SHINE™ Medical Technologies

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

February 6, 2015

SMT-2015-004
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. Application for Construction Permit
Response to Request for Additional Information

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). Via Reference (3), the NRC staff determined that additional information was required to enable the staff's continued review of the SHINE construction permit application. SHINE responded to the NRC staff's requests via References (4) and (5). In the course of reviewing the SHINE responses submitted via Reference (4), the NRC staff determined that additional information was required (Reference 6) to complete the review of the SHINE construction permit application.

Enclosure 1 provides the non-public (proprietary) version of the SHINE response to the NRC staff's request for additional information. Enclosure 1 is being provided via optical storage media (OSM) as OSM#1. In addition to proprietary information, Enclosure 1 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 1 from public disclosure under 10 CFR 2.390.

Enclosure 2 provides the public (non-proprietary) version of the SHINE response to the NRC staff's request for additional information. Enclosure 2 is provided via OSM as OSM#2.

Enclosure 3 provides the non-public (proprietary) version of Revision 1 of the SHINE Response to RAI 11.2-4, previously provided via Reference (5). Revision 1 of the SHINE Response to RAI 11.2-4 addresses administrative errors previously provided. In addition to proprietary information, Enclosure 3 contains security-related information which was identified utilizing the guidance contained in RIS 2005-31. SHINE requests that the NRC withhold Enclosure 3 from public disclosure under 10 CFR 2.390.

Enclosures 1, 3, and 5 contain both proprietary and security-related information.
Withhold from public disclosure under 10 CFR 2.390.
Upon removal of Enclosures 1, 3, and 5, this letter is uncontrolled.

A001
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THIS LETTER CONTAINS ~~PROPRIETARY INFORMATION~~
~~IN ACCORDANCE WITH 10 CFR 2.390~~

Enclosure 4 provides the public (non-proprietary) version of Revision 1 of the SHINE Response to RAI 11.2-4.

Enclosure 5 provides a non-public (proprietary) revision to the SHINE Preliminary Safety Analysis Report (PSAR), incorporating changes based on the SHINE responses to the NRC staff's request for additional information. Enclosure 5 is provided via OSM as OSM#3. In addition to proprietary information, Enclosure 5 contains security-related information which was identified utilizing the guidance contained in RIS 2005-31. SHINE requests that the NRC withhold Enclosure 5 from public disclosure under 10 CFR 2.390.

Enclosure 6 provides a public (non-proprietary) revision to the SHINE PSAR, incorporating changes based on the SHINE response to the NRC staff's request for additional information. Enclosure 6 is provided via OSM as OSM#4.

Enclosure 7 provides an affidavit supporting the proprietary treatment of the SHINE proprietary information pursuant to 10 CFR 2.390. Enclosures 1, 3, and 5 contain information proprietary to SHINE. Upon removal of Enclosures 1, 3, and 5, 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 February 6, 2015.

Very truly yours,

R. V. Bynum

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 1, 3, and 5)

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) 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)

(4) 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 (ML14296A190)

(5) 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

(6) NRC letter to SHINE Medical Technologies, Inc., dated January 8, 2015, SHINE Medical Technologies, Inc. – Request for Additional Information Regarding Application for Construction Permit (TAC Nos. MF2305, MF2307, and MF2308) (ML15005A407)

ENCLOSURE 2

SHINE MEDICAL TECHNOLOGIES, INC.

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

PUBLIC VERSION
(OSM#2)

ENCLOSURE 4

SHINE MEDICAL TECHNOLOGIES, INC.

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

REVISION 1 OF THE SHINE RESPONSE TO RAI 11.2-4 (PUBLIC VERSION)

10 pages follow

Via Reference (1), SHINE provided a response to RAI 11.2-4 (Reference 2), which described revisions to Tables 9b.7-7 and 11.2-1 of the PSAR. These revisions contain an administrative error in the total as-shipped volume of solidified waste and the corresponding 55-gallon drum equivalent. The preparation of grouted waste forms should have been based on a mass ratio of water to cement of 0.5, as opposed to a volume ratio of 0.5 (used to estimate the values provided in the SHINE Response to RAI 11.2-4).

