



July 24, 2012

ATTN: Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555-001

SHINE Medical Technologies, Inc.
SMT-2012-025
Project No. 0792

Subject: Request to Withhold Information from Public Disclosure

A pre-application meeting is scheduled for August 7, 2012 between SHINE Medical Technologies, Inc. (SHINE) and the U.S. Nuclear Regulatory Commission (NRC) to discuss the process chemistry to be employed by SHINE in the production of medical radioisotopes. The purpose of this letter is to request that certain portions of the SHINE presentation materials to be used at this meeting be withheld from public disclosure in accordance with 10 CFR 2.390.

Enclosure 1 provides the slides to be used in the closed portion of the meeting and contain proprietary information held in confidence by SHINE. SHINE requests that the NRC withhold this information from public disclosure in accordance with the requirements of 10 CFR 2.390(a)(4). Enclosure 2 provides the redacted version of the closed meeting presentation slides.

Enclosure 3 contains an appropriate affidavit supporting proprietary treatment of SHINE confidential proprietary information pursuant to 10 CFR 2.390.

There are no new regulatory commitments in this letter.

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

Sincerely,

A handwritten signature in blue ink that reads "R. V. Bynum".

Richard Vann Bynum, PhD
Chief Operations Officer
SHINE Medical Technologies, Inc.
Enclosures: As stated

Y GDI
NRR

cc: (without Enclosures)

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

Mr. Steven Lynch
General Engineer
Mail Stop 12D20
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

Enclosure 3
Affidavit of Dr. Richard Vann Bynum



AFFIDAVIT OF RICHARD VANN BYNUM

STATE OF WISCONSIN)
) ss.
COUNTY OF DANE)

I, Richard Vann Bynum, Chief Operating Officer of SHINE Medical Technologies, Inc. (SHINE), do hereby affirm and state:

1. I am authorized to execute this affidavit on behalf of SHINE. I am authorized to review information submitted to or discussed with the Nuclear Regulatory Commission ("NRC") and apply for the withholding of information from disclosure. I am making this affidavit in conformance with the provisions of the NRC's regulations at 10 CFR 2.390 and in support of SHINE's request for proprietary treatment of certain confidential commercial information to be discussed during the non-public portion of the SHINE meeting with the NRC on August 7, 2012.

2. I have knowledge of the criteria used by SHINE in designating information as sensitive, proprietary, or confidential.

3. Pursuant to the provisions of paragraphs (a)(3) and (a)(4) of 10 CFR 2.390, the following is furnished for consideration by the NRC in determining whether the information sought to be withheld from public disclosure should be withheld.

- a. The information sought to be withheld from public disclosure at the referenced non-public meeting with the NRC is owned by SHINE, its affiliates or third parties to who SHINE has an obligation to maintain its confidentiality and has been held in confidence by SHINE.
- b. The information sought to be protected is not available to the public to the best of my knowledge and belief.
- c. The information is of the type that would customarily be held in confidence by SHINE. The information that SHINE is requesting to be withheld from public disclosure includes trade secret, confidential financial information, commercial information or information that is subject to export controls. SHINE limits access to these elements to those with a "need to know" subject to maintaining confidentiality.

Public disclosure of these elements is likely to harm SHINE because it would allow others to understand SHINE's competitive expectations, assumptions, processes and current position.

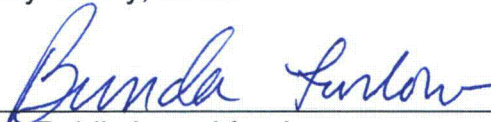
- d. The proprietary information sought to be withheld from public disclosure at the non-public portion of the referenced meeting is radioisotope production technology including modifications to the cintichem process that are unique to SHINE.
- e. The information is transmitted to the NRC in confidence and under the provisions of 10 CFR 2.390; it is to be received in confidence by the NRC.



Richard Vann Bynum, PhD
COO – SHINE Medical Technologies, Inc.

Date: 7/24/12

Subscribed and sworn to before me, a Notary Public, in and for the county and state above named, this 24th day of July, 2012.



Notary Public in and for the
State of Wisconsin

My Commission expires is permanent

Enclosure 2
Closed Meeting Slides (Redacted)



LEU Modified Cintichem Process

Peter Tkac

Argonne National Laboratory

Chemical Sciences and Engineering Division

History - HEU Cintichem Process

- Union Carbide developed a process to produce and separate useful isotopes like Mo-99 from mixed fission products that resulted from the irradiation of highly enriched uranium (HEU) targets at the Cintichem facility, NY
- The Cintichem process originally used 93% high enriched U-235 deposited as UO_2 on the inside of a cylindrical target
- 1974 Patent No. 3799883 (filed in June 1971) describes the original Cintichem process
- The Cintichem process was licensed by NRC
- The research facility was later sold to Hoffman-LaRoche and became Cintichem Inc
- In 1980, Cintichem, Inc. began the production/isolation of Mo-99 in its reactor, and became the single U.S. producer of Mo-99 during the 1980s (~2000 6-day Curies)
- In 1989, underground leak of radioactive products led to the reactor shutdown and an end to the commercial production of Mo-99 in the USA
- US DOE has proprietary rights for the Cintichem process



History - LEU Modified Cintichem Process (BATAN)

- 1986 – R&D begun on modification of the Cintichem processing for LEU targets
- 1992 – BATAN (Indonesian BAdan Tenaga Atom Nasional) and ANL begin joint research in production of Mo-99 from LEU foil target
 - Separation process is based on the modified Cintichem process
 - Dissolution of U foil in HNO_3 instead of H_2SO_4
 - Modified Cintichem process replaces sulfuric acid with nitric acid
- 1995- BATAN describes bench-scale demonstration of ANL-modified Cintichem process for LEU-foil targets, BATAN uses Cintichem process under a licensing agreement
- 1996- University of Illinois and ANL performed tracer-level experiments of LEU-modified Cintichem process
- 1998- 2010 FULL-SCALE DEMONSTRATION >10 processing of irradiated LEU-foil targets in Indonesia using LEU-modified Cintichem process



LEU-Foil Processing at PUSPIPTEK May 2005

