

February 6, 2017

Gregory Piefer, Ph.D.  
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SHINE Medical Technologies, Inc.  
101 E. Milwaukee Street, Suite 600  
Janesville, WI 53545

SUBJECT: SHINE MEDICAL TECHNOLOGIES, INC. – REQUEST FOR ADDITIONAL  
INFORMATION REGARDING SAFEGUARDS INFORMATION PROTECTION  
PROGRAM (TAC NO. MF9090)

Dear Dr. Piefer:

By letter dated December 20, 2016 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML16364A091), SHINE Medical Technologies, Inc. (SHINE) submitted its Safeguards Information (SGI) Protection Program procedures for U.S. Nuclear Regulatory Commission (NRC) review.

In the course of reviewing SHINE's SGI Protection Program procedures, the NRC staff has determined that additional information is required to complete its evaluation. This information is necessary to demonstrate SHINE's compliance with the regulations contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 73, "Physical Protection of Plants and Materials," and 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

The specific information requested is addressed in the enclosure to this letter. A draft of this request for additional information (RAI) was provided to SHINE via e-mail on January 26, 2017, ADAMS Accession No. ML17031A438, to ensure that the request is understandable and the regulatory basis is clear. 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. If information is needed to supplement SHINE's response and complete the NRC's review of SHINE's SGI Protection Program, an additional RAI will be issued.

In accordance with 10 CFR 50.30(b), "Oath or affirmation," 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."

G. Piefer

- 2 -

If you have any questions, please contact Steven Lynch at 301-415-1524, or by e-mail at [Steven.Lynch@nrc.gov](mailto: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:  
As stated

cc: See next page

cc:

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SUBJECT: SHINE MEDICAL TECHNOLOGIES, INC. – REQUEST FOR ADDITIONAL  
INFORMATION REGARDING SAFEGUARDS INFORMATION PROTECTION  
PROGRAM (TAC NO. MF9090) DATED FEBRUARY 6, 2017

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**ADAMS Accession No.: ML17031A443; \*concurrence via e-mail****NRR-088**

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REQUEST FOR ADDITIONAL INFORMATION  
REGARDING THE SAFEGUARDS INFORMATION PROTECTION PROGRAM FOR  
SHINE MEDICAL TECHNOLOGIES, INC.  
DOCKET NO. 50-608  
CONSTRUCTION PERMIT NO. CPMIF-001

The following requests for information are based on the U.S. Nuclear Regulatory Commission (NRC) staff's review of SHINE Medical Technologies, Inc.'s (SHINE's) Safeguards Information (SGI) Protection Program. This information is necessary to demonstrate SHINE's compliance with the regulations contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 73, "Physical Protection of Plants and Materials," and 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." The response to this request will inform the NRC's determination on the effectiveness of SHINE's SGI Protection Program.

**SHINE Procedure 0900-01-08, Revision 0, "Protection of Safeguards Information (SGI)"**

RAI-1      Section 3.3, page 4, of SHINE Procedure 0900-01-08 is missing a description of the individual or individuals responsible for establishing and administering the training that is referenced within this section and other sections of the SHINE SGI Protection Program.

As required by 10 CFR 73.21(a)(1), an SGI program must be established, implemented, and maintained by each licensee who produces, receives, or acquires SGI. This SGI program should include an appropriate training program.

Identify the individual (or individuals) responsible for the establishment, implementation, and maintenance of the SGI training program.

RAI-2      The definition of "material" found in Section 5.10, page 5, of SHINE Procedure 0900-01-08, and used in other sections of SHINE's SGI Protection Program, includes "[a]ny item containing information that is classified as SGI." However, SGI is not a classification type and is considered non-classified information.

As defined in 10 CFR 73.2, SGI means information not classified as National Security Information or Restricted Data.

Use a word other than "classified" in the definition of "material" to avoid confusion with terminology associated with National Security Information or Restricted Data. Appropriate alternatives could include "determined" or "designated."

RAI-3      Section 6.1.2, page 7, of SHINE Procedure 0900-01-08 does not identify the individual or individuals responsible for verifying that an outside organization understands the protection and handling requirements applicable to SGI. However,

Enclosure

Section 6.1.4, page 7, identifies the Safeguard Custodian as responsible for verification.

The requirements of 10 CFR 73.22(b) describe the conditions for access to SGI, including the establishment of a “need to know.” As defined in 10 CFR 73.2, “need to know” means a determination by a person having responsibility for protection SGI that a proposed recipient’s access to SGI is necessary.

