SHINE™
Medical Technologies

THIS LETTER CONTAINS ~~PROPRIETARY INFORMATION~~
IN ACCORDANCE WITH 10 CFR 2.390

June 16, 2015

SMT-2015-031
10 CFR 50.30

50-608

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

References: (1) SHINE Medical Technologies, Inc. letter to NRC, dated March 26, 2013, Part One of the SHINE Medical Technologies, Inc. Application for Construction Permit (ML130880226)
(2) SHINE Medical Technologies, Inc. letter to NRC, dated May 31, 2013, Part Two of the SHINE Medical Technologies, Inc. Application for Construction Permit (ML13172A324)

SHINE Medical Technologies, Inc. Application for Construction Permit
Revision to Sections 13b.3 and 19.4 of the Preliminary Safety Analysis Report

Pursuant to 10 CFR 50.30, SHINE Medical Technologies, Inc. (SHINE) submitted an application for a construction permit to construct a medical isotope facility to be located in Janesville, WI (References 1 and 2). During a review of the Preliminary Safety Analysis Report (PSAR), SHINE determined that Subsection 13b.3.2 and Subsection 19.4.11.2.13 should be revised to ensure consistency with the SHINE hazardous chemical dispersion analysis.

Enclosure 1 provides an evaluation of the revision to Subsections 13b.3.2 and 19.4.11.2.13 of the PSAR.

Enclosure 2 provides a non-public (proprietary) revision to the SHINE PSAR, incorporating the changes summarized in Enclosure 1. Enclosure 2 is being provided via optical storage media (OSM) as OSM#1. In addition to proprietary information, Enclosure 2 contains security-related information which was identified utilizing the guidance contained in Regulatory Information Summary (RIS) 2005-31. SHINE requests that the NRC withhold Enclosure 2 from public disclosure under 10 CFR 2.390.

Enclosure 3 provides a public (non-proprietary) revision to the SHINE PSAR, incorporating the changes summarized in Enclosure 1. Enclosure 3 is provided via OSM as OSM#2.

Enclosure 2 contains both ~~proprietary and security-related information~~.
Withhold from public disclosure under 10 CFR 2.390.
Upon removal of Enclosure 2, this letter is uncontrolled.

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NRR

THIS LETTER CONTAINS ~~PROPRIETARY INFORMATION~~
IN ACCORDANCE WITH 10 CFR 2.390

Enclosure 4 provides an affidavit supporting the proprietary treatment of the SHINE proprietary information pursuant to 10 CFR 2.390. Enclosure 2 contains information proprietary to SHINE. Upon removal of Enclosure 2, this letter is uncontrolled.

If you have any questions, please contact Mr. Jim Costedio, Licensing Manager, at 608/210-1730.

I declare under the penalty of perjury that the foregoing is true and correct. Executed on June 16, 2015.

Very truly yours,

R. Vann Bynum, Ph.D.
Chief Operating Officer
SHINE Medical Technologies, Inc.
Docket No. 50-608

Enclosures

cc: Administrator, Region III, USNRC
Project Manager, USNRC
Environmental Project Manager, USNRC
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health
(w/o Enclosure 2)

Enclosure 2 contains both ~~proprietary and security-related information~~.
Withhold from public disclosure under 10 CFR 2.390.
Upon removal of Enclosure 2, this letter is uncontrolled.

ENCLOSURE 1

SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT REVISION TO SECTIONS 13B.3 AND 19.4 OF THE PRELIMINARY SAFETY ANALYSIS REPORT

EVALUATION OF THE REVISION TO SUBSECTIONS 13B.3.2.3 AND 19.4.11.2.13 OF THE PSAR

Subsection 13b.3.2 and Subsection 19.4.11.2.13 of the Preliminary Analysis Report (PSAR) provide descriptions of the hazardous chemical dispersion analysis for the SHINE facility that require change. The differences between the PSAR descriptions of the analysis and the approved analysis performed using Emergency Prediction Information code (EPICode) are summarized below:

	PSAR Description (Subsection 13b.3.2 and Subsection 19.4.11.2.13)	**SHINE Hazardous Chemical Dispersion Analysis**
Atmospheric Stability	"Stable" (Stability Class F)	"Neutral" (Stability Class D)
Wind Speed	1 m/s (3.3 ft/s)	4.1 m/s (13.5 ft/s)
Deposition Velocity	1 m/s (3.3 ft/s)	0 m/s (No Deposition)(1)
Liquid Chemical Evaporation Time	The entire inventory of liquid hazardous chemicals will evaporate within one hour. (Subsection 19.4.11.2.13)	The inventory of liquid hazardous chemicals evaporates from a 100 ft^2 pool, over a time calculated by EPICode.

