

**ENCLOSURE 2  
ATTACHMENT 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**

**PRELIMINARY SAFETY ANALYSIS REPORT CHANGES  
(MARK-UP)**

## CHAPTER 12

### CONDUCT OF OPERATIONS

#### 12.1 ORGANIZATION

This section describes the SHINE Medical Technologies, Inc. (SHINE) organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying the organizational structure. The organizational structure includes internal and external functions for SHINE including interface responsibilities for multiple organizations. Management gives careful consideration to the timing, extent, and effects of organizational structure changes. The organizational structure facilitates the execution of the conduct of operations (ConOps) program. ConOps is a philosophy of working in a formalized, disciplined manner to achieve operational excellence. The ConOps program emphasizes safety in every aspect of plant operations. The organizational aspects of the radiation protection (RP) program, the production facility safety program, staffing, and selection and training of personnel will also be discussed in this section.

##### 12.1.1 STRUCTURE

The organizational structure for the management and operation of the SHINE facility is provided in Figure 12.1-1. SHINE management levels are described as follows:

- Level 1: Individual responsible for the medical isotope facility license.
- Level 2: Individual responsible for the facility operation.
- Level 3: Individual responsible for day-to-day operation or shift.
- Level 4: Operating staff.

Plant Operators (Level 4) report directly to the Shift Supervisors (Level 3). The RP Supervisor reports directly to the Environment, Safety, and Health (ES&H) Manager (~~Level 2~~) and has communication lines with the Shift Supervisors. The Shift Supervisors report directly to the Operations Manager (Level ~~2~~3). The Operations Manager reports to the Plant Manager (Level 2). The ES&H Manager reports to the Chief Operating Officer (Level 1). The Review/Audit Committees reports to the ~~Plant Manager (Level 1)~~Chief Operating Officer and ~~has have~~ communication lines with the ~~Operations Plant~~ Manager. ~~The ES&H Manager and Operations Manager report to the Plant Manager.~~The Plant Manager reports to the Chief Operating Officer (~~Level 1~~).

