SHINE™
Medical Technologies

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

May 21, 2015

SMT-2015-019
10 CFR 50.30

50-608

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

References: See Below

SHINE Medical Technologies, Inc. Preliminary Safety Analysis Report Revisions Resulting from Request for Additional Information Responses

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). SHINE has determined that Preliminary Safety Analysis Report (PSAR) revisions described in request for additional information (RAI) responses provided via References (3), (4), (5), (6), and (7) could be incorporated, and SHINE has revised the PSAR accordingly.

Enclosure 1 provides Revision 1 of the SHINE Response to RAI 4b-2 and RAI 11.1-6, previously provided via Reference (3) and Reference (4), respectively.

Enclosure 2 provides a non-public (proprietary) summary of the PSAR revisions, including a reference to the RAI response describing the change. Enclosure 2 is being provided via optical storage media (OSM) as OSM#1. 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) summary of the PSAR revisions. Enclosure 3 is being provided via OSM as OSM#2.

Enclosure 4 provides a non-public (proprietary) revision to the SHINE PSAR. In addition to incorporating the mark-ups provided in Enclosures 1 and 2, this PSAR revision incorporates Section 19.4 changes previously provided via Reference (8). Enclosure 4 is provided via OSM as OSM#3. In addition to proprietary information, Enclosure 4 contains security-related information which was identified utilizing the guidance contained RIS 2005-31. SHINE requests that the NRC withhold Enclosure 4 from public disclosure under 10 CFR 2.390.

Enclosures 2 and 4 contain both ~~proprietary and security-related information~~.
Withhold from public disclosure under 10 CFR 2.390.
Upon removal of Enclosures 2 and 4, this letter is uncontrolled.

A001
NRR

2555 Industrial Drive | Monona, WI 53713 | P (608) 210-1060 | F (608) 210-2504 | www.shinemed.com

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

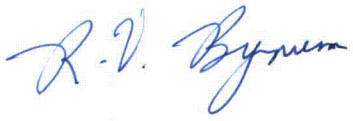
Enclosure 5 provides a public (non-proprietary) revision to the SHINE PSAR. In addition to incorporating the mark-ups provided in Enclosures 1 and 3, this PSAR revision incorporates Section 19.4 changes previously provided via Reference (8). Enclosure 5 is provided via OSM as OSM#4.

Enclosure 6 provides an affidavit supporting the proprietary treatment of the SHINE proprietary information pursuant to 10 CFR 2.390. Enclosures 2 and 4 contain information proprietary to SHINE. Upon removal of Enclosures 2 and 4, 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 May 21, 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 Enclosures 2 and 4)

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

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)
(3) SHINE Medical Technologies, Inc. letter to NRC, dated October 15, 2014, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information (ML14296A189)
(4) 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)
(5) SHINE Medical Technologies, Inc. letter to NRC, dated February 6, 2015. SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information (ML15043A404)
(6) SHINE Medical Technologies, Inc. letter to NRC, dated April 10, 2015. SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information (ML15120A248)
(7) SHINE Medical Technologies, Inc. letter to NRC, dated May 1, 2015. SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information (ML15131A464)
(8) SHINE Medical Technologies, Inc. letter to NRC, dated March 23, 2015, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information 11.1-9 (ML15092A397)

Enclosures 2 and 4 contain both ~~proprietary and security-related information~~.
Withhold from public disclosure under 10 CFR 2.390.
Upon removal of Enclosures 2 and 4, this letter is uncontrolled.

ENCLOSURE 1

SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. PRELIMINARY SAFETY ANALYSIS REPORT REVISIONS RESULTING FROM REQUEST FOR ADDITIONAL INFORMATION RESPONSES

REVISION 1 OF THE SHINE RESPONSE TO RAI 4B-2 AND RAI 11.1-6

Via Reference (1), SHINE provided a Response to RAI 4b-2 (Reference 2). SHINE has determined a revision to the SHINE Response to RAI 4b-2 is required. Revision 1 of the SHINE Response to RAI 4b-2 is provided below.

In addition, via Reference (3), SHINE provided a Response to RAI 11.1-6 (Reference 2). SHINE has determined a revision to the SHINE Response to RAI 11.1-6 is required. Revision 1 of the SHINE Response to RAI 11.1-6 is provided below.

RAI 4b-2

SHINE PSAR, page 4b-29, contains an apparent typographical error. The text in Section 4b.4.1.1.4.1(b.) reads: "The sulfuric acid washes of".

