

## ENCLOSURE 2

### SHINE MEDICAL TECHNOLOGIES, INC.

#### SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT PRELIMINARY SAFETY ANALYSIS REPORT REVISIONS

##### REVISION 1 OF THE SHINE RESPONSE TO RAI 12.1-1 AND RAI 12.2-1

Via Reference (1), SHINE provided a response to RAI 12.1-1 and RAI 12.2-1 (Reference 2), describing the reporting lines and approval authority for the SHINE Review and Audit Committees and the radiation safety function, and details on how the Review and Audit Committees and the radiation safety function interact with facility management.

Based on a review of the management levels described in Section 12.1.1 of the PSAR and Section 6.1.1 of ANSI/ANS-15.1-2007 (Reference 3), SHINE has determined it is appropriate to revise the Plant Manager management level from Level 1 to Level 2, revise the Operations Manager management level from Level 2 to Level 3, and remove management levels from those SHINE management positions outside of plant operations. SHINE has revised Section 2.1 of the SHINE Quality Assurance Program Description (QAPD) to reflect the revised management levels. Revision 7 of the SHINE QAPD is provided as Attachment 1.

Additionally, in order to facilitate a more independent assessment of operations, SHINE has determined it is appropriate for the Chief Operating Officer (COO) to have approval authority for the review and audit committees.

The following information is provided as Revision 1 to the SHINE Response to RAI 12.1-1 and RAI 12.2-1, reflecting the SHINE determinations described above.

#### CHAPTER 12 – CONDUCT OF OPERATIONS

##### **Section 12.1 – Organization**

##### **RAI 12.1-1**

*NUREG-1537, Part 2, Section 12.1, "Organization," Areas of Review, states, in part: "The organization of non-power reactor facilities is discussed in Chapter 14, 'Technical Specifications,' of the format and content guide. Additional details on the areas of review are given in this chapter of the format and content guide."*

*Appendix 14.1 of NUREG-1537, Part 1, Section 6.1.1, "Structure," states: "The information recommended by ANSI/ANS 15.1 should be clearly stated, including how and when the radiation safety staff communicates with the facility manager and level 1 management to resolve safety issues."*

NUREG-1537, Part 1, Section 12.1.1, "Structure," states, in part: "The description of the organizational structure should include the radiation safety function and indicate how the staff implementing that function interacts with the staff responsible for reactor operations and the top administrative officials. The multilevel chart should show the relationship of the review and audit function to the organizational structure. The persons implementing the review and audit function should communicate with the management of the reactor facility but should report to an organizational level above this management to ensure independence of the review and audit function."

The SHINE PSAR provides the functional organization in Figure 12.1-1 (ADAMS Accession No. ML13172A304), and PSAR, Section 12.1, "Structure," states, in part: "The staff implementing the radiation safety function supports on-shift plant operations and interacts with Executive Management through the chain of command." However, the organization chart does not include the review and audit function or the radiation safety function.

- a) Include the review and audit committee and the radiation safety function in the organization chart.
- b) Describe the responsibilities of the review and audit committee and the radiation safety function, including the responsibility for the safe operation of the facility and for the protection of the health and for safety of SHINE staff and the public.

### **SHINE Response**

- a) In accordance with Section 6.2.1 of ANSI/ANS-15.1-2007 (Reference 3), the SHINE Review and Audit Committees will report to the Chief Operating Officer (Level 1 Management), and have communication lines with the Plant Manager (Level 2 Management). In accordance with Section 6.3 of ANSI/ANS-15.1-2007, the SHINE radiation safety function (Radiation Protection Supervisor) will report to the Environmental Safety and Health (ES&H) Manager, and the ES&H Manager will report to the Chief Operating Officer. The Radiation Protection Supervisor has communication lines with the Shift Supervisors (Level 3 Management). Subsection 12.1.2 of the PSAR provides a description of the SHINE management levels.

