



UNITED STATES
NUCLEAR REGULATORY COMMISSION
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September 11, 2013

Richard Vann Bynum, PhD
Chief Operating Officer
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2555 Industrial Drive
Monona, WI 53713

SUBJECT: REQUESTS FOR ADDITIONAL INFORMATION FOR THE ENVIRONMENTAL
REVIEW OF THE SHINE RADIOISOTOPE PRODUCTION FACILITY
CONSTRUCTION PERMIT APPLICATION

Dear Dr. Bynum:

By letter dated March 26, 2013, SHINE Medical, Inc. (SHINE), submitted part of a construction permit application pursuant to Title 10 of the *Code of Federal Regulations* (CFR) Part 50, to construct a proposed radioisotope production facility. The U.S. Nuclear Regulatory Commission (NRC) is reviewing the information contained in the application and has identified areas where additional information is needed to complete the environmental review. Enclosure 1 lists environmental requests for additional information (RAIs).

These RAIs were discussed with Mr. Jim Costedio, and a mutually agreeable date for the response is within 30 days from the date of this letter. If you have any questions, please contact me at 301-415-6509 or by e-mail at Michelle.Moser@nrc.gov.

Sincerely,

A handwritten signature in black ink that reads "Michelle R. Moser".

Michelle R. Moser, Environmental Project Manager
Division of License Renewal
Office of Nuclear Reactor Regulation

Docket No. 50-608

Enclosure:
Requests for Additional Information

cc w/encl: Distribution List

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/RA/

Michelle R. Moser, Environmental Project Manager
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SHINE RADIOISOTOPE PRODUCTION FACILITY
ENVIRONMENTAL REQUESTS FOR ADDITIONAL INFORMATION

Air Quality

1. Air emissions during construction need to be quantified to evaluate potential impacts. Please provide air emission estimated quantities and durations for construction activities, including emissions from construction equipment (onsite equipment use, onsite vehicle emissions, site disturbing activities, etc.), construction-related traffic (commuting workforce), and fugitive dust emissions. Please identify all emission sources, estimate emissions from each source, identify references used and emission factors, and describe all assumptions (e.g., number of workers and workforce commute, construction duration, etc.) and calculations used to estimate emissions.
2. Please describe how air emission estimates from the isotope production activities were quantified. Provide assumptions and calculations for the isotope production air emission estimates provided in Section 19.4.2.1.2.1.1 of the environmental report (ER).
3. Air emission control systems for the SHINE process operations need to be described in detail to assess effectiveness. Please provide ventilation system capture efficiencies, equipment design sizing information (air flow rates, carbon adsorption capacities and breakthrough times, air-to-cloth ratios, etc.), and equipment control efficiencies for the high efficiency particulate air filters and activated carbon beds used in venting.
4. Section 19.4.2.1.2.2.4 of the ER describes air quality modeling, but does not provide detailed input and output data. Please provide the air modeling input and output files, when available. Include associated building, terrain, and meteorological data files. Also, include a scale site map showing modeled stacks, buildings, and property lines.
5. Air emissions during decommissioning need to be quantified to determine potential impacts. Please provide estimated emission quantities and durations for decommissioning activities. Please identify all emission sources, estimate emissions from each source (including fugitive dust emissions), identify references used and emission factors, and describe all assumptions (e.g., number of workers and workforce commute, decommissioning duration, etc.) and calculations used to estimate emissions.
6. Greenhouse gases (GHG) emissions need to be quantified for construction, operation, and decommissioning. Please provide estimates of GHG emissions during construction, operation, and decommissioning. Please identify all GHG emission sources, estimate GHG emissions from each source, identify emission factors used in the calculations and references, and describe all assumptions (e.g., frequency, distance traveled, and type of truck deliveries, and waste shipments, the number of workers and workforce commute distance assumptions, and construction and decommissioning duration, etc.) and calculations used to estimate GHG emissions.
7. Emission rates for hazardous air pollutants and toxic chemicals regulated under Wisconsin regulations need to be quantified. Please provide emission estimates during construction, operation, and decommissioning for hazardous air pollutants and other toxic pollutants regulated under Wisconsin air regulations. Please identify all emission sources (e.g., construction equipment, vehicle emissions, etc.), estimate emissions from each source, and describe all assumptions and calculations used to estimate emissions.