In addition to the changes described above, SHINE has re-calculated the number of shipments of solidified liquid waste based on an expected density of 115.4 lbs/ft^3 for the grouted waste forms and an expected maximum payload of a semi-tractor/trailer of 50,000 lbs per shipment.

SHINE will revise Tables 9b.7-7 and 11.2-1 in the FSAR to document the above change, as described in Revision 1 of the SHINE Response to RAI 11.2-4, below. An Issues Management Report (IMR) has been initiated to track the revisions to Tables 9b.7-7 and 11.2-1 in the FSAR.

The changes described above and documented in Revision 1 of the SHINE Response to RAI 11.2-4, below, also apply to Table 19.2.5-1 of the PSAR. An IMR has been initiated to address the issue.

RAI 11.2-4

SHINE PSAR, Table 11.2-1 presents estimates of waste generation rates and waste classification without sufficient discussion or quantitative values to assess the reasonableness of the estimates presented. For example:

- *The total for all the liquid radioactive waste inputs is presented to five significant figures (59,708 gallons per year) but only one liquid waste stream has an estimated generation rate associated with it in the text (scrubber solution at 20,000 gallons per year).*
- *Coolant cleanup system spent ion exchange resins are not included in PSAR Table 11.2-1. A commitment to include this value in the FSAR exists in the text.*
- *There is insufficient chemical characterization data of the individual waste streams to allow assessment of the potential for unexpected chemical reactions or to estimate volumes of acids or bases that may be needed for pH adjustment.*
- *There is no identification of any anticipated upset or accident condition that could cause an input to the liquid waste processing system.*

Provide a comprehensive liquid waste process flow diagram showing expected liquid waste generation rates (with chemical and radiological properties) for all liquid waste streams, washes, rinses, and chemical additions that flow to the consolidated radioactive liquid waste tanks. The process flow diagram should also quantify tank capacities and processing flow rates that demonstrate the capability to process wastes from normal operations and anticipated upset conditions with margin, or identify locations for interfacing with temporary mobile systems, as needed. The process flow diagram should include an estimate of the area needed for decay in storage of packaged waste and the criteria used to determine shielding requirements.

SHINE Response

Bullet 1

The total for all the liquid radioactive waste inputs is presented to five significant figures (59,708 gallons per year) but only one liquid waste stream has an estimated generation rate associated with it in the text (scrubber solution at 20,000 gallons per year).

SHINE Response

SHINE will revise Table 11.2-1 of the PSAR in the FSAR to show an influent volume of approximately 52,000 gallons per year of liquid waste. The waste volumes provided in the last six rows of Table 11.2-1 will be revised as follows:

Description	Matrix	Class as Generated	As Generated Amount	As Generated Units	As Shipped (cubic feet (ft^3))	Ship Type	Number Shipments	Destination
Spent Washes	Liquid[a]	A	2100	gallons/yr	7540[b]	LSA	19	Energy *Solutions*
Rotary Evaporator Condensate	Liquid[a]	A	200					
UREX Raffinate	Liquid[a]	B	27,000					
NO_x Scrubber Solution	Liquid[a]	A	20,000					
Decontamination Waste	Liquid[a]	A	400					
Spent Eluate Solution	Liquid[a]	A	2600					

a) This liquid waste discharged from the various processes at the SHINE facility is either solidified and then shipped to a waste depository or reused.

b) As shipped volume of waste is in the form of concrete. Total liquid volume of approximately 52,000 gallons/yr is reduced via evaporation to approximately 35,000 gal/yr (volume reduction factor of 1.5). The liquid waste is then solidified by adding Portland cement (or equivalent). Concrete volume is estimated using a conservative waste to cement mass ratio of 0.5.

An IMR has been initiated to track the revision to Table 11.2-1.

Bullet 2

Coolant cleanup system spent ion exchange resins are not included in PSAR Table 11.2-1. A commitment to include this value in the FSAR exists in the text.

SHINE Response

SHINE will revise Table 11.2-1 of the PSAR in the FSAR to include an estimate of spent ion exchange resins from the coolant cleanup systems (LWPS and PCLS). A preliminary estimate for this value is 48 ft^3/year of spent resin, Class A as generated, Shipment Type LSA. This estimate assumes that each demineralizer has a resin bed volume of three ft^3, and that conservatively, one bed is exhausted per year per coolant cleanup system due to the very low expected amount of ionic impurities in a closed, clean water system.