SHINE has revised Figure 12.1-1 of the PSAR to include the Review and Audit Committees and the radiation safety function, and the appropriate reporting and communication lines, as described above. In addition, SHINE has revised Subsection 12.1.1 and Section 12.2 of the PSAR to reflect the updated reporting and communication lines for the Review and Audit Committees and radiation safety function. A mark-up of the PSAR changes is provided in Attachment 2. The non-public (proprietary) version of the PSAR, incorporating the changes provided in Attachment 2, is provided in Enclosure 3. The public (non-proprietary) version of the PSAR, incorporating the changes provided in Attachment 2, is provided in Enclosure 4.

- b) Responsibility for the safe operation of the SHINE facility shall be with the chain of command established in the SHINE functional organization chart. Individuals at the various management levels, in addition to having responsibility for the policies and operation of the SHINE facility, shall be responsible for safeguarding the public and facility personnel from undue radiation exposures and for adhering to all requirements of the operating license and technical specifications.

In accordance with Section 6.2 of ANSI/ANS-15.1-2007 (Reference 3), the SHINE Review and Audit Committees are responsible for the independent review and audit of the safety aspects of the SHINE facility operations, as described in Section 12.2 of the PSAR.

In accordance with Section 6.3 of ANSI/ANS-15.1-2007, the SHINE radiation safety function (Radiation Protection Supervisor) is assigned responsibility for implementing the Radiation Protection Program. The SHINE Radiation Protection Program is described in Subsection 11.1.2 of the PSAR.

SHINE has revised Subsection 12.1.2 of the PSAR to incorporate the responsibilities described above (Reference 4).

## **Section 12.2 – Review and Audit Activities**

### **RAI 12.2-1**

*NUREG-1537, Part 1, Section 12.2, “Review and Audit Activities,” states, in part, “[t]he applicant should explicitly state who holds the approval authority [committee or facility manager] and should specify the committee’s authority and how it communicates and interacts with facility management and...corporate management.”*

*SHINE PSAR, Section 12.2, “Review and Audit Activities,” states: “The PM establishes review and audit committees and ensures that the appropriate technical expertise is available for review and audit activities. These activities are summarized and reported to Executive Management. Independent audits of the SHINE facility are conducted periodically.” However, approval authority is not addressed. Therefore, additional information is needed from the applicant.*

- a) *State who holds approval authority.*
- b) *Provide additional detail on how the review and audit committees interact with management.*

### **SHINE Response**

- a) The Chief Operating Officer (COO) holds approval authority for review and audit activities. SHINE has revised Figure 12.1-1 and Section 12.2 of the PSAR to specify this approval authority. A mark-up of the PSAR changes is provided in Attachment 2. The non-public (proprietary) version of the PSAR, incorporating the changes provided in Attachment 2, is provided in Enclosure 3. The public (non-proprietary) version of the PSAR, incorporating the changes provided in Attachment 2, is provided in Enclosure 4.
- b) The review and audit committees will interact with facility management through the dissemination of meeting minutes and meeting reports. In accordance with Section 6.2.3 of ANSI/ANS-15.1-2007 (Reference 3), SHINE will submit a written report or minutes of the findings and recommendations of the review group to Level 1 management and the review and audit group members in a timely manner after the review has been completed. In accordance with Section 6.2.4 of ANSI/ANS-15.1-2007, SHINE will immediately report deficiencies uncovered that affect nuclear safety to Level 1 management. SHINE will also submit a written report of the findings of the audit to Level 1 management and the review and audit group members within three months after the audit has been complete.

SHINE has revised Section 12.2 of the PSAR to incorporate the above details of how the review and audit committees interact with facility management (Reference 4).

## **References**

- (1) SHINE Medical Technologies, Inc. letter to NRC, dated October 15, 2014, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information (ML14296A189)
- (2) NRC letter to SHINE Medical Technologies, Inc., dated September 19, 2014, SHINE Medical Technologies, Inc. – Request for Additional Information Regarding Application for Construction Permit (TAC Nos. MF2305, MF2307, and MF2308) (ML14195A159)
- (3) American National Standards Institute/American Nuclear Society, “The Development of Technical Specifications for Research Reactors,” ANSI/ANS-15.1-2007, La Grange Park, IL
- (4) SHINE Medical Technologies, Inc. letter to NRC, dated May 21, 2015, SHINE Medical Technologies, Inc. Preliminary Safety Analysis Report Revisions Resulting from Request for Additional Information Responses (ML15161A336)