(1) Conservative, since no material is assumed to settle from the plume prior to reaching the receptor.

The meteorological conditions (atmospheric stability and wind speed) assumed in the SHINE hazardous chemical dispersion analysis represent 50th percentile conditions at the SHINE site. Solid powder material release durations were assumed to be one hour in the hazardous chemical dispersion analysis, corresponding to Emergency Response Planning Guideline (ERPG) exposure times.

Additionally, as described in the SHINE Response to RAI 13b.1-1 (Reference 1), accidents and associated controls related to normal chemical hazards, and not to hazardous chemicals associated with, produced from, or affecting the safety of licensed materials, have been removed from Chapter 13 of the PSAR. The revision to the description of the hazardous chemical dispersion analysis provided in Chapter 13, described in the SHINE Response to RAI 13b.1-1, is also applicable to Subsection 19.4.11.2.13 and Table 19.4.11-1 of the PSAR.

While reviewing the PSAR against the hazardous chemical dispersion analysis for the SHINE facility, SHINE also identified the following administrative errors in the PSAR:

- The Source Term for Potassium Permanganate is listed as 0.001 lbs in Tables 13b.3-2 and 19.4.11-1 of the PSAR, but was assumed to be 0.066 lbs in the hazardous chemical dispersion analysis. The resulting concentrations previously provided in Tables 13b.3-2 and 19.4.11-1 reflect the 0.066 lbs source term; therefore, the resulting concentrations do not require revision.

- The Worker Concentration for Uranyl Nitrate is listed as 0.024 mg/m^3 in Table 13b.3-2, but was calculated to be 0.13 mg/m^3 in the hazardous chemical dispersion analysis. Though higher, the Worker Concentration was still calculated to be below the PAC-1 value of 0.99 mg/m^3 for Uranyl Nitrate.
- The distance to the site boundary was described as 402 m in Subsection 19.4.11.2.13 and Table 19.4.11-1; however, the hazardous chemical dispersion analysis uses a distance of 249 m from the assumed release point to the maximally exposed off-site individual. The resulting concentrations previously provided in Table 19.4.11-1 reflect a distance of 249 m to the site boundary; therefore, the resulting concentrations do not require revision.

The SHINE hazardous chemical dispersion analysis was performed using more realistic conditions than previously described in Subsection 13b.3.2 and Subsection 19.4.11.2.13, and this analysis contains the following conservatisms:

- The receptors are assumed to be located at the plume centerline;
- Releases are assumed to be non-buoyant;
- No deposition of material is assumed;
- Evaporation from a 100 ft^2 area for liquid releases is conservative, since this value is expected to bound chemical storage areas in the facility;
- The maximally exposed off-site individual is assumed to be located at the nearest site boundary;
- The material at risk is taken to be the bounding inventory used with licensed material at the site;
- The airborne fraction, the product of the airborne release fraction times the respirable fraction, is assumed to be 1.0 for evaporating liquids;
- The damage ratio, representing the fraction of the inventory impacted, is assumed to be 1.0, meaning that all available material is involved in the event; and
- A leak path factor (LPF) of 1.0 is assumed for releases, except for nitric acid and dodecane. For nitric acid and dodecane, an LPF of 0.1 was assumed, corresponding to the most conservative LPF used for the bubble-tight isolation dampers.

SHINE has revised Subsection 13b.3.2 and Subsection 19.4.11.2.13 of the PSAR to address the items described above. A mark-up of the PSAR changes is provided in Attachment 1. The non-public (proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 2. The public (non-proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 3.

