is present in any of the experiments chosen from those benchmark sets.

Additional information is needed on SHINE's analysis of benchmark experiments in order for the NRC staff to assess the adequacy of SHINE's preliminary design.

Clarify whether the area of applicability in the SHINE Validation Report, Rev. 2, includes cadmium as a neutron absorber.

RAI 6b.3-34 The ISG Augmenting NUREG-1537, Part 2, Section 6b.3, which 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 $k_{eff} \leq 0.95$ (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.