8. Boiler and heating system load design and firing rate are provided in Tables 19.4.2-3 through 19.4.2-7. Please provide details about the design firing rate and heating load estimated from the natural gas fired boiler and natural gas fired heaters. Please provide details on the assumptions and calculations.
9. Section 19.2.4.2 states that multiple natural gas fired boilers will provide heating water to the HVAC air handlers. However, Section 19.4.2.1.2.1.2 discusses only one natural gas boiler used in the production facility. Details on the natural gas fired boilers that provide heating water to the HVAC air handlers needs to be quantified and documented. Please provide details on the number, characteristics, and air emissions from each of the gas fired boilers.
10. Vehicle emissions need to be quantified and documented. Please provide estimated vehicle emissions for all operational activities such as workforce commuting and truck deliveries. Describe all assumptions (e.g., frequency, distance traveled, and type of truck deliveries and waste shipments, the number of workers and workforce commute distance assumptions, emission factors) and identify references used.
11. The SHINE ER Section 19.4.2.1.1, describes mitigation measures that may be implemented to minimize the impacts of air emissions during construction to air quality. During the scoping period, NRC staff received comments from the Environmental Protection Agency (ML13238A121) regarding specific emission reduction techniques, Please clarify and identify if SHINE will be implementing applicable emission reduction techniques during construction and decommissioning of the facility as discussed in the comments provided by the EPA.
12. In accordance with RAI 10 under Proposed Action, please update Table 19.1.2-1 regarding air permits that will be required for construction and operation (e.g. diesel generator). Table 19.1.2-1 only identifies the Air Pollution Control Construction Permit.

Alternatives

1. Please provide any site selection studies or summaries prepared to support the site evaluation and selection process. For example, please provide the Phase 1 Environmental Site Assessment for Steven's Point and Golder's 2012 Geotechnical & Hydrological Investigation.
2. In describing the alternative technologies, Section 19.5.2.2.1 of the ER states "...the linear accelerator-based approach is not able to produce medical isotopes other than Mo-99, and therefore, does not address the need for domestic SHINE as effectively as the SHINE technology." Other many accelerator-produced medical radioisotopes exist (i.e., see Adelsten, J. and F. Manning, *Isotopes for Medicine and the Ufe Sciences*, 1995). Please clarify why these linear accelerators could not meet SHINE's need.

Ecology

1. Section 19.3.5 describes aquatic biota stream surveys conducted in an unnamed tributary to the Rock River. Please describe the survey equipment and methods, such as the length of the seine nets, distance of stream sampled by seine, time of each kick net sample, and mesh size on seines and kick nets.

In addition, please provide a copy of the Draft Work Plan that describes the methodology used to conduct the ecological, land use, and water resources surveys. When available, please provide the Final Work Plan.

2. Section 19.3.5.5 and Table 19.3.5-2 states that SHINE used a biotic index to assess the ecological integrity of the unnamed tributary to the Rock River. Please clarify what biotic index SHINE used and provide a citation, as appropriate.
3. Section 19.3.5.6 of the ER describes the potential for wetlands to exist on or near the proposed SHINE site. Please clarify who conducted the wetland delineation studies.
4. Section 19.3.5.7 of the ER describes plant communities, wildlife, mammals, and herpetofauna that are likely to occur on or near the proposed SHINE site. For each ecological assemblage, describe the survey methods SHINE used, including the sampling level of effort (time of each sample, distance for each sample, total number of samples per season) and survey locations. In addition, for several ecological assemblages, the ER states that SHINE referred to databases to collect occurrence data. Provide a citation for all databases or other references that SHINE used to research the potential ecological assemblages on or near the SHINE site.