##### 12.1.2 RESPONSIBILITY

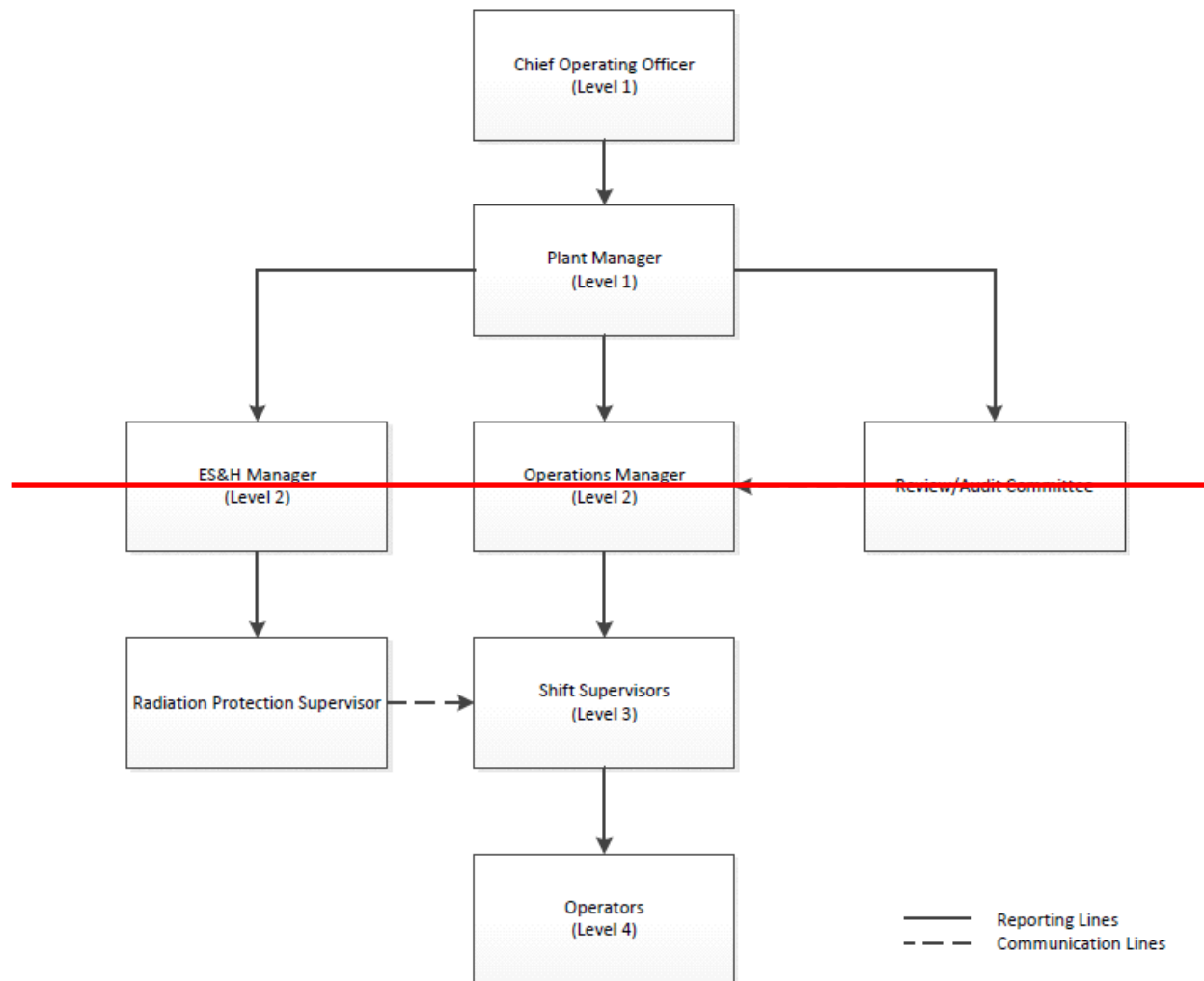
###### 12.1.2.1 SHINE MEDICAL TECHNOLOGIES, INC.

