

June 6, 2011

Dr. Gregory Piefer, PhD
CEO - SHINE Medical Technologies, Inc.
8123 Forsythia Street Suite 140
Madison, WI 53562

SUBJECT: PROJECT NO. 0792, SHINE UPDATED REQUEST FOR REGULATORY INTERPRETATIONS AND REQUEST FOR ADDITIONAL INFORMATION CONCERNING RESTRICTED DATA

Dear Dr. Piefer:

Through this correspondence, we acknowledge receipt of your letter, dated May 3, 2011, requesting U.S. Nuclear Regulatory Commission (NRC) Staff to review and interpret certain regulatory issues. The issues in your previous letter dated February 14, 2011, were discussed at a public meeting at NRC on March 7, 2011, during which you provided an introduction to SHINE's proposed technology and facility and discussed several regulatory issues. Your May 3, 2011, letter withdrew several of the original questions included in your February 14, 2011, letter; retained two of the original questions about restricted data and agreement state interactions; and added two new questions about two-part licensing and accident analysis guidance.

In your February 14, 2011, letter, you asked whether or not data related to the SHINE process should be classified as Restricted Data (RD), as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) 50.2 and 70.4. The Department of Energy (DOE) is responsible for RD-related classification decisions. DOE has requested, in an enclosure to this letter, additional information about SHINE's process. Prior to submittal, SHINE should mark the responses appropriately using information security procedures. The NRC may withhold your response from public disclosure in accordance with 10 CFR 2.390(d).

You also requested the assignment of a project number for review and licensing of the SHINE project. We have assigned Project No. 0792 to SHINE pre-licensing activities. In accordance with 10 CFR 170, SHINE will be billed for NRC staff's hours applied to this project number beginning in the current fiscal quarter. After you submit a license application, NRC will assign a docket number and technical assignment control (TAC) numbers to licensing tasks, and you will be billed for NRC staff's hours applied to those TAC numbers in accordance with 10 CFR 170. After a license is issued, you may be billed an annual fee in accordance with 10 CFR 171.

Since your May 3, 2011, letter was more closely related to the Part 50 licensing process than to the Part 70 licensing process, indicating that SHINE may be more likely to apply for a license under Part 50, we request that you address future correspondence related to a potential Part 50 license to Timothy McGinty, Director, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation, (NRR) Mail Stop O-12-E-1. NRR will coordinate communications with the Office of Nuclear Material Safety and Safeguards as necessary.

In accordance with 10 CFR, Section 2.390 of the NRC's "Rules of Practice," a copy of this letter and the enclosure will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records Systems component of the NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

If you have questions about this letter, please contact Mary Adams at 301-492-3113 or via e-mail to Mary.Adams@nrc.gov. For any other question please contact Marcus Voth at 301-415-1210 or at Marcus.Voth@nrc.gov or Ossy Font at 301-415-2490 or at Ossy.Font@nrc.gov.

Sincerely,

/RA/

Dennis Morey, Acting Chief
Conversion, Deconversion
and Enrichment Branch
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

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If you have questions about this letter, please contact Mary Adams at 301-492-3113 or via e-mail to Mary.Adams@nrc.gov. For any other question please contact Marcus Voth at 301-415-1210 or at Marcus.Voth@nrc.gov or Ossy Font at 301-415-2490 or at Ossy.Font@nrc.gov

Sincerely,

/RA/

Dennis Morey, Acting Chief
Conversion, Deconversion
and Enrichment Branch
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

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OFFICE	NMSS/FCSS	NMSS/FCSS	NMSS/FCSS	NMSS/FCSS
NAME	MAdams	LAllen	DMorey	PSilva by email
DATE	05/19/2011	05/19/2011	06/06/2011	06/06/2011

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**REQUEST FOR ADDITIONAL INFORMATION
SHINE MEDICAL ISOTOPES**

To enable the U.S. Nuclear Regulatory Commission (NRC) to make an informed determination of the classification of the information, provide the following:

1. A detailed description of the process and equipment which you will be using to make the Mo-99, and that will produce the plutonium. This description should include any information that will allow NRC to determine if your process is a new or novel approach to making plutonium.
2. We would also need accurate projections of the amounts of materials that will be produced in the process. This should include all fission and activation products, including waste stream amounts. How much plutonium and other fission and activation products will be produced per amount of feed material used? How much feed material will be used per batch and per year?