Correct this this text to read: "The sulfuric acid washes off"

SHINE Response

SHINE stated in the original response to this RAI (Reference 1) that the Final Safety Analysis Report (FSAR) will be updated to correct the typographical error contained in Subsection 4b.4.1.1.4.1 of the Preliminary Safety Analysis Report (PSAR). SHINE has reviewed the wording in Subsection 4b.4.1.1.4.1 regarding the phrase "The sulfuric acid washes of" and determined that this wording is correct.

The sulfuric acid washes are being applied to the columns in the Molybdenum Extraction and Purification System (MEPS) hot cell, and these washes are then fed to the uranyl nitrate conversion tank. Therefore the phrase "The sulfuric acid washes of" is appropriate to use.

RAI 11.1-6

SHINE PSAR, Section 11.1.7.2.2.1, "Air Sampling Locations," discusses the proposed air monitoring program. When discussing the equipment that will be used for air sampling, the applicant uses the term CAM (continuous air monitor). The conventional use of the term "continuous air monitor" denotes equipment that both samples and quantifies the activity on the sample media (i.e., real-time monitoring). Normally, CAMs are not used for such purposes and the NRC guidance document, NUREG-1301, "Offsite Dose Calculation Manual Guidance: Standard Radiological Effluent Controls for Pressurized Water Reactors," that the applicant cites, does not specify CAMs for environmental air sampling.

Clarify whether the term "air monitoring" is intended to refer to sample collection followed by laboratory analysis or real-time air monitoring.

SHINE Response

SHINE inappropriately used the term "CAM" to refer to a continuous air sampler in Subsection 11.1.7.2.2.1 of the PSAR. SHINE will employ continuous air samplers at the stated locations, with the samples collected and analyzed in a laboratory. SHINE has revised Subsection 11.1.7.2.2.1, Table 11.1-8, and Figure 11.1-3 to correct the terminology. 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 4. The public (non-proprietary) version of the PSAR, incorporating the changes provided in Attachment 1, is provided in Enclosure 5.

The changes described above also apply to Subsection 19.4.8.3.2.3, Table 19.4.8-6, and Figure 19.4.8-1 of the PSAR. An IMR has been initiated to address the issue.

References

(1) SHINE Medical Technologies, Inc. letter to NRC, dated October 15, 2014, SHINE Medical Technologies, Inc. Application for Construction Permit, Response to Request for Additional Information (ML14296A189)

(2) NRC letter to SHINE Medical Technologies, Inc., dated September 19, 2014, SHINE Medical Technologies, Inc. – Request for Additional Information Regarding Application for Construction Permit (TAC Nos. MF2305, MF2307, and MF2308) (ML14195A159)

(3) 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)

ENCLOSURE 1
ATTACHMENT 1

SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. PRELIMINARY SAFETY ANALYSIS REPORT REVISIONS RESULTING FROM REQUEST FOR ADDITIONAL INFORMATION RESPONSES

REVISION 1 OF THE SHINE RESPONSE TO RAI 4B-2 AND RAI 11.1-6

PRELIMINARY SAFETY ANALYSIS REPORT CHANGES (MARK-UP)

5 pages follow

Acronyms and Abbreviations

Acronym/Abbreviation	Definition
10 CFR	Title 10 of the Code of Federal Regulations
ALI	annual limit on intake
ALARA	as low as reasonably achievable
ANSI	American National Standards Institute
APF	assigned protection factor
ATS	accelerator target systems
Bq/100 cm^2	Becquerel per 100 square centimeters
CAM	continuous air monitors
CAS	continuous air samplers
CEMP	Community Environmental Monitoring Program
CEO	chief executive officer
Ci	curies (unit of measurement of radioactivity)
Ci/yr	curies per year
cm	centimeter
COO	chief operations officer
D/Q	ground level deposition factor
DAC	derived air concentration
DOT	United States Department of Transportation
dpm/100 cm^2	disintegrations per minute per 100 square centimeters
DQO	data quality objectives
DSSI	Diversified Scientific Services, Inc.
EPA	U.S. Environmental Protection Agency
ES&H	environment, safety, and health
ft^3/yr	cubic feet per year
FSAR	final safety analysis report
GTCC	Greater-than-Class C

Environmental airborne sampling is performed to identify and quantify particulates and radioiodine in airborne effluents. Regulatory Position C.3.b of Regulatory Guide 4.1 indicates that airborne sampling should always be included in the environmental monitoring programs for nuclear power plants since the airborne effluent pathway exists at all sites. Since the SHINE facility includes airborne effluent releases and radioactivity in the airborne effluent can result in measurable off-site doses and since there is a potential for a portion of the dose to be attributable to radioactive iodine and possibly airborne particulate radioactivity releases, the radiological environmental monitoring program includes airborne sampling.