The revised Subsection 13b.3.2 and Subsection 19.4.11.2.13, describing the SHINE hazardous chemical dispersion analysis, provide a conservative estimate of the potential consequences to the worker and the public in accordance with Part 1 of the Interim Staff Guidance (ISG) augmenting NUREG-1537 (Reference 2).

References

(1) SHINE Medical Technologies, Inc. letter to NRC, dated December 3, 2014, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information (ML14356A527)

(2) U.S. Nuclear Regulatory Commission, "FINAL Interim Staff Guidance Augmenting NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content," for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors," October 17, 2012 (ML12156A069)

ENCLOSURE 1
ATTACHMENT 1

SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT REVISION TO SECTIONS 13B.3 AND 19.4 OF THE PRELIMINARY SAFETY ANALYSIS REPORT

EVALUATION OF THE REVISION TO SUBSECTIONS 13B.3.2.3 AND 19.4.11.2.13 OF THE PSAR

PRELIMINARY SAFETY ANALYSIS REPORT CHANGES (MARK-UP)

6 pages follow

transported outside of the facility (leakpath factor [LPF]). The five-factor formula is being used to determine the source term of dispersible/respirable material that is released to the environment; namely:

Source term = MAR x DR x ARF x RF x LPF (Equation 13b.3-1)

Source terms are evaluated using models and/or computer codes that conform to NUREG/CR-6410's methodologies. Conservatively, it is assumed that IEs impact the entire inventory in the bounding location; that is, a DR of 1.0 is assumed for postulated accidents.

Releases of liquid toxic chemicals are modeled to limit evaporation since none of the tanks or vessels containing toxic chemicals are pressurized. In all cases, the evaporation of the entire inventory takes several hours.

ARFs/RFs for solid or powder chemicals have been selected to bound those in NUREG/CR-6410, namely an ARF/RF of 1E-03/1.0 from a spill of powders. Notice that some chemicals are delivered in solid or powder form (e.g., caustic soda) but are prepared or used in liquid form; however, for conservatism, these were modeled as powders, since the source term is higher than when modeled as being released from an evaporating pool. An LPF of 1.0 has been assumed conservatively at this time for all chemicals except for nitric acid and n-dodecane. For nitric acid and n-dodecane, only those inventories associated with licensed materials have been analyzed for release. These inventories exist inside tank vault or hot cells. As such, an LPF of 0.1 has been assumed for these two release scenarios (see Table 13b.3-1). This LPF corresponds to the most conservative LPF used for the bubble-tight isolation dampers.

13b.3.2.3 Chemical Concentrations and Comparison to Acceptable Limits

Consequence or chemical dose modeling are evaluated using dispersion models and/or computer codes that conform to NUREG/CR-6410 methodologies.

Typical computer codes to model chemical releases and determine the chemical dose (or concentration) are the ALOHA and EPIcode; as indicated previously both computer codes are widely used for supporting accident analysis and emergency response evaluations. Both codes have been used and accepted by DOE. V&V for both codes has been performed for modeling chemical hazards for the SHINE facility. Because ALOHA only can readily model only about half of these chemicals, the EPIcode was selected to perform chemical dose calculations in this section, and ALOHA was used to benchmark some of the EPIcode runs.

In running EPIcode, no credit is taken for depletion or plateout of chemicals within the facility or during transport to the site boundary or nearest population location. Dispersion calculations performed are done assuming ~~stable~~neutral meteorological conditions (i.e., ~~s~~Stability Class ~~F~~D) and ~~3.3~~13.5 ft/s (~~1~~4.1 m/s) wind speed. These represent 50th percentile meteorological conditions ~~are typically seen about 15 percent of the time~~ at the site. Ambient temperature was assumed to be 75°F (24°C). ~~A deposition velocity of 3.3 ft/s (1 m/s)~~No deposition of airborne material was assumed, a receptor height of 5 ft. (1.5 m) was used to simulate the height of an individual, and concentrations are plume centerline values. Releases were conservatively modeled as ground non-buoyant.

Chemical doses or concentrations were determined for the 11 chemicals for a postulated collocated worker within the site boundary (328 ft. [100 m]) at the site boundary and at the nearest residence (817 ft. and 2585 ft. [249 m and 788 m], respectively). Table 13b.3-2, summarizes the results of the source term and concentration calculations for the 11 chemicals. The acceptance limits were those identified in NUREG/CR-6410 and correspond to Protective Action Criteria (PAC) values corresponding to AEGLs, ERPGs, or TEELs values for such chemicals.

