May 7, 2021

2021-SMT-0048
10 CFR 50.30

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

References:

(1) SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Application for an Operating License," dated July 17, 2019 (ML19211C143)

(2) NRC letter to SHINE Medical Technologies, LLC, "Request for Additional Information Related Meteorological Data, Cooling Systems, and Physical Security Plan (EPID NO. L-2019-NEW-0004)," dated April 8, 2021 (ML21089A001)

(3) SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Application for an Operating License Response to a Request for Additional Information", dated April 30, 2021

<u>SHINE Medical Technologies, LLC Application for an Operating License
Response to Request for Additional Information</u>

Pursuant to 10 CFR Part 50.30, SHINE Medical Technologies, LLC (SHINE) submitted an application for an operating license for a medical isotope production facility to be located in Janesville, WI (Reference 1). The NRC staff determined that additional information was required to enable the staff's continued review of the SHINE operating license application (Reference 2).

Enclosure 1 provides the SHINE response to the NRC staff's request for additional information related to meteorological data.

SHINE previously submitted the SHINE response to the NRC staff's request for additional information related to the physical security plan via Reference (3). The SHINE response to the NRC staff's request for additional information related to cooling systems (i.e., RAI 4a-15) will be provided by June 7, 2021.

If you have any questions, please contact Mr. Jeff Bartelme, Director of Licensing, at 608/210-1735.

I declare under the penalty of perjury that the foregoing is true and correct.
Executed on May 7, 2021.

Very truly yours,

DocuSigned by:
Jim Costedio
F52DB96989224FF...

James Costedio
Vice President of Regulatory Affairs and Quality
SHINE Medical Technologies, LLC
Docket No. 50-608

Enclosure

cc: Project Manager, USNRC
SHINE General Counsel
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health

ENCLOSURE 1

SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL TECHNOLOGIES, LLC OPERATING LICENSE APPLICATION RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

The U.S. Nuclear Regulatory Commission (NRC) staff determined that additional information was required (Reference 1) to enable the continued review of the SHINE Medical Technologies, LLC (SHINE) operating license application (Reference 2). The following information is provided by SHINE in response to the NRC staff's request.

Chapter 2 – Site Characteristics

RAI 2.3-1

The acceptance criteria for Section 2.3, "Meteorology," of NUREG-1537, Part 2, states, in part, that "the information on meteorology, and local weather conditions is sufficient to support dispersion analyses for postulated airborne releases…."

As stated, in part, in Section 2.3.2.2, "Local Data Sources," of the SHINE FSAR, "[s]urface meteorological data were available from the Southern Wisconsin Regional Airport (SWRA) in Janesville, Wisconsin (NOAA station identifier KJVL)," and were used to support relative atmospheric concentration and radiological dose assessments. Regulatory Guide (RG) 1.23, "Meteorological Monitoring Programs for Nuclear Power Plants," provides guidance for designing and operating an onsite meteorological measurements program, including the resolution and specification for meteorological instrumentation. Although there is no requirement that SHINE use RG 1.23, or follow the guidance therein, the RG provides the basis for the meteorology data used in NRC-approved atmospheric dispersion models. With this in mind, the NRC staff developed the following information requests to confirm the quality and appropriate use of the meteorological data from the SWRA in SHINE's dispersion modeling:

a. SHINE has provided wind direction, as shown in the Annual Wind Rose data from the SWRA in Figure 2.3 of the SHINE FSAR, only by wind direction sector (N, NNW, NW, etc.), and not discrete degrees, resulting in wind directions being recorded every 22.5 degrees.

   Discuss and account for any bias introduced by using wind direction sector rather than discrete wind direction degrees.

b. Wind speed instrumentation at National Weather Service stations or airfields may have insufficient resolution at lower wind speeds which could result in underestimated X/Q values.

   Discuss the resolution of the SWRA wind speed instrumentation and its acceptability for accurately calculating the X/Q values.

c. As discussed in FSAR Section 2.3.2.5, "Atmospheric Stability," SHINE determined stability classes using the Turner 1964 method. However, the vertical temperature difference is the preferred method for determining Pasquill stability classes for NRC licensing purposes, as specified in RG 1.145, “Atmospheric Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants,” Revision 1, Section 1.1, “Meteorological Data Input.”

Discuss any differences in the parameters and approach SHINE used to determine atmospheric stability via the Turner 1964 method as compared to the vertical temperature difference method. Discuss any bias introduced into the dispersion results by using the Turner 1964 method.