Geology and Soils/Water Resources

1. Please provide a reference for Figure 19.3.3-5, "Site Cross Section" and Figure 19.3.3-4, "Regional Structural Geology."
2. Please make available the following documents and references:
 - A non-proprietary water balance-flow diagram for the proposed facility (similar to ER Figure 19.2.3-1);
 - Preliminary Geotechnical Engineering Report, Janesville, Wisconsin: August 3, 2012 (ER Section 19.3.3.1);
 - Preliminary Hydrological Analyses, Janesville, Wisconsin: August 3, 2012 (ER Section 19.3.3.1);
 - Seismic Hazard Assessment Report, Janesville, Wisconsin: August 3, 2012 (ER Section 19.3.3.1); and
 - American Engineering Testing, Inc.: 2011. Report of Subsurface Exploration. (Section 19.5.2.1.2.1.4).
3. Please provide any available well log/well construction data, depth to water, and groundwater quality data from the existing well(s) adjacent to the proposed SHINE site. In addition, please provide any available well log/well construction data, depth to water, and groundwater quality data at or near the two alternative sites, including for any and all site characterization/monitoring wells or borings.

Historic and Archaeological

1. Please clarify whether SHINE intends to disturb any additional land, beyond the current property boundary, for construction or decommissioning (i.e., temporary storage, laydown, and staging sites)?

2. Please clarify whether SHINE intends to construct any additional pipelines for the facility. The ER references connections to the main sewage, commercial natural gas, and underground electrical distribution, and municipal water lines.
3. Please submit SHINE's Cultural Resource Management Plan, or provide a summary of SHINE's procedures for inadvertent finds. In addition, please provide a description of the Issues Management Report process as it would relate to an inadvertent find.

Noise

1. Traffic volumes, vehicle mixes, and traffic speeds are critical elements of traffic models. Please identify and describe the model used to estimate noise levels due to highway traffic for the existing conditions. Please provide the supporting modeling input and output files. Please provide the traffic data used to model existing highway traffic noise levels (e.g. input and output files) and describe any assumptions or data manipulations used in preparing model inputs.
2. Noise measurements and simultaneous traffic counts are typically used to validate traffic models. Please provide any noise measurements collected for model validation or other purposes. If applicable, please provide copies of data sheets, instrument calibration sheets, and simultaneous traffic counts.
3. Clarify if SHINE intends to perform noise modeling for construction, operation, and decommissioning.
4. Please make available the following document:
 - Southern Wisconsin Regional Airport, 2004 (Section 19.3.2.6.1)

Proposed Action

1. Please describe the power requirements to operate each accelerator and irradiation unit (IU) pair. Please provide an overall facility power requirement (i.e., load demand and annual energy consumption).
2. Please provide an estimate of the amount of natural gas that the facility would use annually.
3. Please provide an estimate of the amount of diesel fuel that the facility would use annually, both during construction and operations. Please explain if there is any equipment, other than the standby generator, that would use diesel fuel.
4. Please provide a high-level non-proprietary schematic that visually describes the overall isotope production process. Please include target solution loading, tritium target loading, accelerator startup, chemical adjustment, off-gas removal, heat removal/dissipation, target solution removal, product separation, recycle of target solution, cleanup of target solution, removal of solid/liquid/gaseous discharges, and other relevant process steps that show input and output of resources and wastes.
5. Please describe the SHINE facility's total footprint in square feet, and clarify the footprint of the main production building footprint and each of the remaining areas (parking lots, roads, retention ponds, etc.).