A final waste estimate will be developed during detailed design. An IMR has been initiated to track the revision to Table 11.2-1, which will include a final estimate of spent ion exchange resins from the coolant cleanup systems.

Bullet 3

There is insufficient chemical characterization data of the individual waste streams to allow assessment of the potential for unexpected chemical reactions or to estimate volumes of acids or bases that may be needed for pH adjustment.

SHINE Response

Table 9b.7-7 of the PSAR provides the waste stream chemical characterizations. To be consistent with the revision to Table 11.2-1 described above, SHINE will revise the waste volumes provided in Table 9b.7-7 in the FSAR, as follows:

Description	Matrix	Class as Generated	Contents	Volume	Volume as Shipped (ft^3)	55-gallon drum equivalent as shipped	Ship Type	Number of Shipments/yr	Destination
Spent Washes	Liquid[a]	A	[Proprietary Information]	2100 gallons/yr	7540[b]	1143[c]	LSA	19	Energy *Solutions*
Rotovar Condensate	Liquid[a]	A	[Proprietary Information]	200 gallons/yr					
UREX Raffinate	Liquid[a]	B	[Proprietary Information]	27,000 gallons/yr					
Decontamination Waste	Liquid[a]	A	Decon fluid unknown	400 gallons/yr					
Spent Eluate Solution	Liquid[a]	A	[Proprietary Information]	2600 gallons/yr					
NO_x Scrubber Solution	Liquid[a]	A	[Proprietary Information]	20,000 gallons/yr					

a) This liquid waste discharged from the various processes at the SHINE facility is either solidified and then shipped to a waste depository or reused.

b) As shipped volume of waste is in the form of concrete. Total liquid volume of approximately 52,000 gallons/yr is reduced via evaporation to approximately 35,000 gal/yr (volume reduction factor of 1.5). The liquid waste is then solidified by adding Portland cement (or equivalent). Concrete volume is estimated using a conservative waste to cement mass ratio of 0.5.

c) A 55-gallon drum, filled to 90 percent to account for minor voiding, has a volume of approximately 6.6 ft^3.

An IMR has been initiated to track the revision to Table 9b.7-7.

Bullet 4

There is no identification of any anticipated upset or accident condition that could cause an input to the liquid waste processing system.

SHINE Response

Margin is included in the design of the liquid waste processing equipment to account for anticipated upset or accident conditions by the inclusion of two liquid waste storage tanks. The liquid waste processing equipment will be sized to allow processing of one tank while the other is filling in order to maintain buffer storage capacity. Anticipated upset conditions may include the production of extra decontamination waste used to clean up small spills, extra waste from UNCS if a portion of it needs to be repeated for a specific batch (i.e., contactor failure leads to inadequate separation), extra column wash solution due to a failure of the wash delivery system, or contaminated fire protection water caused by a sprinkler failure. Accident conditions that may produce additional liquid waste are described in Subsections 13a2.1.4 and 13b.2.4 of the PSAR.

Paragraph (Bullet 5)

Provide a comprehensive liquid waste process flow diagram showing expected liquid waste generation rates (with chemical and radiological properties) for all liquid waste streams, washes, rinses, and chemical additions that flow to the consolidated radioactive liquid waste tanks. The process flow diagram should also quantify tank capacities and processing flow rates that demonstrate the capability to process wastes from normal operations and anticipated upset conditions with margin, or identify locations for interfacing with temporary mobile systems, as needed. The process flow diagram should include an estimate of the area needed for decay in storage of packaged waste and the criteria used to determine shielding requirements.

SHINE Response

A liquid process flow diagram is provided as Figure 9b.7-5 of the PSAR. Figure 11.2-4-1, below, provides a modified version of Figure 9b.7-5 showing expected liquid waste generation rates and chemical and radiological properties for the liquid waste streams, washes, rinses, and chemical additions that flow to the liquid waste storage tanks (1-RLWS-01TA/B). Figure 11.2-4-1 also shows tank capacities, processing flow rates, a location for interfacing with temporary mobile systems if needed, and an estimate of the area needed for decay in storage. SHINE will update Figure 9b.7-5 of the PSAR in the FSAR to incorporate the process details described above. An IMR has been initiated to track the update to Figure 9b.7-5 in the FSAR.