11.1.7.2.2.1 Air Sampling Locations

The guidance provided in Table 3.12-1 of NUREG-1301 is used to establish locations for airborne sample acquisition, sampling frequency, and type of sample analysis. Continuous air sample locations are specified in accordance with guidance provided in Table 3.12-1 of NUREG-1301. The ~~CAMs~~continuous air samplers (CAS) that are used to obtain continuous air samples include a radioiodine canister for weekly iodine-131 (I-131) analysis and a particulate sampler which is analyzed for gross beta radioactivity and for quarterly isotopic analysis.

Four ~~CAM~~CAS locations are near the facility property line in the north, south, east, and west direction sectors to ensure all directions are monitored. The north and east direction sectors (with respect to the SHINE facility vent stack) have the highest calculated annual ground level deposition factor (D/Q) values. There is also a ~~CAM~~CAS located a sufficient distance from the SHINE facility to provide background information for airborne activity. Table 3.12-1 of NUREG-1301 suggests an additional ~~CAM~~CAS location in the vicinity of a community having the highest calculated annual average ground-level D/Q. This ~~CAM~~CAS requirement is combined with the ~~CAM~~CAS located at the site boundary in the north direction (refer to Table 11.1-8). A description of air sample locations and the rationale for air sample locations are provided in Table 11.1-8. ~~CAM~~CAS locations are shown on Figure 11.1-3.

11.1.7.2.3 Ingestion Pathway (Biota Monitoring)

NUREG-1301 suggests sampling of various biological media as a means to indirectly assess doses due to particulate and iodine ingestion. This type of monitoring may include sampling of soils, broad leafed plants, fish, meat, or milk. Nuclear power plants have long monitored this pathway and have seen neither appreciable dose nor upward trending. Since the SHINE source term is more modest than that of a nuclear power plant and particulate and iodine radionuclides are not normally expected to be present in significant quantities within airborne effluent releases from the SHINE facility, biota monitoring is not routinely included in the REMP. Monitoring of the milk pathway will be performed as part of the CEMP, as described in Subsection 11.1.7.3

In the event that the results of environmental airborne samples, effluent monitor sample results, or milk sampling results indicate iodine or particulates in quantities large enough to result in a calculated dose greater than that predicted for normal releases (e.g., from GENII models used to show compliance with the 10 CFR 20.1101(d) dose constraint), then a more comprehensive sampling campaign is undertaken. The sampling campaign is planned under the DQO process thus ensuring the appropriate types and numbers of samples are collected to best represent potential public doses based on the radionuclides of concern in the environmental airborne, effluent monitor, or milk samples.

11.1.7.3 Community Environmental Monitoring Program

In addition to the monitoring that is performed to meet regulatory requirements, SHINE has a CEMP. The CEMP initially includes groundwater monitoring and monitoring of the milk pathway. Additional initiatives may be undertaken in the future.

Milk is one of the most important foods contributing to the radiation dose to people if milk animals are pastured in an area near a facility that releases radioactive material. Dairy production takes place approximately one-half mile (mi.) (0.8 kilometers [km]) to the east of the SHINE facility and goat production takes place at approximately 0.69 mi. (1.1 km) northeast of the facility. A description of the milk sampling program will be provided with the FSAR.

11.1.7.3.1 Groundwater Monitoring

There is no liquid effluent release pathway from the RCA associated with the SHINE facility and thus, surface waters of the rivers in the vicinity of the plant (e.g., the Rock River and its tributaries) are not expected to accumulate detectable levels of radioactivity. As such, surface water sampling is not included in the radiological environmental monitoring plan. Similarly marine life in the rivers is not expected to accumulate detectable levels of radioactivity and thus sampling of fish or other marine creatures for the ingestion pathway is not included in the radiological environmental monitoring plan.

Measured local water table elevations for the site identify the groundwater gradient and indicate that the groundwater flow is to the west and to the south. The nearest drinking water source is a well located approximately a third of a mile (0.54 km) to the northwest of the facility. There are four test wells within the property boundary for the SHINE facility that were used for monitoring groundwater in support of a hydrological assessment of the site.

One test well is located north, one south, one east, and one west of the SHINE facility building. Although there are no defined liquid effluent release pathways from the RCA and the groundwater is not expected to be contaminated due to operation of the SHINE facility, the test wells to the west and the south are sampled for the presence of radionuclide contaminants. Sampling is in accordance with the recommendations in Table 3.12-1 of NUREG-1301, i.e., quarterly with gamma isotopic and tritium analysis. The rationale for sampling the test wells to the west and south of the SHINE facility is provided in Table 11.1-8.