6. The SHINE process uses tritium gas to produce neutrons. Tritium is required for start up, some is recycled by the tritium purification system, some is consumed by the process, and some is ultimately emitted. Please clarify where the initial input of tritium comes from and how much SHINE would initially use. In addition, please clarify how much tritium SHINE will consume annually that would need to be replaced from an external source. Please describe how much tritium the facility would emit. Please estimate the maximum tritium inventory that would be stored at the SHINE site.
7. SHINE intends to acquire water from the Janesville municipality to use for isotope production, product processing, potable water, blowdown and facility heating water, fire protection system makeup, and chilled water makeup, as described in the ER. Please provide an estimate of the volume of water expected to be required for various construction activities and supply source. Please estimate the annual water use by the chilled water cooling system that must be discharged to the sanitary sewer after treatment. Describe the nature of wastewater proposed for discharge to the Janesville Waste Treatment Facility, including source volume(s) and the expected constituents and concentrations (e.g., estimate of the thermal levels and chemical concentrations) (ER Section 19.2.3.1). Clarify whether any specific permits or limitations would apply to the discharge (e.g., industrial user provisions).
8. Page 19.2-6 of the ER states "There are no daycare centers or retirement homes located within 5 mi. (8 km) of the SHINE facility." An internet search indicated that there are several daycare centers and at least one retirement home within the 5 mi. (8 km) radius. Please clarify whether SHINE conducted a physical survey or used another source to determine the number of daycare centers and retirement homes within the 5 mi (8 km) radius.
9. Please clarify the extent to which SHINE will conduct activities in accordance with 10 CFR 50.10(a)(2) prior to receiving a construction permit. If known, please provide a description of the activities that SHINE will conduct, the timeline for performing these activities, and any regulatory, or other requirements that must be met prior to commencing these activities.
10. For the permits identified in Table 19.1.2-1 of the ER, please provide a timeline or status update for when SHINE expects to apply for and receive the permits. If relevant, please provide a specific regulatory or other milestone on which a given permit may be dependent upon.
11. Please provide a high-level discussion of the production process for iodine-131 (I-131) and xenon-133 (Xe-133), the methodology SHINE used to estimate environmental impacts for I-131 and Xe-133, and the assumed shipment routes and customers for I-131 and Xe-133.

Socioeconomics

1. Please clarify the estimated annual total projected costs for materials, equipment, and services to be purchased in the local communities.

Transportation

1. SHINE suggested that traffic could be optimized using traffic signals at the entrance and exit. Please clarify whether SHINE intends to obtain a traffic light (optimization) at the entrance and exit to mitigate traffic issues. If so, please describe the current status of obtaining this traffic light (i.e., has it been negotiated, or otherwise agreed upon?). In addition, please clarify whether SHINE expects employees to arrive within a staggered schedule due to shift changes, or all at one time.
2. Please describe in more detail the proposed methods and schedules of transporting radioactive materials (Le., common carrier, exclusive use, etc.) for all the various radionuclides SHINE intends to transport and applicable Department of Transportation, NRC, and other applicable regulations. In addition, please clarify the number and frequency of incoming and outgoing shipments of radionuclides, and the radioactive levels of such radionuclides, during construction and operations.
3. Please provide information on the sources of raw materials, such as concrete/asphalt plants and structural steel distribution points, from which SHINE would transport construction materials to the proposed and alternate sites. Are there designated/restricted routes for these materials to and from the sites, and would any of these routes significantly impact residential or sensitive areas?

Human Health

1. Section 19.3.8.2, Background Radiation Exposure, discusses the background radiation levels in the vicinity of the proposed facility. The statement is made that "... there are no abnormal radiation hazards in the vicinity of the SHINE site; therefore, the background radiation exposure due to both natural and man-made sources is 6.2 millisievert per year (mSv/yr) {620 millirem [roentgen equivalent man] per year [mrem/yr]} ..." with a reference to an NRC document to support the statement. A site-specific evaluation of the background radiation levels prior to the operation of the facility is needed to provide baseline data that can be compared to the data obtained from the proposed radiological environmental monitoring program. Provide information on the type of radiological monitoring program that may be used to determine the baseline radiation levels.
2. Section 19.4.8.1, Nonradiological Impacts, contains a list of "potentially applicable" environmental management regulations. Provide, as appropriate, the applicable environmental management regulations that will apply to the proposed facility.
3. Section 19.4.8.1.2.2, Gaseous Wastes, contains a discussion on the use of "zones" to control non-radiological gaseous wastes within the proposed facility. Provide a discussion, with examples, explaining the use of "zones" to manage gaseous waste.
4. Section 19.4.8.1.3, Nonradioactive Effluents Released, provides a general discussion of the release of non-radioactive chemicals to the Janesville wastewater treatment facility but provides no quantification of the projected releases. Provide quantification of the projected types and amounts of chemicals that may be sent to the Janesville wastewater