SHINE Response

a. SHINE dispersion modeling was performed in accordance with Regulatory Guide 1.145, “Atmospheric Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants” (Reference 3), as described in Section 13a2.2 of the FSAR. Consistent with Section C.1.1 of Regulatory Guide 1.145, the meteorological data input needed for atmospheric dispersion (χ/Q) calculations are binned into 16 compass directions (22.5-degree sectors), as provided in Tables 2.3-24 through 2.3-30 of the FSAR. The annual wind roses provided in Figures 2.3-19 through 2.3-36 of the FSAR use 16 sectors for consistency with binned wind direction data input into the χ/Q calculations.

   Table 2 of Regulatory Guide 1.23, “Meteorological Monitoring Programs for Nuclear Power Plants” (Reference 4), states that the measurement resolution for wind direction should be 1.0 degree with a system accuracy of ±5 degrees. The Southern Wisconsin Regional Airport (SWRA) (Weather Station ID KJVL) is an AWOS III type observation station. Performance standards for automated weather observing systems (AWOS) require wind direction sensors at AWOS-type observation stations have a minimum resolution of 1 degree and a minimum system accuracy of ±5 degrees (Reference 5).

   Since SHINE calculated the χ/Q consistent with the guidance specified in Regulatory Guide 1.145, and the calculations were based off wind direction data from instrumentation which meets the measurement resolution for wind direction of 1.0 degree with a system accuracy of ±5 degrees provided in Regulatory Guide 1.23, there is no evidence that using wind direction sectors introduce any bias into the SHINE dispersion modeling.

   Subsection 2.3.2.2 of the FSAR contains an administrative error, identifying the SWRA meteorological monitoring station (Weather Station ID KJVL) as an AWOS IIIP type observation station. As stated above, the SWRA meteorological monitoring station is an AWOS III type observation station. SHINE has revised Subsection 2.3.2.2 to correct the administrative error. A mark-up of the FSAR incorporating this change is provided as Attachment 1.

b. As discussed in Part a of this response, the SWRA meteorological monitoring station (Weather Station ID KJVL) is an AWOS III type observation station. Performance standards for AWOS require wind speed sensors at AWOS-type observations standards to have a resolution of 1 knot and a minimum threshold of 2 knots (Reference 5).

   Consistent with the modeling guidance of Regulatory Guide 1.145 (Reference 3), measured wind speeds and directions are input as a joint wind direction/wind speed frequency distribution in the χ/Q calculations. The distributions are provided in Tables 2.3-24 through 2.3-30 of the FSAR. Wind directions are binned into 16 sectors as described in Part a of this response. Wind speeds are binned into non-zero wind speed bins and a zero (calm) bin.

The size of the wind speed bins is 1 meter per second (m/s) for wind speeds up to 6 m/s and 2 m/s for wind speeds between 6 m/s and 10 m/s. The size of the wind speed bins exceeds the resolution of the wind speed measurements (i.e., 1 knot [0.5 m/s]) for an AWOS-type observation station, so wind speeds are binned appropriately for input into the χ/Q calculations.

Wind speeds below the 2-knot (approximately 1 m/s) threshold are counted as calm winds in the joint wind direction/wind speed frequency distribution. To ensure that below-threshold wind speeds are incorporated into the χ/Q calculations, the below-threshold wind speeds are conservatively distributed among the 16 wind directions in the 0 m/s to 1 m/s wind speed bin according to the directional distribution of recorded wind speeds in the 1 m/s to 2 m/s bin, consistent with Section C.1.1 of Regulatory Guide 1.145. Therefore, the lowest wind speeds below the threshold of the wind speed sensor are appropriately included in the χ/Q calculations.

Since the resolution of the SWRA wind speed instrumentation allows for appropriate binning of wind speeds for input into the χ/Q calculations, and the χ/Q calculations appropriately account for below-threshold wind speeds, there is no evidence that the calculated χ/Q values are underestimated.

c. The meteorological tower at the SWRA is a single-level tower, as described in Subsection 2.3.2.2 of the FSAR. Temperatures are not measured at multiple levels at the SWRA; therefore, a method that uses a vertical temperature difference (ΔT) to estimate the Pasquill stability class cannot be used using data from the SWRA. Instead, the Pasquill stability class is estimated using a method developed by Turner (Reference 6) and implemented into computer code by the U.S. Environmental Protection Agency (Reference 7), as described in Subsection 2.3.2.5 of the FSAR. The input meteorological parameters are observations of hourly wind speed, ceiling height, and sky cover.

Regarding the performance of the method with respect to over-predicting or under-predicting certain stability classes, Table 2.3-23 of the FSAR presents the resulting annual Pasquill class frequency distributions for each year and combined period. This table shows that the Pasquill class “D” stability is the most frequently occurring class for each year and combined period. The Pasquill class “A” stability is the least frequently occurring class. Both of these results are consistent with generally observed stability class climatologies, such as Stern, et al. (Reference 8). Comparisons of Pasquill stability class frequency distributions derived using methodology based on Turner (Reference 6) and methods using ΔT show similar stability class distributions resulting from application of the two methods (Reference 9). Therefore, SHINE determined there is no evidence that the method developed by Turner introduces a bias in atmospheric stability computations compared to the ΔT method.