11.1.7.3.2 Other Potential Special Sampling Initiatives

After SHINE operations are underway, additional sampling initiatives may be undertaken. For example, detectors may be placed within areas of community interest to allow for real-time gamma monitoring that can be observed via the internet. Other initiatives may include collection of high-volume air samples using portable air samplers in areas of community interest.

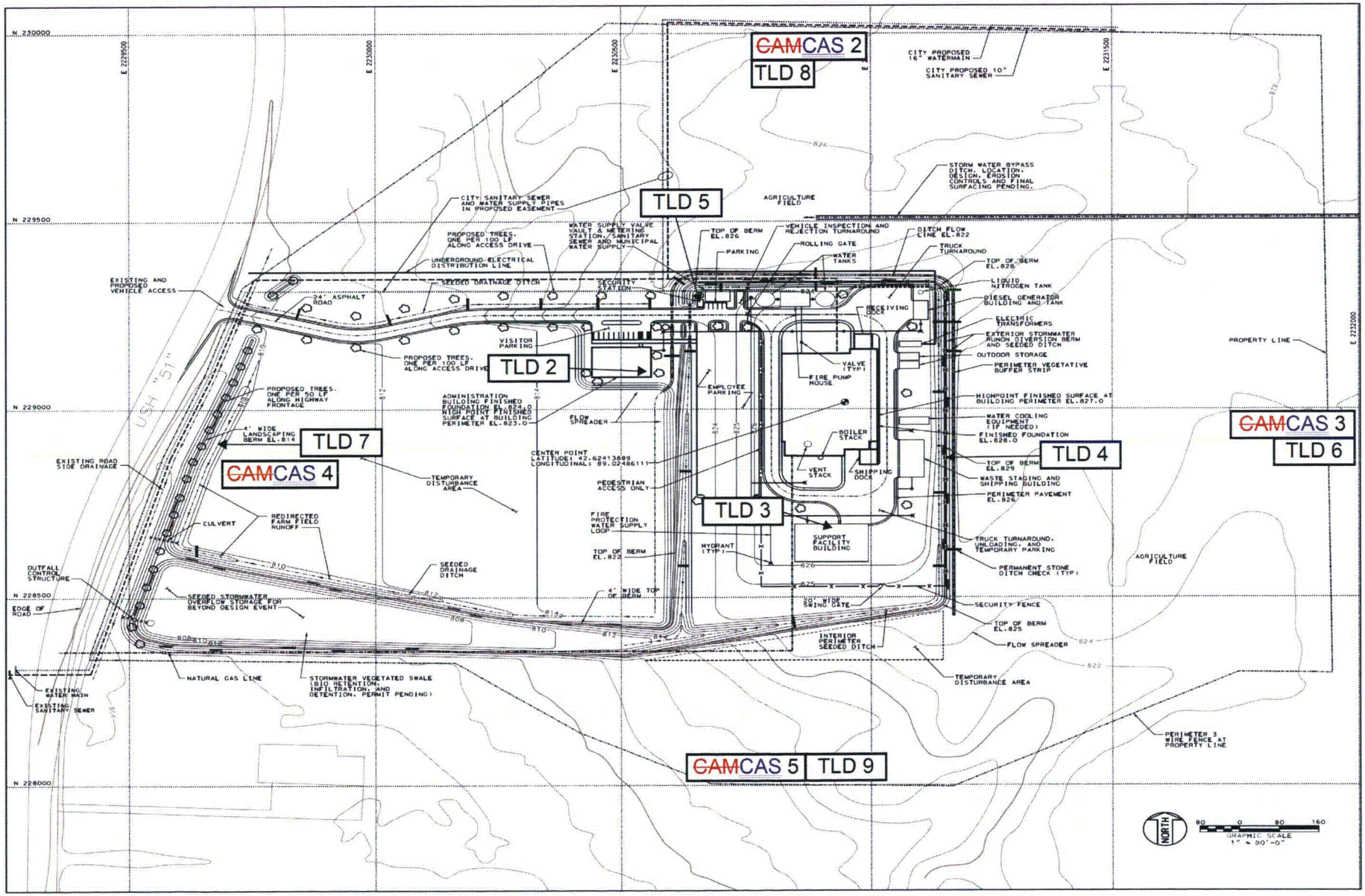
11.1.7.4 Preoperational Baseline Monitoring

As previously indicated, effluent releases from the SHINE facility are limited to releases via the airborne pathway. Environmental monitoring of the SHINE facility includes the use of TLDs for monitoring direct radiation and ~~CAMs~~CAS for detecting iodine and particulate activities in airborne effluents. A preoperational baseline survey is performed to obtain TLD readings at the nine TLD locations and to obtain air sample radioactive iodine and particulate surveys at the five

