SHINE
Medical Technologies

July 10, 2012

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U.S. Nuclear Regulatory Commission
Washington, DC 20555-001

**SHINE Medical Technologies, Inc.**
**Project 0792**
**SMT-2012-0023**

**Subject: Request for Regulatory Interpretations regarding 10 CFR 2.101 and Environmental Report Submittal**

The purpose of this letter is to provide follow-up to the June 21, 2012 public meeting between SHINE Medical Technologies, Inc. (SHINE) and the Nuclear Regulatory Commission (NRC) staff. This letter is to request regulatory interpretations regarding the regulatory process for submitting a construction permit application in multiple parts as described in 10 CFR 2.101(a)(5). SHINE requests the staff provides responses for the requests by the dates requested in order to minimize any regulatory uncertainly or unpredictability in the license application process.

**Regulatory Interpretation Requests:**

**Request No. 1**

**10 CFR 2.101(a)(5) – Verification of SHINE position regarding two part construction permit submittal**

It is clear that 10 CFR 2.101(a)(5) provides a path for an applicant for a construction permit under 10 CFR 50 to do so in two parts if certain criteria are satisfied. We wish to verify that SHINE in fact meets those criteria and is able to submit the construction permit in two parts.

One possible interpretation of the eighth sentence of 10 CFR 2.101(a)(5) is that the two part filing is only available to *"a production or utilization facility which is subject to § 51.20(b)"*. However, not all production or utilization applicants necessarily need an Environmental Impact Statement (EIS) or an EIS supplement, as discussed in § 51.20(b), based on their respective environmental reports. For example, most research reactors do not require an EIS and are evaluated through an Environmental Assessment process. The determination of need for an EIS or and EA occurs after the applicant's environmental report is submitted, accepted and docketed and reviewed by the staff.

8123 Forsythia St, Suite 140 · Middleton, WI · 53562 · (877) 512-6554 · (608) 831-8110 fax
www.shinemed.com

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SHINE believes the intent of the statement is to provide identification of entities that can use a two part submittal process, but the language does not prohibit others from following the same process. The SHINE facility will be licensed as one specified in § 50.22 which will satisfy the additional criteria in the first sentence. SHINE requests the NRC staff provide clarification that if an EIS or EIS supplement is not required under § 51.20(b), then an applicant filing under part 50 may still submit an application in two parts, subject to satisfying the remainder of the criteria in the first sentence in § 2.101(a)(5) and the respective Office Director will be able to accept and docket an application for a construction permit submitted under part 50.

As the regulatory interpretation results are integral to the SHINE construction permit submittal and internal schedule, SHINE requests the staff make a timely determination of this regulatory request and provide a response to SHINE by July 27, 2012.

**Request No. 2**

**10 CFR 2.101(a)(5) – Verification of SHINE position regarding scope of initial filing**

The second sentence of 10 CFR 2.101(a)(5) provides the requirements for the contents of a two part submittal, with one part consisting of the information required by § 50.30(f) (Environmental Report) (ER) and the other consisting of information required by § 50.34(a) (Preliminary Safety Analysis Report) (PSAR), and if applicable, by § 50.34a (Design objectives for equipment to control releases of radioactive material in effluents – nuclear power reactors). As SHINE has previously informed the NRC staff, it currently plans to use the two part submittal process and file its ER first, followed several months thereafter by its PSAR. We wish to confirm with the staff that this approach complies with the relevant regulations. One reading of 10 CFR 2.101(a)(5) and particularly the seventh sentence of that part, is that all information required by § 50.34(a)(1)(i) may also need to be filed with the first part of the two-part application. The last sentence in § 50.34(a)(1)(i) identifies paragraphs (a)(2) through (a)(8) as needing to be included to support the application for a construction permit. However, SHINE does not believe the regulation at § 50.34(a)(1), which directs the applicant to § 50.34(a)(1)(i), includes the referenced paragraphs (a)(2) through (a)(8) when viewed in the context of a two part submittal. Since paragraphs (a)(2) through (a)(8) contain the requirements for the complete contents of a PSAR for a non-stationary power reactor, that interpretation would result in a complete PSAR having to be submitted at the time part 1 is submitted, even if part 1 was the ER, which would negate the benefit of having the opportunity for a two part construction permit submittal.

SHINE requests the staff review and provide concurrence with the interpretation that the information in paragraphs (a)(2) through (a)(8) identified in § 50.34(a)(1)(i) are not required to be submitted in a two part submittal when part 1 of the submittal is the ER and that the information needed to support the description and safety assessment of the site is adequately addressed in NUREG-1537 and its associated Interim Staff Guidance for non-power reactors. Although the SHINE technology is not reactor-based, NUREG-1537 and its associated Interim Staff Guidance will be the regulatory framework SHINE will use for license application guidance and structure.

As the regulatory interpretation results are integral to the SHINE construction permit submittal and internal schedule, SHINE requests the staff make a timely determination of this regulatory request and provide a response to SHINE by July 27, 2012.

If you have any questions regarding this letter, please contact Mr. Jim Freels, Licensing Project Manager, at 865.719.5061.

Sincerely,

R. V. Bynum

R. Vann Bynum, PhD
Chief Operating Officer
SHINE Medical Technologies, Inc.

cc:

Mr. Charles A. Castro
Regional Administrator
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road Suite 210
Lisle, IL 60532-4352

Mr. Steve Lynch
General Engineer
Mail Stop 12 D20
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Ms. Cheryl Rogers
Supervisor, Radioactive Materials Programs
Wisconsin Division of Public Health
P.O. Box 2659
Madison, WI 53701-2659