



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 3, 2013

Richard Vann Bynum, PhD
Chief Operating Officer
SHINE Medical Technologies, Inc.
2555 Industrial Drive
Monona, WI 53713

SUBJECT: ENVIRONMENTAL SITE AUDIT REGARDING SHINE MEDICAL, INC.
PROPOSED RADIOISOTOPE PRODUCTION FACILITY

Dear Dr. Bynum:

The U.S. Nuclear Regulatory Commission (NRC) is reviewing SHINE Medical, Inc.'s (SHINE) construction permit application for its proposed radioisotope production facility. The environmental site audit will be conducted at and near the proposed site during the week of July 29, 2013, by NRC staff and its contractors. The environmental audit activities will be conducted in accordance with the environmental audit plan (Enclosure 1).

To develop the environmental impact statement, the NRC staff requests the information described in the environmental audit needs list (Enclosure 2) be made available, to the extent possible, during the environmental site audit. A draft schedule of tours and meetings for the audit is also provided (Enclosure 3). The NRC staff informally transmitted this information to your staff, Jim Costedio, by e-mail on July 3, 2013.

If you have any questions, please contact me by telephone at 301-415-6509 or by e-mail at Michelle.Moser@nrc.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Michelle Moser".

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

Docket No. 50-608

Enclosures:
As stated

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Chief Operating Officer
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/RA/

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NAME	IKing	MMoser	MWong
DATE	6/20/13	7/1/13	7/3/13

OFFICIAL AGENCY RECORD

SHINE ENVIRONMENTAL AUDIT PLAN

1. Background

By letter dated March 26, 2013, SHINE Medical, Inc. (SHINE or applicant), submitted to the U.S. Nuclear Regulatory Commission (NRC), a construction permit application for a proposed radioisotope production facility. The NRC staff is reviewing the information contained in the environmental report (ER) of the construction permit application.

During the NRC staff's review, an environmental audit is conducted at the proposed site. This audit is conducted with the intent to gain understanding, to verify information, and to identify information that will require docketing to support the basis of the licensing or regulatory decision. Specifically, the NRC staff will identify pertinent environmental data, review the proposed and alternative sites and vicinity, and obtain clarifications regarding information provided in the ER.

Per NRC guidance, the NRC staff has prepared a regulatory audit plan that provides a clear overview of audit activities and scope, team assignments, and schedule.

2. Environmental Audit Bases

Environmental review requirements are specified in 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions." Review guidance for the staff is provided in NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content, Part 1, Chapter 19, Environmental Data Needs" and in "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan, Part 2, Chapter 19, Environmental Review."

During the scoping process required in 10 CFR Part 51, NRC staff is required to define the proposed action, identify significant issues which must be studied in depth, and to identify those issues that can be eliminated from further study.

3. Environmental Audit Scope

The scope of this environmental audit for the SHINE environmental review is to identify those issues which are significant, to identify those issues which can be eliminated from further study, and to identify the environmental resources that must be adequately described and evaluated in the environmental impact statement. Audit team members will focus on reviewing the documents and requested information listed in the SHINE Environmental Site Audit Needs List (Enclosure 2) and discussing the information with the applicant's subject matter experts.

4. Information and Other Material Necessary for the Environmental Audit

As described in the Environmental Site Audit Needs List (Enclosure 2).

5. Tentative Team Assignments Area of Review Assigned Auditor

The environmental audit team members and their specific discipline assignments are shown in Table 1. Those members of the team who are contractors from Los Alamos Technical Associates (LATA) are denoted with "LATA" after their name.