Table 11.1-8 Environmental Monitoring Locations
(Sheet 2 of 2)

Monitoring Type	Location	Rationale
TLD #7	Property line to the west of the SHINE facility	This location ensures all directions are monitored.
TLD #8	Property line to the north of the SHINE facility vent stack	This location is in the direction of Janesville.
TLD #9	Property line to the south of the SHINE facility vent stack	This location is in the direction of the nearest occupied structure.
Air Sampler Locations		
Air Sampler (~~CAM~~ CAS #1)	Off-site location	Control air sampler located a sufficient distance from the SHINE facility such that airborne samples are unaffected by airborne effluent releases from the facility.
Air Sampler (~~CAM~~ CAS #2)	Close to property line, directly north of the SHINE facility vent stack	This direction has high D/Q and is in the direction of Janesville. Since the community of Janesville is relatively close to the site boundary, this air sampler location is credited with satisfying two of the conditions for air sample location recommendations in Table 3.12-1 of NUREG-1301.
Air Sampler (~~CAM~~ CAS #3)	Close to property line, East of the SHINE facility vent stack	This direction has high D/Q and is in the direction of dairy production and the horse pasture.
Air Sampler (~~CAM~~ CAS #4)	Close to property line, west of the SHINE facility	This location ensures all directions are monitored.
Air Sampler (~~CAM~~ CAS #5)	Close to property line, South of the SHINE facility vent stack	This location is in the direction of the nearest occupied structure.

Figure 11.1-3 – Locations of Environmental Monitors



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

ENCLOSURE 2

SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. PRELIMINARY SAFETY ANALYSIS REPORT REVISIONS RESULTING FROM REQUEST FOR ADDITIONAL INFORMATION RESPONSES

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

Enclosures 2 and 4 contain both ~~proprietary and security-related information~~.
Withhold from public disclosure under 10 CFR 2.390.
Upon removal of Enclosures 2 and 4, this letter is uncontrolled.

ENCLOSURE 3

SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. PRELIMINARY SAFETY ANALYSIS REPORT REVISIONS RESULTING FROM REQUEST FOR ADDITIONAL INFORMATION RESPONSES

SUMMARY OF PRELIMINARY SAFETY ANALYSIS REPORT CHANGES PUBLIC VERSION (OSM#2)

ENCLOSURE 4 CONTAINS ~~PROPRIETARY INFORMATION~~
IN ACCORDANCE WITH 10 CFR 2.390

ENCLOSURE 4

SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. PRELIMINARY SAFETY ANALYSIS REPORT REVISIONS RESULTING FROM REQUEST FOR ADDITIONAL INFORMATION RESPONSES

PRELIMINARY SAFETY ANALYSIS REPORT
NON-PUBLIC VERSION
(OSM#3)

Enclosures 2 and 4 contain both ~~proprietary and security-related information~~.
Withhold from public disclosure under 10 CFR 2.390.
Upon removal of Enclosures 2 and 4, this letter is uncontrolled.

ENCLOSURE 5

SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. PRELIMINARY SAFETY ANALYSIS REPORT REVISIONS RESULTING FROM REQUEST FOR ADDITIONAL INFORMATION RESPONSES

PRELIMINARY SAFETY ANALYSIS REPORT PUBLIC VERSION (OSM#4)

ENCLOSURE 6

SHINE MEDICAL TECHNOLOGIES, INC.

SHINE MEDICAL TECHNOLOGIES, INC. APPLICATION FOR CONSTRUCTION PERMIT RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

AFFIDAVIT OF RICHARD VANN BYNUM

2 pages follow

SHINE™
Medical Technologies

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 response to the NRC staff's requests for additional information transmitted by letter SMT-2015-019 with enclosures. SHINE requests that the confidential information contained in Enclosures 2 and 4 be withheld from public disclosure in their 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 Enclosures 2 and 4 of SMT-2015-019 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 Enclosures 2 and 4 is not available to the public to the best of my knowledge and belief.

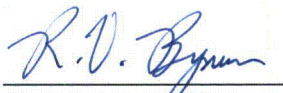
c. The information contained in Enclosures 2 and 4 is of the type that is customarily held in confidence by SHINE, and there is a rational basis for doing so. The information that SHINE is requesting to be withheld from public disclosure includes trade secret, commercial financial information, commercial 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 Enclosures 2 and 4 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 Enclosures 2 and 4 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 Enclosures 2 and 4 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 Enclosures 2 and 4 of SMT-2015-019 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 May 21, 2015.



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