Table 9b.7-7 of the PSAR provides the waste stream chemical characterizations and the expected liquid waste generation rates. As described above, Table 9b.7-7 will be revised in the FSAR to be consistent with the waste generation rates in the corrected Table 11.2-1. An IMR has been initiated to track the revision to Table 9b.7-7.

The radiological properties of the streams are described qualitatively as follows, and summarized in Table 11.2-4-1 below.

Irradiated target solution is passed through the Molybdenum Extraction and Purification System (MEPS) extraction column and then processed for re-irradiation. The large majority of fission products stay with this stream, to be removed as waste into the UREX raffinate stream after [Proprietary Information] cycles of irradiation. Therefore, the UREX raffinate stream is the largest contributor to the radiological inventory of the consolidated liquid waste, comparable to the radiological properties of irradiated target solution after the removal of uranium, molybdenum, and small fractions of other elements that are expected to be retained on the extraction column. The estimated radioactive inventory from one TSV batch is [Proprietary Information], as stated in Subsection 4b.4.1.2.1.2 of the PSAR.

The spent washes consist of potassium permanganate and water washes of the extraction column after the target solution has been passed through the column. Between 0 percent and 30 percent of each element in the target solution stream is expected to be partitioned to the wash streams, with the partitioning of most elements being less than approximately 5 percent. Therefore, the estimated radioactive inventory is expected to be less than 30 percent of the radioactive inventory of one TSV.

Spent eluate solution from the [Proprietary Information] and rotary evaporate condensate are both waste streams created in process steps downstream of the extraction column. As described above, the majority of fission products are partitioned into earlier process waste streams, and as the volume of these two streams is much lower than other streams (see corrected Table 9b.7-7 above), the radiological inventory is also expected to be low in comparison to the waste generated in upstream processes.

Decontamination waste will have variable radiological properties, but is expected to have a low radiological inventory based on the low volume of generated waste and the low amount of leakage or spillage that will require cleanup and decontamination.

NO_x scrubber solution is also expected to have a low radiological inventory. The PVVS uses a caustic solution to remove acid gases and byproduct material. The byproduct material consists of vent gases from process tanks and from the NGRS after at least 40 days of decay, where the majority of this byproduct material, specifically short-lived isotopes of noble gases, has decayed to stable isotopes.

Volumes for Cintichem liquid waste and NGRS condensate are both expected to be less than one gallon per TSV batch, and are therefore not significant inputs and are not included in Table 9b.7-7 of the PSAR or Table 11.2-4-1, below. The generation rates, chemical properties, and radiological properties of these two streams will be determined during detailed design and provided in the FSAR. An IMR has been initiated to track the inclusion of this information in the FSAR.

Table 11.2-4-1: Radiological Properties of Liquid Waste Streams, Washes, Rinses, and Chemical Additions

Description	Radiological Inventory (Relative to Other Liquid Waste Streams)	Qualitative Radiological Properties
Spent Washes	Medium	Most fission products pass through the extraction column, though some are expected to be retained on the column and then removed with column washes.
Rotary Evaporate Condensate	Low	Fission products remaining after majority removed in prior MEPS processing steps.
UREX Raffinate	High	The majority of non-volatile fission products are removed from target solution during UREX processing. The estimated radioactive inventory from one TSV batch is [Proprietary Information].
NOx Scrubber Solution	Low	Byproduct material from process tank vents and NGRS gases after 40 days of decay.
Decontamination Waste	Low	Dependent on decontamination needs
Spent Eluate Solution	Low	Fission products remaining after majority removed in prior MEPS processing steps.
Chemical Additions	None	Non-radioactive chemicals may be added as needed for pH adjustment.