RAI 2.3-2

The acceptance criteria for Section 2.3 of NUREG-1537, Part 2, states, in part, that “[h]istorical summaries of local meteorological data based on available onsite measurements and National Weather Service station summaries or summaries from other nearby sources are presented.”

As stated in part, in Section 2.3.2.2 of the SHINE FSAR, “[s]urface meteorological data were available from the Southern Wisconsin Regional Airport (SWRA) in Janesville, Wisconsin (NOAA station identifier KJVL)” and were used to support relative atmospheric concentration and radiological dose assessments. However, the NRC staff is seeking additional information to confirm that the data used by SHINE is representative of onsite conditions for the facility.

Discuss the representativeness of the offsite meteorological measurements for the local conditions at the SHINE site, specifically addressing the dispersion characteristics of the modeled releases. Note any differences in dispersion characteristics between the SHINE site and the Southern Wisconsin Regional Airport.

The information requested in RAI 2.3-2 is necessary to support the NRC staff's evaluation findings, consistent with Section 2.3 of NUREG-1537, Part 2. Specifically, the requested information is intended to support the NRC staff's determination that meteorological information presented by SHINE in its FSAR is sufficient to support analyses applicable to and commensurate with the risks of the dispersion of airborne releases of radioactive material in the unrestricted environment at the site. The methods and assumptions are applied to releases from both normal facility operations and postulated accidents at the facility.

SHINE Response

Surface meteorological data are available from the SWRA in Janesville, Wisconsin. As shown in Figure 2.2-1 of the FSAR, the SWRA is located directly across U.S. Highway 51 from the SHINE site, approximately 0.25 mi. (0.40 kilometers [km]) west of the SHINE site. The SWRA was the closest source of meteorological data to the SHINE site.

The SHINE site and the SWRA are located in a relatively open, rural area. U.S. Geological Survey (USGS) topographical maps of the area (References 10 and 11) show that the SHINE site and the adjacent SWRA are relatively flat. The base elevation of the meteorological station at the SWRA is 808 feet (ft.) (246 meters [m]), while the finished SHINE site grade elevation is approximately 825 ft. (251 m). Therefore, the SHINE site and SWRA meteorological station are located at approximately the same grade elevation.

Since the SHINE site and the SWRA meteorological station are located at approximately the same grade elevation in a relatively open, flat, and rural location, air dispersion conditions as sampled by the meteorological instruments at the SWRA are expected to be representative of dispersion conditions at the SHINE site.

Chapter 4 – Irradiation Unit and Radioisotope Production Facility Description

RAI 4a-15

Paragraph (b)(2) of Section 50.34, “Contents of applications; technical information,” to 10 CFR Part 50 requires, in part, that an FSAR include a description and analysis of the structures, systems, and components of the facility, with emphasis upon performance requirements, the bases, and the evaluations required to show that safety functions will be accomplished. The description shall be sufficient to permit understanding of the system designs and their relationship to safety evaluations.

The ISG to NUREG-1537, Part 2, Section 4a2.6, "Thermal-Hydraulic Design,” states that the criteria for the thermal-hydraulic design should include that there be no coolant flow instability in any cooling coil that could lead to a decrease in cooling, and that the departure from nucleate boiling (DNB) ratio should be no less than 2.0 along a cooling coil. The NRC staff did not identify information in the FSAR to confirm that that any primary closed loop cooling system (PCLS) heat transfer surface, under any design conditions, will not undergo DNB.

Clarify whether any PCLS cooling surface, considering all system design conditions, could exceed critical heat flux resulting in DNB. If so, explain how such a condition is prevented and mitigated. If not, explain how much margin is available to avoid DNB in the worse-case scenario.

This information is necessary to confirm that primary coolant hydraulics and thermal conditions have been specified for the SHINE facility, consistent with the evaluation findings in the ISG to NUREG-1537, Part 2, Section 4a2.6. The analysis provided by the applicant should consider the various approaches and systems for heat removal, such as the cooling coils, the pool, and the gas management system. The analyses should give the limiting conditions of the features that ensure barrier integrity.

SHINE Response

The SHINE Response to RAI 4a-15 will be provided by June 7, 2021.