The chemical dose or concentration for the nearest residence is below the PAC 1, 2 and 3 levels (equivalent to ERPG-1, 2 and 3). For the workers postulated to be located within the boundary 328 ft. (100 m) downwind, the concentrations are below the PAC-2 values.

Table 13b.3-2 SHINE Toxic Chemical Source Terms and Concentrations

Hazardous Chemical/Release Mechanism	MAR (lb)	ARF/RF	Source Term[(a)] (lb)	PAC-1	PAC-2	PAC-3	Worker Concentration (100 m)	MEI Concentration (249 m)	Nearest Residence Concentration (788 m)
Nitric Acid, 12 M, associated with licensed materials (Evaporating Liquid)	721	1.0	721	0.53 ppm	24 ppm	92 ppm	0.49 ppm	0.090 ppm	0.012 ppm
Sulfuric Acid (Evaporating Liquid)	7,770	1.0	7,770	0.20 mg/m^3	8.7mg/m^3	160 mg/m^3	2.4E-06 ppm	4.7E-07 mg/m^3	6.3E-08 mg/m^3
Calcium Hydroxide (Dispersed Solid)	3,182	0.001	3.182	15 mg/m^3	240 mg/m^3	1,500 mg/m^3	0.86 mg/m^3	0.16 mg/m^3	0.020 mg/m^3
Caustic Soda (Dispersed as both a powder and liquid)	1,488	0.001	1.488	0.5 mg/m^3	5 mg/m^3	50 mg/m^3	0.40 mg/m^3	0.073 mg/m^3	0.010 mg/m^3
[Proprietary Information] (Dispersed Solid)	4,104	0.001	4.104	[Proprietary Information]	[Proprietary Information]	[Proprietary Information]	1.1 mg/m^3	0.20 mg/m^3	0.026 mg/m^3
Ammonium Hydroxide (Evaporating Liquid)	59	0.001	0.059	61 ppm	330 ppm	2300 ppm	0.011 ppm	2.0E-03 ppm	2.6E-04 ppm
[Proprietary Information] (Dispersed Solid)	606	0.001	0.606	[Proprietary Information]	[Proprietary Information]	[Proprietary Information]	0.16 mg/m^3	0.03 mg/m^3	3.9E-03 mg/m^3
Dodecane associated with licensed materials (Evaporating Liquid)	304	1.0	304	0.0028 ppm	0.031 ppm	7.9 ppm	0.0023 ppm	4.4E-04 ppm	5.9E-05 ppm
Potassium Permanganate (Dispersed Solid)	66	0.001	~~0.001~~ 0.066	8.6 mg/m^3	14 mg/m^3	78 mg/m^3	0.018 mg/m^3	3.3E-03 mg/m^3	4.2E-04 mg/m^3
Tributyl Phosphate (Evaporating Liquid)	333	0.001	0.333	0.6 mg/m^3	3.5 mg/m^3	125 mg/m^3	0.0082 ppm	1.5E-03 ppm	2.0E-04 ppm
Uranyl Nitrate (Dispersed as a powder)	480	0.001	0.480	0.99 mg/m^3	5.5 mg/m^3	33 mg/m^3	~~0.024~~ 0.13 mg/m^3	0.024 mg/m^3	3.1E-03 mg/m^3

a) With the potential for exceeding ERPG-2 limits at site boundary

process equipment that could lead to a radiological release is most likely inside a confined enclosure such as a hot cell, glove box, or tank enclosure. Small spaces such as these provide the confinement of the products of combustion, which can lead to development of a damaging fire environment. Development of damaging fire environment in the general area of the RPF is much less likely due to the large volume of the area. Direct fire damage to important equipment which could lead to a significant radiological release is not likely because redundant control or power circuits are separated by distance to prevent such damage from a single fire, accordingly the DBA is considered to be a fire in an enclosure that may lead to the development of a damaging fire environment.