Subsection 9b.7.4.2.3 of the PSAR contains a description of the radioactive liquid waste storage system. This section describes the two liquid waste storage tanks, configured in parallel, each with a working volume of approximately [Security-Related Information]. This provides around 40 days of buffer storage capacity of liquid wastes produced by normal facility operations. The buffer storage capacity will provide margin for anticipated upset conditions. Anticipated upset conditions may include the production of extra decontamination waste used to clean up small spills, extra waste from UNCS if a portion of it needs to be repeated for a specific batch (i.e., contactor failure leads to inadequate separation), extra column wash solution due to a failure of the wash delivery system, or contaminated fire protection water caused by a sprinkler head failure. Accident conditions that may produce additional liquid waste are described in Subsections 13a2.1.4 and 13b.2.4 of the PSAR.

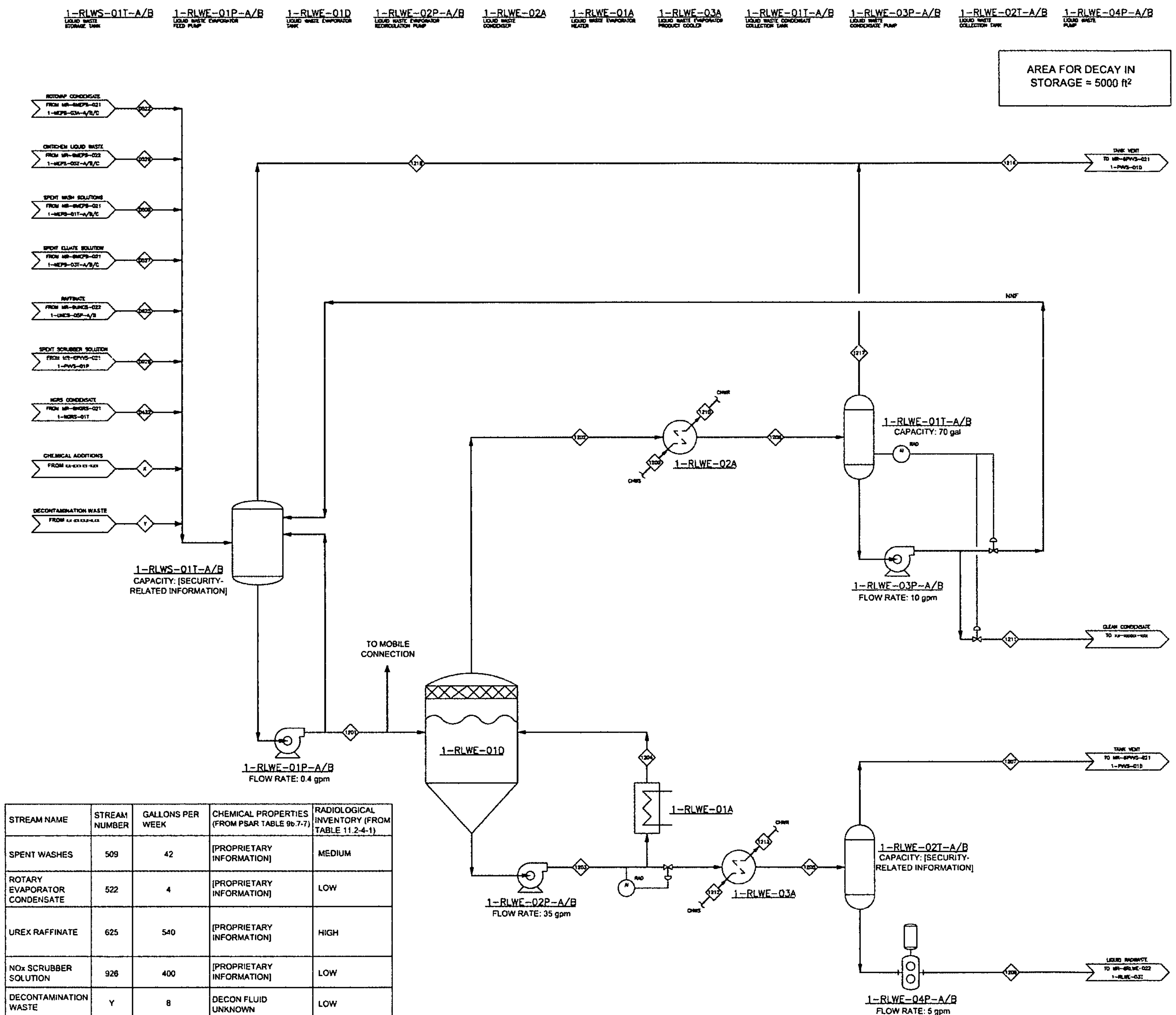
Processing flow rate into the liquid waste storage tanks is expected to be approximately 1040 gallons per week, based on a 50-week year (see the SHINE response to RAI 11.2-3 (Reference 4)). The equipment downstream of the liquid waste storage tanks will be specified in detailed design, and will be sized to allow processing of one tank while the other is filling in order to maintain the buffer storage capacity. Preliminary equipment specifications are provided in Table 9b.7-3 of the PSAR, and included in Figure 11.2-4-1, below. Liquid waste is expected to be processed in batches, so the flow rates provided in Figure 11.2-4-1 will only be applicable when the equipment is in operation. An IMR has been initiated to ensure the equipment downstream of the liquid waste storage tanks is specified in detailed design, and is sized to allow processing of one tank while the other is filling in order to maintain the buffer storage capacity.