References

1. NRC letter to SHINE Medical Technologies, LLC, "Request for Additional Information Related Meteorological Data, Cooling Systems, and Physical Security Plan (EPID NO. L-2019-NEW-0004)," dated April 8, 2021 (ML21089A001)

2. SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Application for an Operating License," dated July 17, 2019 (ML19211C143)

3. U.S. Nuclear Regulatory Commission, "Atmospheric Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants," Regulatory Guide 1.145, Revision 1, November 1982

4. U.S. Nuclear Regulatory Commission, "Meteorological Monitoring Programs for Nuclear Power Plants," Regulatory Guide 1.23, Revision 1, March 2007

5. U.S. Department of Transportation, "Automated Weather Observing Systems (AWOS) for Non-Federal Applications," AC No. 150/5220-16E, March 2017

6. Turner, D.B., "A Diffusion Model for an Urban Area," Journal for Applied Meteorology, Volume 3, 1964

7. U.S. Environmental Protection Agency, "PCRAMMET.FOR," FORTRAN Program, Version 99169, Technology Transfer Networks Support Center for Regulatory Atmospheric Modeling, 1999

8. Stern, A.C., R.W. Boubel, D.B. Turner, D.L. Fox, "Fundamentals of Air Pollution," Academic Press, 1984

9. U.S. Environmental Protection Agency, "An Evaluation of a Solar Radiation/Delta-T Method for Estimating Pasquill-Gifford (P-G) Stability Categories," EPA-454/R-93-055, October 1993

10. U.S. Geological Survey, "Janesville West Quadrangle, Wisconsin – Rock County, 7.5-Minute Series," 2018

11. U.S. Geological Survey, "Beloit Quadrangle, Wisconsin – Rock County, 7.5-Minute Series," 2018

ENCLOSURE 1
ATTACHMENT 1

SHINE MEDICAL TECHNOLOGIES, LLC

SHINE MEDICAL TECHNOLOGIES, LLC OPERATING LICENSE APPLICATION
RESPONSE TO REQUEST FOR ADDITIONAL INFORMATION

FINAL SAFETY ANALYSIS REPORT CHANGES
(MARK-UP)

1 page follows

Local dispersion climatology includes consideration of airflow and atmospheric turbulence. The following subsections address local topography, the source of local meteorological data, wind roses, and atmospheric stability distribution.

2.3.2.1 Topography

The site is located approximately at the center of Rock County, Wisconsin, about 13 mi. (20.9 km) north of the Illinois/Wisconsin border, and 2.5 mi. (4.0 km) east of the Rock River. The site is located within till plains glacial deposits on the Central Lowland Province of the Interior Plains Division of the United States. Within a radial distance from the site of approximately 10 mi. (16.1 km), additional ground surface features include the following:

a. There is terminal kettle-moraine topography in the central, north, and east sections, which represent effects of the last advance of the continental glacier, including uneven hills and ridges, varying drainage patterns, and gently rolling terrain (WISDOT, 2017).
b. There is dissected upland with isolated bluffs in the west and southwest sections, part of the “driftless area” (Regional Climate) which was not overrun by ice during the last continental glaciation (Moran and Hopkins, 2002).
c. The Rock River watershed, the main waterway, bisects the county from north to south (Rock County, 2012). The Rock River valley is typically less than 1 mi. (1.6 km) wide, with minor slopes at the edges of the river floodplain with heights of approximately 50 ft (15.2 m).
d. Most land is used for agriculture, including corn and soybean farming (Rand McNally, 1982 and 2005).
e. The main urban centers of Janesville and Beloit are located along the Rock River.
f. The finished site grade elevation is approximately 825 ft. (251 m) NAVD 88. The project site and adjacent ground within a radius of approximately 1 mi. (1.6 km) is flat farmland. Within a 10 mi. (16.1 km) radius from the site, topographic elevations range from approximately 750 ft. (230 m) NAVD 88 along the Rock River, to approximately 1033 ft. (315 m) NAVD 88 at the highest bluffs (USGS, 1980). Therefore, the topography within a 10 mi. (16.1 km) radius ranges from approximately 72 ft. (21.9 m) below the site elevation, to 206 ft. (62.8 m) NAVD 88 above the site elevation.

2.3.2.2 Local Data Sources

To support relative atmospheric concentration (χ/Q) and radiological dose assessments, a surface meteorological data set covering the period of 2005-2010 was developed as described below.

Surface meteorological data were available from the Southern Wisconsin Regional Airport (SWRA) in Janesville, Wisconsin (NOAA station identifier KJVL). That airport is located approximately 0.25 mi. (0.40 km) west of the site. The SWRA meteorological monitoring station is an automated weather observation station (AWOS) with precipitation sensors installed (AWOS III~~P~~). The FAA describes the specifications of an AWOS system in an Advisory Circular (FAA, 2017). Specifications from this Advisory Circular are listed in Table 2.3-19. The AWOS anemometer height at SWRA for the period of interest in this study (2005 to 2010) is 26 ft. (7.9 m) above ground level (NCDC, 2012).

The FAA Advisory Circular (FAA, 2017) describes the FAA standard for procurement, construction, installation, activation, and maintenance of non-Federal AWOS systems. That