Table 1. Environmental Site Audit Team Members and Resource Assignments

Discipline	Team Members
Branch Chief	Melanie Wong, NRC
Environmental Project Manager	Michelle Moser, NRC
Safety Project Manager	Steven Lynch, NRC
Air Quality and Noise	Nancy Martinez, NRC Mike Stafford, LATA*
Ecology	Michelle Moser, NRC
Water Resources	Kevin Folk, NRC
Land Use	Michael Wentzel, NRC Mitch Strain, LATA*
Socioeconomics	Emily Larson, NRC Vicki Kraus, LATA*
Transportation	Emily Larson, NRC Steve Klementowicz, NRC* Joe Molter, LATA*
Cultural Resources	Emily Larson, NRC
Human Health, Waste Management	Stephen Klementowicz, NRC*
Alternatives	Allison Travers, NRC Robert Hull, LATA
Cumulative Impacts	Emily Larson, NRC George Pratt, LATA*
* Will not attend environmental site audit but will participate via conference call.	

6. Logistics

The environmental audit will be conducted near the SHINE facility from July 30- August 1, 2013. An entrance meeting will be held with SHINE staff towards the beginning of the audit on July 30, 2013. An exit meeting will be held towards the end of this audit on August 1, 2013.

7. Special Requests

The NRC staff requests the applicant make available the information identified on the Environmental Site Audit Needs List (Enclosure 2). SHINE staff or contractors who are subject matter experts in the disciplines listed on the Environmental Site Audit Needs List should be available for interviews and to provide tours which have been identified on the Environmental Site Audit Schedule (Enclosure 3).

8. Deliverables

An audit summary report is scheduled to be issued by NRC staff within 90 days from the end of the environmental audit.

SHINE MEDICAL, INC. ENVIRONMENTAL SITE AUDIT NEEDS LIST

The U.S. Nuclear Regulatory Commission (NRC) staff has reviewed Chapter 19, the Environmental Report (ER), of the SHINE Medical, Inc. (SHINE) construction permit application.

Please be prepared to discuss the following issues and make the following available during the environmental site audit.

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.) as well as construction-related traffic (commuting workforce). Please identify all emission sources, estimate emissions from each source, and describe all assumptions 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 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. 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, and describe all assumptions 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, and describe all assumptions 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, 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.
11. Please make available the following document:
 - Lake Michigan Air Directors Consortium, 2011 (Section 19.4.2.1.2.2.4.2),

Alternatives

1. Clarify the numerical scoring summary values shown on page 19.5-8 of the ER. Please provide a knowledgeable expert to describe the scoring and alternative site selection process.
2. Please make available any site selection studies or summaries prepared to support the site evaluation and selection process.
3. 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 Life Sciences*, 1995). Please clarify why these linear accelerators could not meet SHINE's need.
4. The production of commercial products could have a socioeconomic impact to local communities at the proposed site and at each of the alternative sites. Please provide an estimated gross annual revenue for the proposed commercial products (Mo-99, I-131, and Xe-133) based on the current annual average price per dose of each product. Please provide a publically available reference to support the estimated price per dose.

Ecology

1. Please provide consultation letters and other communication documents indicating correspondence to and from the U.S. Fish and Wildlife Service, Wisconsin Department of Natural Resources, and any other natural resource agencies or organizations.
2. Section 19.3.5 of the ER states that several special status species and six communities of special interest are likely to occur near the proposed SHINE site. Please quantify the likely distance between special status species and the six communities of special interest to the proposed SHINE site.

3. 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.
4. 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.
5. 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.
6. 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.
7. Tables 19.3.5-3 through 19.3.5-6 of the ER summarizes the survey results for ecological assemblages. Please clarify which species are likely to occur on the site and which species are likely to occur near the site. For those species likely to occur near the site, please clarify which species are likely to occur within 2 miles (3.2 km) of the site, 5 miles (8 km) of the site, or greater than 5 miles (8 km) to the 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-propriety 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).

Historic and Archaeological Resources

1. Please provide a map detailing the level of previous and existing ground disturbance at the proposed site, including documentation on how this level of disturbance was determined.