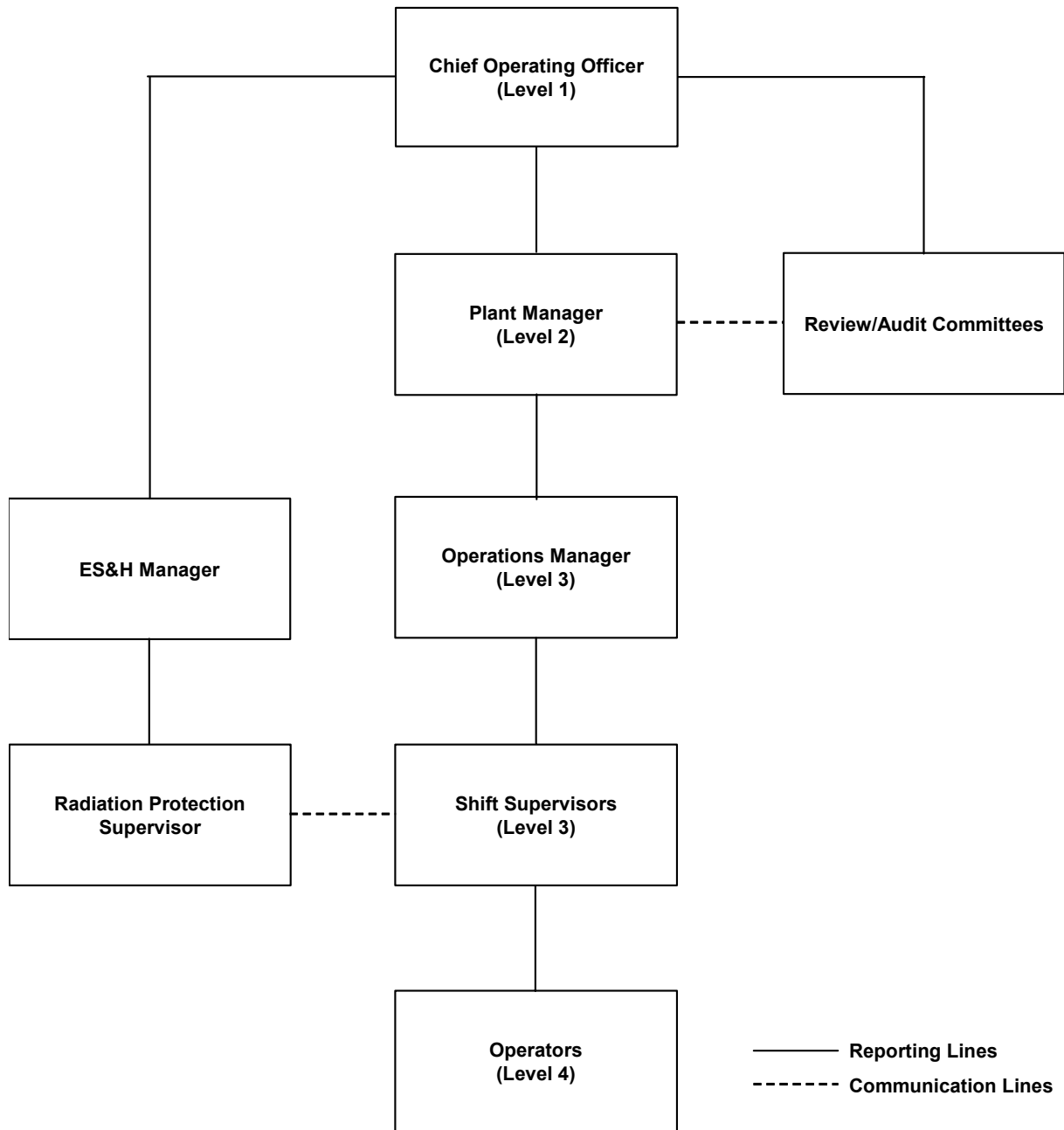
SHINE Medical Technologies, Inc. is the entity with legal responsibility for holding the Construction Permit and the facility Operating License.

###### 12.1.2.2 CHIEF EXECUTIVE OFFICER

The CEO is responsible for the overall management and leadership of the company. The CEO provides direction to the COO and reports to the Board of Directors.

Figure 12.1-1 – SHINE Operational Organization Chart





## 12.2 REVIEW AND AUDIT ACTIVITIES

The PMCOO establishes review and audit committees and ensures that the appropriate technical expertise is available for review and audit activities. The PMCOO holds approval authority for review and audit activities. Independent audits of the SHINE facility are conducted periodically.

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 (ANSI/ANS, 2007), 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 completed.

### 12.2.1 COMPOSITION AND QUALIFICATIONS

Audit and review committees with the appropriate expertise and experience are established and members, designated by the PMCOO, provide the SHINE Management an independent assessment of the operation. The minimum number of committee members, qualification of committee members, and the potential use of members from outside the organization will be discussed in the FSAR.

### 12.2.2 CHARTER AND RULES

The charter and rules of the review and audit committees will be developed for the FSAR. The charter for the committees will address the required meeting interval (at least one per year), quorum required for meetings (not less than one-half the committee membership), issuance of meeting minutes, and voting methods.

### 12.2.3 REVIEW FUNCTION

At a minimum, the following items shall be reviewed:

- Determinations that proposed changes in equipment, systems, test, experiments, or procedures are allowed without prior authorization by the responsible authority.
- All new procedures and major revisions thereto having safety significance, proposed changes in production facility equipment, or systems having safety significance.
- All new experiments or classes of experiments that could affect reactivity or result in the release of radioactivity.
- Proposed changes in technical specifications or license.
- Violations of technical specifications or license. Violations of internal procedures or instructions having safety significance.