The design basis fire accident is postulated to occur in an RPF supercell where it contributes to the release of the contents of the Mo extraction feed tank. Fire damage to the tank, associated valves, or process piping could lead to a release of Mo-99 eluate into the supercell enclosure. Release of this material into the enclosure could lead to an airborne release of radiological material into the cell enclosure and ultimately migration into the RCA ventilation system. The potential release would be mitigated by closure of the bubble-tight dampers in the RCA ventilation system in response to a smoke alarm signal or detection of the radioactive material by the radiation monitoring system. Isolation of the ventilation system would prevent significant release to the environment.

Radiological release of this DBA is bounded by the MHA and contained by the facility and RCA ventilation system. Postulated fire strengths are insufficient to breach the credited facility barrier walls or components. The effects of this DBA and any associated radiological release will be contained by the facility construction and RCA ventilation system components.

19.4.11.2.13 Hazardous Chemical Releases

The consequence of chemical releases are evaluated using dispersion models and/or computer codes that conform to NUREG/CR-6410 methodologies.

Typical computer codes to model chemical releases and determine the chemical dose (or concentration) are the ALOHA and EPICode; both computer codes are widely used for supporting accident analysis and emergency response evaluations. Both codes have been used and accepted by government agencies such as DOE. Verification and validation for both codes have been performed for modeling chemical hazards for the SHINE facility. Because ALOHA can readily model only about half of these chemicals, the EPICode was selected to perform chemical dose calculations in this subsection. Both computer codes give comparable results for the hazardous chemicals that they have in common and both codes implement release and dispersion models that are consistent with the guidance in NUREG/CR-6410.

In running ~~I~~EPICode, no credit is taken for depletion or plate out of chemicals within the facility or during transport to the site boundary or nearest population location. All dispersion calculations performed are done assuming ~~stable~~neutral meteorological conditions (i.e., Stability Class ~~F~~D) and ~~1~~4.1 m/s wind speed. These represent 50th percentile meteorological conditions ~~are typically seen about 15 percent of the time~~ at the site. Ambient temperature was assumed to be 75 ^{o}F, ~~the deposition velocity is 1 m/s~~no deposition of airborne material was assumed, and a receptor height of 1.5 m was used to simulate the height of an individual. Concentrations are plume centerline values. Releases were conservatively modeled as ground non-buoyant.

Chemical dose or concentrations were determined for the 11 chemicals at the site boundary and the nearest residence (~~402~~249 and 788m, respectively). Table 19.4.11-1 summarizes the results of the source term and concentration calculations for the 11 chemicals. The material-at-risk (MAR) represents the inventory of hazardous material that is at risk from the postulated scenario. The MAR for most of the chemicals represents the amount of material in storage. In some cases, the MAR represents the total facility inventory. For other chemicals, the quantity assumed to be released is reduced to account for separate storage locations, or to account for normal industrial chemicals not interacting with licensed materials or affecting the safety of licensed materials. The 11 chemicals were selected for evaluation based on the combination of anticipated bounding facility inventory amounts and high toxicity characteristics (lowest PAC values). The acceptance limits were those identified in NUREG/CR-6410 and correspond to Protective Action Criteria (PAC) values corresponding to Acute Exposure Guideline Levels (AEGLs), Emergency Response Planning Guideline (ERPG), or Temporary Emergency Exposure Limits (TEEL) values for such chemicals.

The results from the analysis indicate that the chemical dose or concentration for the ~~MOI~~MEI and the nearest residence is below the PAC-1, PAC-2, and PAC-3 levels (equivalent to ERPG-1, ERPG-2, and ERPG-3). These concentrations are ~~very~~ conservatively calculated, and are based on the assumption that the entire inventory of liquid hazardous chemicals ~~will~~ evaporates ~~within one hour~~from a 100 ft^2 pool, over a duration calculated by EPICode. ~~In most circumstances including nitric acid, evaporation takes longer than one hour, thus significantly reducing the potential concentrations downwind~~Solid powder material release durations were assumed to be one hour to correspond with ERPG exposure times.