2. Please provide U.S. Geological Survey (USGS) 7.5 minute topographic quadrangle maps at 1:24,000 scale that show the boundaries of the SHINE property and the plant site and footprint of alternative sites discussed in the ER. Note that NRC staff will need to take the hard copy maps for the file search at the Wisconsin State Historic Preservation Office (SHPO). Therefore, NRC staff needs the actual USGS-named quad sheets at 1:24,000 scale- not GIS maps with underlying topographic data.
3. Please provide vegetation and land-use maps of the SHINE property and any areas of proposed development.
4. Please provide the applicant's Cultural Resource Management Plan. This plan is referenced in Section 19.4.6.1 in the ER.
5. Please provide SHINE's Excavation Construction and Safety Standards procedures. For example, please provide any procedures related to inadvertent discovery of historic and cultural resources during construction, operation, or decommissioning. Clarify whether SHINE has a cultural resource monitoring plan to be implemented during construction.
6. Please provide SHINE's final environmental evaluations that have been prepared for new construction.
7. Please provide copies of all documents and reports cited in the historic and cultural resource sections of the ER. Additionally, maps of any historic or cultural site locations and previously surveyed areas within the entire SHINE property (plant site and plant property) and within any areas of proposed development. If there are none, please note this. These maps will not be docketed, as they are considered sensitive information. NRC will be independently collecting any location data, as available, at the Wisconsin State Historic Preservation Office (SHPO), but that may be after the site visit is completed.
8. Please provide information on whether the medical isotope production facility would be visible from any surrounding National Register of Historic Places (NRHP)-listed or -eligible historic properties, including, but not limited to, those historic properties identified in Tables 19.3.6-2 and 19.3.6-3 of the ER.
9. Please provide copies of all letters and communications to and from the Wisconsin or Illinois SHPO specific to determining the NRHP-eligibility of any cultural resources identified to date within the SHINE property, including the plant site and within any areas of proposed development. If there are none, please note this.
10. Please provide consultation letters and other communication documents indicating correspondence to and from the SHPOs and to and from Federally recognized Indian tribes that have ancestral or historical ties to the project area and surrounding lands. Additionally, clarify whether SHINE has communicated with local historical societies or other local organizations with an interest in historic preservation.
11. Is any additional land, beyond the current property boundary, needed for construction or decommissioning (i.e., temporary storage, laydown, and staging sites)?

12. 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.
13. Please provide a knowledgeable expert to discuss the cultural resources management procedures and to discuss how SHINE intends to avoid impacting historic and archaeological resources, and deal with inadvertent discovery of historic and archaeological materials and human remains. Based on references in the ER, supporting material for this discussion may include the Cultural Resource Management Plan for the project and any other plans or procedures specific to environmental compliance and cultural resources management at the proposed site.

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 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. Please explain if there is any equipment, other than the standby generator, that would use diesel fuel.
4. Please provide a simplified schematic-like or pictorial drawing with buildings labeled to describe the site plan. Alternatively, please provide electronic files of the current site plan engineering drawings in a format that can be re-manipulated (such as Adobe Illustrator or ArcGIS).

5. 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.
6. 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.).
7. Please clarify whether the neutron multiplier is made of beryllium or another material.
8. Please clarify whether radiolytic off-gassing occurs in the neutron reflector vessel. If so, clarify whether the target solution vessel (TSV) off-gas system would collect these gases.
9. 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.
10. Please clarify whether the Thermal Cycling Absorption Process identified in the ER is the same as that described by M. W. Lee (*Thermal Cycling Absorption Process - A New Way to Separate Hydrogen Isotopes*, WSRC-MS-2000-00061, 2000).
11. 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), expected constituents and concentrations (ER Section 19.2.3.1). Clarify whether any specific permits or limitations would apply to the discharge (e.g., industrial user provisions).
12. During the site tour, please provide a knowledgeable individual(s) to discuss the proposed facility's water supply, cooling water, and wastewater and stormwater discharge and treatment systems.
13. 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.