Identify the individual (or individuals) responsible for verifying than an outside organization understands the protection and handling requirements applicable to SGI.

- RAI-4 The storage container labels described in Section 6.3.2, page 8, of SHINE Procedure 0900-01-08 and Attachment A, “Security Storage Container Label (Example),” appear to conflict with Section 6.3.1.1, which indicates that there shall be no visible markings or indications that the container houses SGI.

Per 10 CFR 73.22(c)(2), containers shall not identify the contents of the container.

Revise the text of the storage container label shown in Attachment A such that it does not contain the word “safeguard” or otherwise identify the contents of the container.

- RAI-5 Section 6.4.2, page 9, of SHINE Procedure 0900-01-08 provides guidance for completing Form 0900-01-08-02, “Security Storage Container Information.” However, it is unclear whether this form, once completed, will be added to the inventory log. Sections 6.6.1.6 and 6.9.1 of SHINE Procedure 0900-01-08 indicate that any document containing SGI will be marked as SGI and added to the inventory log.

As required by 10 CFR 73.22(c)(2), access to lock combinations must be strictly controlled so as to prevent disclosure to an individual not authorized access to SGI. Further, 10 CFR 50.9(a) requires that information required by statute or by the Commission’s regulations, orders, or license conditions to be maintained by the applicant or licensee shall be complete and accurate in all material respects.

Revise the procedure for completing Form 0900-01-08-02 in Section 6.4.2 to indicate that the form will be added to the SGI inventory log in accordance with Sections 6.6.1.6 and 6.9.1.

- RAI-6 The word “vault,” as used in Sections 6.5.2 and 6.5.3.2, page 10, of SHINE Procedure 0900-01-08, is undefined. It is unclear whether this is an independent term or is intended to be synonymous with the term “security storage container,” as defined in Section 5.16.

The terms “vault” and “security storage container” are defined in 10 CFR 73.2. Further, 10 CFR 50.9(a) requires that information required by statute or by the

Commission's regulations, orders, or license conditions to be maintained by the applicant or licensee shall be complete and accurate in all material respects.

Clarify what is meant by the term "vault." If it is a unique term, provide a definition in the SGI Protection Program that describes what a vault is and how it is used. If a "vault" is synonymous with a "security storage container," correct this terminology to be consistent with defined terms in the regulations and the SHINE SGI Protection Program.

RAI-7 Section 6.10.3, page 16, references a "Section 6.10.1.1," which is not in SHINE Procedure 0900-01-08.

As described in 10 CFR 50.9(a), information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or licensee shall be complete and accurate in all material respects.

Revise this referenced section number to reflect the intended section in the SHINE SGI Protection Program.

**SHINE Procedure 0900-01-09, Revision 0, "Safeguards Information (SGI) Access Authorization"**

RAI-8 SHINE Procedure 0900-01-09 does not address a process for approving an individual whose Federal Bureau of Investigation (FBI) fingerprint criminal history records check contains insufficient information to form a basis for granting access to SGI.

As prescribed by 10 CFR 73.22(b)(2) and 10 CFR 73.57(b)(1), trustworthiness and reliability must be determined based on a background check or other means.

Discuss other means the Reviewing Official will use to determine the trustworthiness and reliability of an individual whose FBI fingerprint criminal history check does not provide sufficient information. These means should assure both the Reviewing Official and the Commission that granting the individual access to SGI does not constitute an unreasonable risk to the public health and safety or the common defense and security.

RAI-9 The definition of "trustworthiness and reliability" provided in Section 5.6, page 6, of SHINE Procedure 0900-01-09 differs from the definition of "trustworthiness and reliability" provided in both 10 CFR 73.2 and SHINE Procedure 0900-01-08.

The term "trustworthiness and reliability" is defined in 10 CFR 73.2. Further, 10 CFR 50.9(a) requires that information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or licensee shall be complete and accurate in all material respects.

Revise the definition “trustworthiness and reliability” such that it is consistent throughout the SHINE SGI Protection Program and with the NRC’s regulations.

- RAI-10 Form 0900-01-09-01 references Public Law 99-399 as the basis for 10 CFR 73.57 as opposed to the Atomic Energy Act of 1954, as amended (AEA).

The requirements of 10 CFR 73.57 comply with Section 652 of the Energy Policy Act of 2005, which amended Section 149 of the AEA. This amendment required fingerprinting and FBI identification and criminal history records checks of individuals permitted unescorted access to a utilization facility.

Revise the statutory citation in Form 0900-01-09-01 to more accurately reflect the legal basis for 10 CFR 73.57.