limitations on the types, concentrations, and volume of chemical effluents the Janesville wastewater treatment facility will accept from the proposed facility.

5. Section 19.4.8.1.4.1, Air Emissions, discusses the projected gaseous chemical effluents. In a prior section, Table 19.4.2-1 lists sulfuric acid as a gaseous effluent. However, there is no discussion in this section on the projected impact from the release of gaseous sulfuric acid. Provide a discussion of the projected impact to the public from the release of gaseous sulfuric acid.
6. Section 19.4.8.1.5, Physical Occupational Hazards, discusses that the evaluation of the non-radiological hazards to the workforce will be defined when the operating strategies are finalized. This information is needed for the environmental review.
7. Section 19.4.8.1.6, Chemical Exposure to the Workforce, discusses the impacts to the workforce from the use of hazardous chemicals. Provide some specific examples of the controls, industrial hygiene practices, and protective equipment and clothing that are expected to be used to minimize chemical exposure to the workforce.
8. Section 19.4.8.1.7, Environmental Monitoring Programs, discusses the non-radiological environmental monitoring programs to ensure compliance with Wisconsin's regulations. Provide specific examples of the environmental monitoring program that are expected to be used to ensure liquid and gaseous effluents comply with the regulations and permits listed in this section.
9. Section 19.4.8.2.2.2, Liquid Sources of Radiation, discusses radioactive liquid waste produced at the proposed facility. However, there is no discussion of ways to minimize contamination of the facility in accordance with 10 CFR 20.1406, Minimization of Contamination.

10 CFR 20.1406 states the following:

Applicants for licenses, other than early site permits and manufacturing licenses under part 52 of this chapter and renewals, whose application are submitted after August 20, 1997, shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable the generation of radioactive waste.

As required by 10 CFR 20.1604, provide the information related to minimize contamination of the facility.

10. In Table 19.4.8-4, "Annual Average Airborne Radioactivity ECI Fraction at Bounding Dose Receptors" and Table 19.4.8-5, "Annual Total Effective Dose Equivalent to the Public at Bounding Dose Receptors," tritium is listed as being released from the proposed facility. However the footnote to these tables states that tritium was not

included in the dose assessment. Provide the dose contribution from tritium to the maximally exposed individual or provide an evaluation to demonstrate that the dose would be negligible.

11. Table 19.4.8-7, "Administrative Dose Limits," lists the 10 CFR Part 20 dose limit as the same value as the SHINE annual administrative limit. As listed, the administrative dose value appears to be an error. Provide the expected annual administrative dose limit.
12. Section 19.4.13.8.1 of Section 19.4.13.8 Human Health, discusses the cumulative impacts associated with the proposed facility and the potential NorthStar facility and the operating Mercy Clinic South and Mercy Hospital for wastewater sent to the Janesville wastewater treatment facility. Provide information on discussions, if any, that have taken place with the Janesville wastewater treatment facility on whether the additional wastewater from the proposed facility in combination with the Mercy Clinic South and the Mercy Hospital will have any significant impacts to the wastewater treatment facility. There is a potential cumulative impact to the workers at the Janesville treatment facility if it is not able to adequately process the increased amounts of effluents and to the public if effluent discharges from the treatment facility are significantly increased.

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