The area used for decay in storage of packaged waste is the Waste Staging and Shipping Building. This building is identified in Figure 1.3-4 of the PSAR, where it has approximate dimensions of 50 ft by 100 ft. Therefore, the estimated total area needed for decay in storage of packaged waste is approximately 5000 ft^2. The exact dimensions of the Waste Staging and Shipping Building will be determined during detailed design and provided in the FSAR. An IMR has been initiated to ensure the exact dimensions of the Waste Staging and Shipping Building are determined during detailed design and provided in the FSAR.

The criteria for shielding requirements of packaged grouted waste in the Waste Staging and Shipping Building will be selected to ensure the site dose limits of 10 CFR 20 are met. An IMR has been initiated to ensure the final design of the Waste Staging and Shipping Building incorporates criteria for shielding requirements such that the site dose limits of 10 CFR 20 are met.

The criteria will follow ALARA principles to manage radiation exposure in the Waste Staging and Shipping Building to ensure that occupational and off-site doses are maintained ALARA.

Figure 11.2-4-1: RLWE Liquid Waste Evaporator and Storage System Process Flow Diagram



STREAM NAME	STREAM NUMBER	GALLONS PER WEEK	CHEMICAL PROPERTIES (FROM PSAR TABLE 9b.7-7)	RADIOLOGICAL INVENTORY (FROM TABLE 11.2-4-1)
SPENT WASHES	509	42	[PROPRIETARY INFORMATION]	MEDIUM
ROTARY EVAPORATOR CONDENSATE	522	4	[PROPRIETARY INFORMATION]	LOW
UREX RAFFINATE	625	540	[PROPRIETARY INFORMATION]	HIGH
NOx SCRUBBER SOLUTION	926	400	[PROPRIETARY INFORMATION]	LOW
DECONTAMINATION WASTE	Y	8	DECON FLUID UNKNOWN	LOW
SPENT ELUATE SOLUTION	527	52	[PROPRIETARY INFORMATION]	LOW
CHEMICAL ADDITIONS	X	TBD	ACID OR BASE AS REQUIRED FOR pH ADJUSTMENT	NONE
CINTICHEM LIQUID WASTE	529	TBD (LESS THAN 1 GALLON PER TSV BATCH)	TBD	TBD
NGRS CONDENSATE	432	TBD (LESS THAN 1 GALLON PER TSV BATCH)	TBD	TBD

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

(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)

ENCLOSURE 6

SHINE MEDICAL TECHNOLOGIES, INC.

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

PRELIMINARY SAFETY ANALYSIS REPORT
PUBLIC VERSION
(OSM#4)

ENCLOSURE 7

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-2015-004 with enclosures. SHINE requests that the confidential information contained in Enclosure 1, Enclosure 3, and Enclosure 5 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 Enclosure 1, Enclosure 3, and Enclosure 5 of SMT-2015-004 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 1, Enclosure 3, and Enclosure 5 is not available to the public to the best of my knowledge and belief.

c. The information contained in Enclosure 1, Enclosure 3, and Enclosure 5 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 1, Enclosure 3, and Enclosure 5 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 1, Enclosure 3, and Enclosure 5 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. The information contained in Enclosure 1, Enclosure 3, and Enclosure 5 of SMT-2015-004 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 February 6, 2015.

R. V. Bynum

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