Table 19.4.11-1 SHINE Hazardous (Toxic) Chemical Source Terms and Concentrations

Hazardous Chemical/ Release Mechanism	MAR (lb)	ARF/RF	Source Term* (lb)	PAC-1	PAC-2	PAC-3	Site Boundary Concentration (~~402~~249 m)	Nearest Residence Concentration (788 m)
Nitric Acid, 12M, associated with licensed materials (Evaporating Liquid)	~~6,229~~ 721	1.0	~~6,229~~ 721	0.53 ppm	24 ppm	92 ppm	~~3.0~~0.090 ppm	~~0.4~~0.012 ppm
Sulfuric Acid (Evaporating Liquid)	7,770	1.0	7,770	0.20 mg/m^3	8.7mg/m^3	160 mg/m^3	4.7E-07 mg/m^3	6.3E-08 mg/m^3
Calcium Hydroxide (Dispersed Solid)	3,182	0.001	3.182	15 mg/m^3	240 mg/m^3	1,500 mg/m^3	0.16 mg/m^3	0.020 mg/m^3
Caustic Soda (Dispersed Solid)	1,488	0.001	1.488	0.5 mg/m^3	5 mg/m^3	50 mg/m^3	0.073 mg/m^3	0.010 mg/m^3
[Proprietary Information] (Dispersed Solid)	4,104	0.001	4.104	[Proprietary Information]	[Proprietary Information]	[Proprietary Information]	0.20 mg/m^3	0.026 mg/m^3
Ammonium Hydroxide (Dispersed Solid)	59	0.001	0.059	61 ppm	330 ppm	2300 ppm	2.0E-03 ppm	2.6E-04 ppm
[Proprietary Information] (Dispersed Solid)	606	0.001	0.606	[Proprietary Information]	[Proprietary Information]	[Proprietary Information]	0.03 mg/m^3	3.9E-03 mg/m^3
Dodecane associated with licensed materials (Evaporating Liquid)	~~1,033~~ 304	1.0	~~1,033~~ 304	0.0028 ppm	0.031 ppm	7.9 ppm	~~4.4E-03~~ 4.4E-04 ppm	~~5.9E-04~~ 5.9E-05 ppm
Potassium Permanganate (Dispersed Solid)	66	0.001	~~0.001~~ 0.066	8.6 mg/m^3	14 mg/m^3	78 mg/m^3	3.3E-03 mg/m^3	4.2E-04 mg/m^3
Tributyl Phosphate (Dispersed Solid)	333	0.001	0.333	0.6 mg/m^3	3.5 mg/m^3	125 mg/m^3	1.5E-03 ppm	2.0E-04 ppm
Uranyl Nitrate (Dispersed Solid) (Likely in solution at SHINE)	480	0.001	0.480	0.99 mg/m^3	5.5 mg/m^3	33 mg/m^3	0.024 mg/m^3	3.1E-03 mg/m^3

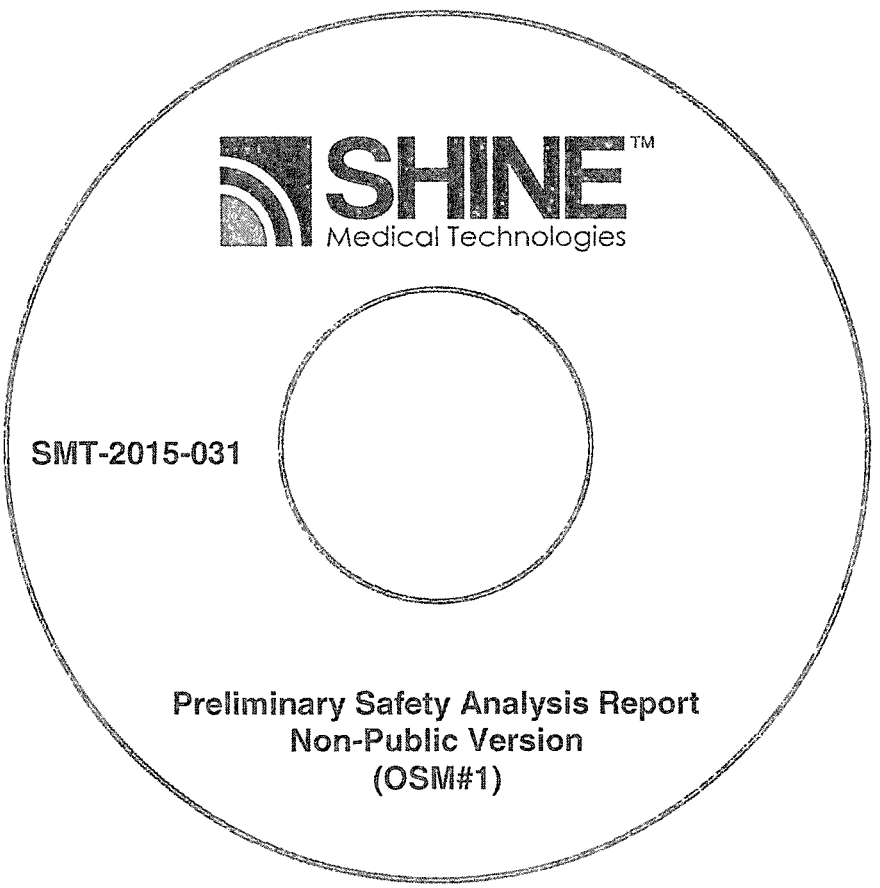
ENCLOSURE 2 CONTAINS ~~PROPRIETARY INFORMATION~~
IN ACCORDANCE WITH 10 CFR 2.390