14. 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.
15. For the permits identified in Table 19.1.2-1 of the ER, please provide a timeline for when SHINE expects to receive the permits. If relevant, please provide a specific regulatory or other milestone on which a given permit may be dependent upon.

Socioeconomics

1. In the ER, the total number of workers is listed as 205 – 257. The construction phase lists 420 workers, the operation phase lists 150 workers, and the decommissioning phase lists 268. Please clarify how many of these workers are anticipated to be employed for more than one phase of the project. Clarify the number of workers anticipated for each phase of the project and the overlap, if any.
2. The ER stated that 143 workers would need to relocate and find housing in the various communities during the construction phase. The ER also states that SHINE anticipates 51 workers to meet operational workforce needs and 107 workers for decommissioning. Please clarify whether SHINE is assuming that the 51 and 107 workers are currently living in the nearby local communities and therefore not in need of new housing.
3. Please clarify the estimated annual total projected costs for materials, equipment, and services to be purchased in the local communities.

Transportation

1. An article in the Wisconsin Gazette Xtra (Saturday, Feb 23, 2013) stated that the Southern Wisconsin Regional Airport (SWRA) tower could close due to sequestration cuts. If the SWRA airport tower closes due to air traffic controller funding cuts would SHINE still transport medical isotopes from this location? Clarify whether SHINE would use an alternate airports and whether this decision would be decided by SHINE, FedEx, or the selected common carrier? Similarly, please clarify whether SHINE has alternate transportation plans if SWRA becomes unavailable.
2. Table 19.4.11-1 of the ER, "SHINE Hazardous (Toxic) Chemical Source Terms and Concentrations" identifies what appear to be the limiting quantities of hazardous materials on site. Please provide a complete table that is not proprietary. Also, please clarify whether these materials will be procured at regular intervals or all at one time.
3. 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?).
4. Please describe where the non-radioactive domestic waste will be sent. What would be the frequency of sanitary and industrial waste shipments from the SHINE site?
5. Please clarify whether SWRA require any infrastructure changes as a consequence of the SHINE facility construction and traffic changes.

6. Please describe in more detail the proposed methods and schedules of transporting radioactive materials (i.e., common carrier, exclusive use, etc.) for all the various radionuclides SHINE intends to transport and applicable Department of Transportation, NRC, and other applicable regulations.
7. 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?
8. SHINE has suggested that infrastructure upgrades in the form of new road construction could occur. Please clarify whether SHINE would construct new access roads to the Stevens Point alternative (if it were selected) or the SHINE site.

Human Health/Waste Management

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 treatment facility. In addition, provide relevant information on the requirements and 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 ECL 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.

SHINE Environmental Site Audit Schedule

Monday, July 29

Travel to Madison, Wisconsin

Tuesday, July 30

SHINE Presentations

- Overview of radioisotope production process
- Overview of alternative site selection process

Site Visit

- Walk down of proposed site, including areas with typical crop cover and the general location where facility will be built,
- Driving tour within a 4-mile (6.4- km) radius of the site but focusing on the area south of the site and extending to the Rock River,
- Rock River,
- Sampling sites 1 and 2 along the unnamed tributary to the Rock River, and
- If accessible, a tour of the Janesville Wastewater Treatment Facility, including the outfall structure to the Rock River.

Wednesday, July 31

Resource-specific meetings on information needs

Thursday, August 1

Visit alternative sites

- Stevens Point
- Chippewa Falls

Friday, August 2

Travel to Washington, D.C.

Letter to R. Bynum from M. Moser dated July 3, 2013

SUBJECT: ENVIRONMENTAL SITE AUDIT REGARDING SHINE MEDICAL, INC.'S
PROPOSED RADIOISOTOPE PRODUCTION FACILITY

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CFrazier, RIII

SPrice, OGC

MYoung, OGC

RSkarda, RES

MConley, OPA