

**SMT-2012-021**  
**June 8, 2012**

**Enclosure 2**

**SHINE Medical Technologies, Inc. Redacted Responses  
to Requested Information**

The U.S. Nuclear Regulatory Commission (NRC) staff is projecting future resource needs for evaluating applications for the licensing of medical isotope production facilities (both reactor and production facilities). To be prepared for the timely review of applications the NRC staff needs accurate information regarding your plans. If you intend to submit an application for a medical isotope facility, please provide the following information:

- Whether you intend to submit a two-step application (construction permit application and operating license application) or a single application under provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Section 2.105(c).

**Response:** SHINE intends to submit a two-step application for the medical radioisotope facility, one for a construction permit and the second for an operating license.

- Whether you intend to submit your environmental report with a construction permit application or if it will be filed separately within the six month window allowed by 10 CFR 2.101(a-1)(1).

**Response:** SHINE currently intends to utilize a bifurcated submittal approach under 10 CFR 2.101(a)(5), if that provides a docketing date advantage. Pursuant to 10 CFR 2.101(a)(5), SHINE would submit the Environmental Report, which will be considered as an Appendix to Preliminary Safety Analysis Report (PSAR) Chapter 12, per the draft Interim Staff Guidance for NUREG-1537, initially, and then plan to complete the remainder of the PSAR submittal within the next six months from Environmental Report submittal date. SHINE will only use the bifurcated submittal process, however, if there is some advantage to obtaining an early docketing date and Environmental Report review based on early submittal of the Environmental Report.

If instead, SHINE is required to submit all of the information specified in 10 CFR 2.101(a)(5) related to 10 CFR 50.34(a)(1) (which appears to include most if not all of the information required by a complete PSAR), SHINE may instead choose to submit the entire PSAR in a single filing.

- The expected submittal dates for each of the above documents.

**Response:** [Proprietary information – withheld from public disclosure per 10 CFR 2.390]

- Any significant assumptions (e.g., successful placement of external funding or board of directors approval) that submission of an application is dependent upon.

**Response:** [Proprietary information – withheld from public disclosure per 10 CFR 2.390]