ENCLOSURE 2

SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT REVISION TO SECTIONS 13B.3 AND 19.4 OF THE PRELIMINARY SAFETY ANALYSIS REPORT

PRELIMINARY SAFETY ANALYSIS REPORT NON-PUBLIC VERSION (OSM#1)



Enclosure 2 contains both ~~proprietary and security-related information~~.
Withhold from public disclosure under 10 CFR 2.390.
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ENCLOSURE 3

SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT REVISION TO SECTIONS 13B.3 AND 19.4 OF THE PRELIMINARY SAFETY ANALYSIS REPORT

PRELIMINARY SAFETY ANALYSIS REPORT
PUBLIC VERSION
(OSM#2)

ENCLOSURE 4

SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT REVISION TO SECTIONS 13B.3 AND 19.4 OF THE PRELIMINARY SAFETY ANALYSIS REPORT

AFFIDAVIT OF RICHARD VANN BYNUM

2 pages follow

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 public disclosure. The purpose of this affidavit is to provide the information required by 10 CFR 2.390(b) in support of SHINE's request for proprietary treatment of certain confidential commercial and financial information submitted in the SHINE letter SMT-2015-031 with enclosures. SHINE requests that the confidential information contained in Enclosure 2 be withheld from public disclosure in its entirety.

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

3. Pursuant to the provisions of paragraph (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 contained in Enclosure 2 of SMT-2015-031 is owned by SHINE, its affiliates, or third parties to whom SHINE has an obligation to maintain its confidentiality. This information is and has been held in confidence by SHINE.

   b. The information sought to be protected in Enclosure 2 is not available to the public to the best of my knowledge and belief.

c. The information contained in Enclosure 2 is of the type that is customarily held in confidence by SHINE, and there is a rational basis for doing so. The information that SHINE is requesting to be withheld from public disclosure includes trade secret, commercial 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," and subject to maintaining confidentiality.

d. The proprietary information sought to be withheld from public disclosure in Enclosure 2 includes, but is not limited to: structural configuration, primary and supporting systems of the medical isotope facility, process and system locations, and process details. This would include information regarding the types, quantities, and locations of materials stored on site as would be referenced in facility configuration drawings. Public disclosure of the information in Enclosure 2 would create substantial harm to SHINE because it would reveal trade secrets owned by SHINE, its affiliates, or third parties to whom SHINE has an obligation to maintain its confidentiality.

e. Public disclosure of the information in Enclosure 2 would create substantial harm to SHINE because it would reveal valuable business information regarding SHINE's competitive expectations, assumptions, processes, and current position. Its use by a competitor could substantially improve their competitive position in the design, manufacture, shipment, installation, assurance of quality, or licensing of a similar product.

f. The information contained in Enclosure 2 of SMT-2015-031 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. The information is properly marked.

I declare under the penalty of perjury that the foregoing is true and correct.
Executed on June 16, 2015.

Richard Vann Bynum, Ph.D.
COO – SHINE Medical Technologies, Inc.